DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS–4208–F3 and CMS–4212–F]

RIN 0938–AV40 and 0938–AV63

Medicare Program; Contract Year 2027 and Certain Contract Year 2026 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: Final rule.

SUMMARY: This final rule revises 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:

Effective date: These regulations are effective June 1, 2026.

Applicability date: These regulations are applicable to coverage beginning January 1, 2027.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose

The primary purpose of this 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 rule includes a number of changes that would improve these programs for contract year 2027 as well as codify existing subregulatory guidance.

We note that, as with previous rules, the new marketing and communications policies in this rule are applicable for all contract year 2027 marketing and communications, beginning October 1, 2026.

B. Summary of the Key Provisions

1. Medicare Part D Redesign

We are implementing 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 codifying the statutory changes to the phases of the Part D benefit made by the IRA related to the deductible, the 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 codifying technical and conforming changes to our specialty tier regulations. We are codifying 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 are codifying 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 are revising § 423.2300 by adding paragraph (b) to establish applicability dates for the Coverage Gap Discount Program, revising § 423.2345 by adding paragraph (f) to terminate all Coverage Gap Discount Program agreements, and making conforming changes for clarity.

3. Manufacturer Discount Program

We are codifying 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 are adding new subpart AA to part 423 to codify the Manufacturer Discount Program requirements and are making 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 final rule, we are finalizing changes to simplify and refocus the areas included in the Star Ratings, including changes to the measure set with the exception of the Diabetes Care—Eye Exam measure which will remain in the Star Ratings. We are also finalizing that we will 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 will continue to include the historical reward factor in the Star Ratings methodology at §§ 422.166(f)(1) and 423.186(f)(1). We appreciate commenters' suggestions on ways to further simplify and modify the Star Ratings program to further drive improved quality of care and reduce regulatory burden.

The measure removals will apply (that is, data will be collected and performance measured) for the 2027 measurement period and the 2029 Star Ratings, except for the Call Center—Foreign Language Interpreter and TTY Availability (Part C and D) measures and the Statin Therapy for Patients with Cardiovascular Disease (Part C) measure, which will apply beginning with the 2028 Star Ratings. Not proceeding with the HEI reward and maintaining the historical reward factor, finalizing additional information about the data available to Medicare Advantage (MA) organizations and Part D sponsors during the plan preview periods before each Star Ratings release at §§ 422.166(h)(2) and 423.186(h)(2), and clarifying the process for measure

removals at §§ 422.164(e)(2), 422.164(e)(3), 423.184(e)(2) and 423.184(e)(2), will be applicable upon the effective date of this final rule and apply beginning with the 2027 Star Ratings. We are also finalizing the technical clarification proposed in 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 proposed rule, which appeared in the **Federal Register** on December 10, 2024 (89 FR 99340) (hereinafter referred to as the ''Contract Year 2026 proposed rule'') to provide details about how the enrollment-weighted measure score is calculated when a consumed or surviving contract is missing data for a measure; this provision will be applicable upon the effective date of this final rule and apply beginning with the 2027 Star Ratings.

5. Provisions Related to Supplemental Benefits Being Finalized From the Contract Year 2026 Proposed Rule

In the Contract Year 2026 proposed rule (89 FR 99340), we proposed several policies that were not finalized at that time, some of which are being finalized in this CY 2027 final rule. Specifically, we proposed to strengthen the administration of Special Supplemental Benefits for the Chronically Ill (SSBCI) by increasing transparency and clarifying eligibility requirements, including a requirement to make plan-developed SSBCI eligibility criteria publicly available; we are finalizing this provision as proposed. We also proposed to codify and clarify requirements for the administration of supplemental benefits through debit cards to promote transparency, consistency, and program integrity, and are finalizing this proposal with modifications, including not finalizing the proposed prohibition on marketing the dollar value of supplemental benefits. We are finalizing these proposals to support beneficiary access, informed choice, and appropriate administration of MA benefits.

C. Summary of Costs and Benefits

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TABLE 1: SUMMARY OF PROVISIONS AND FINANCIAL IMPACTS

Provision	Description	Financial Impact
Medicare Part D Redesign	We are codifying the changes made to the Part D benefit design by section 11201 of the IRA. This includes sunsetting the Coverage Gap Discount Program as of January 1, 2025, under section 1860D-14A(h) of the Act, and codifying policies for the Manufacturer Discount Program beginning January 1, 2025, under section 1860D-14C of the Act.	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 finalizing changes to simplify and refocus the areas included in the Star Ratings, including changes to the measure set and are finalizing our proposal 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.	The net impact of the Star Ratings updates to the Medicare Trust Fund is estimated to be $18.56 billion from 2027 through 2036 or 0.21 percent of Medicare payments to private health plans during this 10-year period.
Administration of Supplemental Benefits Coverage through Debit Cards	We are codifying existing guidance on debit card administration for supplemental benefits and adding guardrails, including real-time verification mechanisms, enhanced disclosure requirements, and improved customer support.	We do not anticipate any impact on the Medicare Trust Fund. This provision primarily clarifies existing guidance and expectations. While it does include requirements for real-time verification of purchases and an alternate reimbursement process, these practices are already widely adopted by many plans. Additionally, the use of debit cards to administer benefits remains voluntary for participating plans.
Eligibility for Supplemental Benefits for the Chronically Ill (SSBCI) and Technical Changes to the Definition of Chronically Ill Enrollee	We are codifying a requirement for MA plans to post their objective SSBCI eligibility requirements on their public-facing website.	The changes will not impact the Medicare Trust Fund. The estimated financial impact of this provision arises from a plan's obligation to update a public website annually with any changes to covered benefits or eligibility criteria.

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D. Publication of the Proposed Rule, Responding to Public Comments, Finalization of Proposed Provisions, and Requests for Information

The proposed rule titled ''Medicare Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program,'' appeared in the **Federal Register** on November 28, 2025 (90 FR 54894) (hereinafter referred to as the ''Contract Year 2027 proposed rule'').

In response to the Contract Year 2027 proposed rule, we received approximately 42,632 timely pieces of correspondence containing a variety of comments on the proposed rule and the requests for information (RFIs) contained within the rule. Summaries of the public comments within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading. We note that some of the public comments were outside of the scope of the proposed rule and are not addressed in this final rule. We also note that we do not respond specifically to the comments pertaining to the RFIs, but we thank commenters for their feedback.

In this final rule, CMS is not finalizing the proposal to establish a special enrollment period for provider terminations and are not addressing comments received on this proposal. We acknowledge the broad interest related to this topic and will continue to consider the extent to which it may be appropriate to engage in future rulemaking in this area.

E. Conclusion

Finally, we are clarifying and emphasizing our intent that if any provision of this rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from 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 are codifying 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 took effect before the Contract Year 2027 proposed rule and other changes went 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 for the first cohort of selected drugs went 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. The IRA made 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 consists 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, we pay a 10 percent subsidy for selected drugs during a price applicability period.*** This phase ends when the enrollee has

[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 (FFDCA) 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.

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 provides 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)

We proposed to codify at §§ 423.100 and 423.104 changes to the Part D benefit made by the IRA related to the deductible, the 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 proposed 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 proposed to revise § 423.104(d)(2) and (d)(3) to reflect the elimination of the initial coverage limit beginning in CY 2025. Specifically, we proposed 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 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 also proposed 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 proposed 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

[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.*

[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.*

annual OOP threshold specified in § 423.104(d)(5)(iii).

We also proposed to revise § 423.104(d)(3), which specifies how the initial coverage limit is determined. We first proposed to remove the references in § 423.104(d)(3) to paragraphs (d)(4) and (d)(5) of this section because those 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 proposed 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 also proposed to add new § 423.104(d)(3)(iii) to state that, for 2025 and each subsequent year, there is no initial coverage limit.

Finally, we proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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.

We proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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.

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

We proposed 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 proposed 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 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 proposed 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 proposed 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 proposed 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 proposed 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 this final 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 a 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 § 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 final 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 proposed 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 proposed to revise § 423.104(e)(5) to align our requirements for alternative prescription drug coverage with the changes made by the IRA. We proposed to revise § 423.104(f)(1) to align our requirements for enhanced alternative drug coverage with the changes made by the IRA.

We first proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 did not propose any additional changes to this section.

Comment: Many comments were supportive of our proposals to codify the changes to the phases of the Part D benefit made by the IRA. We did not receive any comments opposed to our codification of these requirements.

Response: We thank the commenters for their support of our proposals.

Comment: A few comments expressed support for our proposed revision to the regulatory text at § 423.104(d)(1) to specify that the deductible does not apply to ACIP-recommended adult vaccines or covered insulin products. A commenter encouraged CMS to provide simple and clear guidance on immunization coverage to plans, their beneficiaries, as well as the range of providers who serve them.

Response: We thank the commenters for their support of this proposal. We agree that clear guidance is important to support implementation of these requirements. We will continue to provide guidance to Part D plan sponsors, providers, and beneficiaries regarding coverage of ACIP-recommended adult vaccines as appropriate. We refer the commenter to *Medicare.gov*, the Medicare Learning Network Fact Sheet on Medicare Part D Vaccines, and Chapters 5 and 6 of the Medicare Prescription Drug Benefit Manual for some of our existing guidance on this topic.[11]

Comment: Many commenters who were supportive of our proposals to codify the changes to the phases of the Part D benefit also expressed concerns about potential unintended consequences of the redesigned Part D benefit. Commenters stated that the reallocation of financial risk under the redesigned Part D benefit creates incentives for plans to control costs through increased utilization management, increased usage of step therapy protocols, narrower formularies, restricted pharmacy networks, and reduced coverage for certain brand or specialty drugs.

Several commenters emphasized that, without sufficient safeguards, these behaviors could undermine the intended affordability and access benefits of the redesigned Part D benefit. A few commenters highlighted the potential negative impacts these behaviors may have on high-cost and medically complex populations, including beneficiaries with end-stage renal disease (ESRD), hospitalized patients transitioning from inpatient to outpatient care, and low-income beneficiaries. A commenter noted that these behaviors may also increase administrative burden for hospital clinicians, thus delaying treatment initiation and complicating discharge planning and care coordination.

Due to these concerns, several commenters urged CMS to strengthen its oversight of Part D plans, particularly with respect to formulary design, utilization management practices, and appeals processes. A commenter also urged CMS to require minimum formulary protections for certain drugs and prohibit Part D plans from removing drugs mid-year in response to increased plan liability.

A few commenters requested that CMS monitor the impacts on access to drugs and evaluate whether costs are being shifted to beneficiaries. A couple of commenters emphasized the importance of monitoring both standalone prescription drug plans and Medicare Advantage prescription drug plans. A few commenters also requested that CMS increase transparency around formulary and evidentiary review findings so stakeholders can better understand how access is evolving under the redesigned Part D benefit.

Response: We thank the commenters for their support of our proposals to codify the changes made by the IRA to the phases of the Part D benefit. We appreciate the commenters sharing their concerns regarding potential unintended consequences of the redesigned Part D benefit, including the possibility that changes in plan liability could influence formulary design, utilization management practices, and beneficiary access to prescription drugs. We agree that robust oversight and monitoring are essential to the successful implementation of the redesigned Part D benefit, particularly for medically complex beneficiaries and those transitioning across care settings. We will continue to monitor the implementation of the redesigned Part D benefit as part of our ongoing program oversight.

We emphasize that Part D plan sponsors remain subject to existing statutory and regulatory requirements regarding formulary design, utilization management, pharmacy access, coverage determinations, and appeals. We will continue to oversee plan compliance with these requirements and monitor plan behavior through our comprehensive clinical formulary review process, which includes

[11] MLN Fact Sheet on Part D Vaccines: *https://www.cms.gov/files/document/mln908764-medicare-part-d-vaccines.pdf;* Chapter 5: *https://www.cms.gov/files/document/chapter-5-benefits-and-beneficiary-protection-v92011.pdf;* Chapter 6: *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf.*

evaluation of tier placement and utilization management restrictions and criteria.

We note that there are several longstanding statutory and regulatory safeguards in place to protect beneficiary access to critical medications. Section 1860D–11(e)(2)(D)(i) of the Act and § 423.272(b)(2)(i) require that CMS not approve a bid from a Part D sponsor if the design of its plan and its benefits, including its formulary structure and utilization management program, are ''likely to substantially discourage enrollment by certain Part D eligible individuals.'' In addition, § 423.120(b) establishes requirements for Part D formularies, including the requirement at § 423.120(b)(2)(i) that formularies include at least two Part D drugs within each therapeutic category and class. Section 1860D–4(b)(3)(G) of the Act and § 423.120(b)(2)(v) further require Part D sponsors to include all covered Part D drugs in the classes and categories of clinical concern identified by the Secretary, with limited exceptions as described in § 423.120(b)(2)(vi) and Chapter 6, Section 30.2.5 of the Medicare Prescription Drug Benefit Manual. Finally, § 423.120(e) limits the circumstances under which a Part D sponsor may make negative formulary changes during a contract year.

We appreciate the commenters' recommendations regarding transparency and will consider appropriate opportunities to share additional information regarding the formulary review and oversight process in the future.

Comment: Several commenters requested that we develop clear and simple beneficiary communications about the changes to the Part D benefit. The commenters stated that beneficiaries and their caregivers must understand how costs accrue over the plan year, what payments count towards the annual OOP threshold, how catastrophic coverage works, and what costs to expect across benefit phases. Another commenter recommended that CMS encourage plans to use mobile applications and digital tools for beneficiary education on the new benefit structure.

Response: We thank the commenters for their suggestions. We agree that beneficiary education and clear communication are critical to the successful implementation of the redesigned Part D benefit. We will continue to support the development of educational materials to help beneficiaries understand the redesigned Part D benefit. We encourage the commenters to refer beneficiaries to the Medicare & You Handbook, which provides general information on Medicare benefits, costs, rights, and protections; the Evidence of Coverage document provided by their Part D plan, which provides details on what their plan covers, how much they will pay, how to file a complaint, and more; and Medicare Plan Finder on Medicare.gov which allows users to compare Medicare health and drug plans in their area and compare costs.

Comment: A commenter requested that CMS establish a formal mechanism for patients and patient advocacy organizations to communicate directly with CMS, including any barriers to getting prescribed medications when enrollees need them. Another commenter urged CMS to commit to ongoing provider and hospital engagement as part of a long-term monitoring and evaluation strategy for the Part D redesign. The commenter noted that hospitals and frontline clinicians are uniquely positioned to identify access barriers and unintended consequences as they emerge and that their input should be systematically incorporated into CMS oversight frameworks.

Response: We appreciate the commenters' recommendations. There are multiple avenues through which beneficiaries, providers, and other stakeholders may raise concerns regarding access to prescription drugs, including through the grievance, coverage determination, or appeals processes, consistent with the requirements outlined in 42 CFR part 423, subpart M. Beneficiaries may also submit inquiries, complaints, grievances, appeals, and requests for information to the Medicare Beneficiary Ombudsman and 1–800–MEDICARE. Additionally, we developed the Complaint Tracking Module (CTM) in the Health Plan Management System (HPMS) to track complaints received by CMS from beneficiaries, providers, and their representatives regarding specific plans. Complaints are recorded in the CTM and assigned to the appropriate plan and, as required under the contract provisions established at § 422.504(a)(15) and § 423.505(b)(22), plans are required to address and resolve the complaints received by CMS against them in the CTM. Plans must also adhere to the timelines to resolve complaints in compliance with § 422.125 and § 423.129. We will consider additional opportunities to engage with stakeholders as part of our ongoing oversight of the Part D program as appropriate.

Comment: A commenter who supported CMS's proposal to codify the Part D benefit changes also expressed concerns about the unintended consequences of the IRA's changes. The commenter stated that plans have experienced higher-than-anticipated costs due to changes in plan liability, higher utilization among beneficiaries reaching the out-of-pocket cap, and continued growth in the prescription drug pipeline. The commenter noted that if current utilization trends continue, there may be additional pressure on bids in CY 2027.

The commenter expressed prior concerns related to premium increases resulting from the Part D benefit redesign. They noted that they appreciated CMS's voluntary Part D Premium Stabilization Demonstration but indicated that additional policy changes are needed to assist Part D plan sponsors in preserving the affordability historically associated with Part D plans. Specifically, the commenter recommended modifications to the RxHCC model, including incorporating Direct and Indirect Remuneration (DIR) into the model and using drug utilization to better account for variation in drug costs among beneficiaries.

The commenter also urged CMS to provide additional flexibility to Part D plans to manage costs by streamlining regulations and reducing administrative burdens.

Response: CMS acknowledges the commenter's concerns about balancing changes in plan liability under the Part D redesign with a need to preserve affordability for Part D enrollees. We will continue to monitor impacts of the redesigned Part D benefit and seek to identify opportunities to improve program efficiency and reduce unnecessary administrative burden. We appreciate the commenter's recommendations on streamlining regulations and reducing administrative burden and will consider this feedback in future rulemaking as appropriate. However, we note that changes to the RxHCC model are outside the scope of this rulemaking.

After consideration of the public comments we received, we are finalizing these proposals as proposed.

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.

As described further later, 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 the Contract Year 2027 proposed rule, we proposed 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 proposed 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 proposed to correct this inadvertent technical error.

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 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), 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 went 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 proposed to revise § 423.104(d)(2)(iv)(B)(1) and (2) by adding language to allow CMS to reduce the cost threshold under certain circumstances. Specifically, in paragraph (B)(1) of this section, we proposed to replace ''increase'' with ''modifies'' and add ''or below'' following ''10 percent above.'' In paragraph (B)(2), we proposed 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 coinsurance for the beneficiary regardless of the plan deductible, represented by the following equation:

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

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, under statutory changes made by the IRA, 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 proposed 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 reflects the defined standard benefit, we proposed 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 proposed 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 proposed 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 2.

TABLE 2: 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%

[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.*

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 proposed to codify this methodology for determining specialty-tier coinsurance/deductible ranges. Thus, we proposed 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 proposed 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.

Comment: We received several comments that were supportive of our proposal to allow for a decrease in the specialty-tier cost threshold when market conditions might warrant such a change.

Response: We thank the commenters for their support of our proposal.

Comment: Several commenters opposed our proposal to allow for a decrease in the specialty-tier cost threshold when market conditions might warrant such a change. These commenters stated that lowering the specialty-tier cost threshold would expand the number of drugs eligible for placement on the specialty tier and expose beneficiaries to higher cost sharing. Commenters expressed concern that this would move drugs from non-specialty tiers with fixed copayments or lower coinsurance into the specialty tier, resulting in increased and less predictable out-of-pocket (OOP) costs. A few commenters also noted that because tiering or cost-sharing exception requests may be denied for specialty-tier drugs, beneficiaries have no recourse to appeal their cost-sharing liability, even when the drug is needed for clinical reasons and expanding their specialty tier would exacerbate these issues.

Some commenters asserted that this proposal would undermine the goals of the IRA's Part D redesign provisions and prevent beneficiaries from benefitting from the IRA's affordability protections. Some commenters further noted that Part D plans have increasingly shifted from fixed copayments to coinsurance in response to IRA-related changes, and they argued that allowing the specialty-tier cost threshold to decrease would exacerbate these trends rather than limit them.

Several commenters also raised concerns about beneficiary access to prescription drugs. A few commenters stated that higher specialty-tier cost sharing contributes to delayed initiation of therapy, treatment disruptions, and prescription abandonment, particularly for beneficiaries with serious or complex medical conditions who rely on specialty drugs as well as those living in long-term care settings. Additionally, some commenters expressed concern that decreasing the specialty-tier cost threshold would lead to increased usage of utilization management, including prior authorization and step therapy, further limiting access to medically appropriate therapies.

A few commenters raised concerns that lowering the specialty-tier cost threshold could also increase opportunities for vertically integrated Pharmacy Benefit Managers (PBMs) to inappropriately steer beneficiaries toward PBM-affiliated pharmacies or favor higher-cost drugs on their formularies. These commenters recommended anti-steering provisions, increased formulary oversight, and other guardrails.

Response: We appreciate the commenters' feedback on our proposal to allow for a decrease in the specialty-tier cost threshold. We do not agree that movement of drugs to the specialty tier will necessarily result in increased beneficiary cost sharing. Under § 423.104(d)(2)(iv)(D)(1) through (3), the maximum allowable cost sharing for drugs on the specialty tier is set between 25 percent and 33 percent. In contrast, drugs placed on non-preferred tiers may be subject to coinsurance rates that exceed these limits, up to 50 percent. Further, we do not agree that specialty-tier placement uniformly increases beneficiary out-of-pocket costs.

As noted by many commentors, more plans are moving non-specialty drug tiers from a copayment to a coinsurance cost-sharing structure, so we do not agree that placement on the specialty tier will always result in a change from a fixed copayment amount to a coinsurance. Placement on the specialty tier may, in some cases, result in lower cost sharing than placement on other formulary tiers.

We also note that the specialty-tier cost threshold is established through a data-driven methodology that examines a year's worth of prescription drug event (PDE) data to determine the dollar amount associated with the top one percent of Part D drug claims. This methodology is intended to ensure that the specialty tier remains focused on the highest-cost drugs in the program. Historically, the dollar amount associated with the top one percent of claims has increased over time, and we do not anticipate that the specialty-tier cost threshold will decrease in the near term. However, we believe it is appropriate to maintain regulatory flexibility to account for future market changes, including those that may result from the increasing number of drugs subject to negotiation in the Medicare Drug Price Negotiation Program.

We acknowledge the commenters' concerns regarding affordability and access, including the interaction between specialty-tier placement, cost sharing, and utilization management requirements. As discussed earlier, Part D sponsors remain subject to existing requirements related to formulary design, utilization management, pharmacy access, and beneficiary protections. Given that the cost-sharing limits on the specialty tier are intended to align with the defined standard benefit, we do not consider placement on the specialty tier to be a cause for concern regarding access and affordability. In addition, the redesigned Part D benefit includes affordability protections, such as the reduced annual out-of-pocket threshold, which will mitigate beneficiary exposure to high prescription drug costs across the benefit.

Comment: A few commenters who opposed our proposal to allow for a decrease in the specialty-tier cost threshold urged CMS to establish clear guardrails before any downward adjustment is made in the future. These commenters stated that such guardrails should include a beneficiary impact analysis, advance notice, meaningful stakeholder input, and strengthened affordability protections so beneficiaries do not experience higher out-of-pocket costs. Another commenter recommended that CMS conduct research on the effects of our proposed regulatory change on patient out-of-pocket costs and health outcomes.

Response: We thank the commenters for their suggestions. We remain committed to robust oversight and monitoring of Part D formularies and utilization management practices. If future evidence indicates that additional safeguards or refinements to our specialty-tier policies are warranted, we may consider such adjustments in future rulemaking.

Comment: A commenter who supported our proposal to allow for a decrease in the specialty-tier cost threshold recommended that CMS establish clear guardrails to ensure that this bidirectional flexibility does not inadvertently enable routine mid-year tiering changes or create cost-sharing disruptions.

Response: We thank the commenter for their recommendation. We clarify that specialty-tier cost threshold adjustments are effective at the start of a contract year and should not result in mid-year formulary changes. All

existing formulary change policies and protections remain in place. As stated previously, if future evidence indicates that additional safeguards or refinements to our specialty-tier policies are warranted, we may consider such adjustments in future rulemaking.

Comment: A commenter requested that we explain why we are retaining the 33 percent specialty-tier maximum allowable coinsurance when our calculations show a maximum allowable coinsurance percentage of 32 percent. The commenter noted that CMS reports that this calculation, using the CY 2025 values of $590 for the defined standard benefit deductible and $2,000 for the out-of-pocket limit, results in an effective coinsurance rate of 32.1 percent. The commenter also noted that the same calculation, using the CY 2026 values of $615 for the defined standard benefit deductible and $2,100 for the out-of-pocket limit, results in an effective coinsurance rate of 32.0 percent. By retaining the 33 percent maximum coinsurance percentage, the commenter stated that enrollees in Part D plans with deductibles below that of the defined standard benefit cost-sharing would be charged cost sharing that is above the effective coinsurance rate, thus, reducing access to covered Part D drugs and potentially leading to negative health outcomes. The commenter recommended that CMS set the maximum allowable coinsurance percentage for the specialty tier at 32 percent.

Response: To maintain continuity in transitioning our specialty-tier calculation from the prior methodology to the updated methodology reflecting the redesigned Part D benefit, CMS opted to maintain consistency in the cost-sharing thresholds compared to the thresholds prior to redesign. CMS agrees with the commenter's calculations of effective coinsurance amount. When performing the annual calculation using updated benefit parameters, we note that the effective coinsurance amount calculated using the full deductible amount and 25 percent coinsurance results in a value that varies slightly from year to year. For CY 2025, the calculation resulted in an effective coinsurance of 32.10 percent compared to 32.04 percent for CY 2026. We note that similar magnitudes of variance existed in the calculation of this annual effective coinsurance even before the IRA's changes to the Part D benefit design went into effect. An alternative approach to the calculation could use this calculated value as the upper limit to the specialty tier coinsurance; however CMS opted to use a single value annually to maintain stability year-over-year. As such, the methodology laid out in this final rule relies on the effective coinsurance value of 33 percent as the basis for all calculations. We also note that this is a mathematical equivalence calculation, for a hypothetical beneficiary taking only specialty-tier drugs, and not intended to reflect actuarial equivalence.

Comment: A commenter thanked CMS for the detailed illustrative example of how the maximum coinsurance percentage would be calculated, noting that it provides important clarity for plans.

Response: We thank the commenter for their support.

After consideration of the public comments we received, we are finalizing our specialty-tier proposals as proposed.

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.

As discussed in the Contract Year 2027 proposed rule, section 11201 of 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.

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).

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.

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.

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.

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 the Contract Year 2027 proposed rule, we proposed 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 proposed 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 proposed 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.

Comment: Many commenters opposed CMS' proposal to codify the inclusion of supplemental coverage provided by enhanced alternative Part D plans in the calculation of TrOOP. Several commenters asserted that Congress's intent in amending the definition of ''incurred costs'' under section 1860D–2(b)(4)(C)(iii)(II) of the Act was to address the specific and unique situation of EGWP beneficiaries who faced higher out-of-pocket costs and longer stays in the coverage gap due to their supplemental coverage. These commenters asserted that if Congress intended to include supplemental coverage provided by Part D enhanced alternative plans in the definition of ''incurred costs,'' they would have done so explicitly. Several commenters stated that the use of the term ''insurance'' to describe costs that are included as incurred costs and the use of the phrase ''coverage provided by a prescription drug plan or an MA–PD plan'' to describe basic coverage that is not included as incurred costs illustrates Congress's intent that supplemental coverage provided by Part D plans should not be included in TrOOP because Congress typically uses the latter language rather than the term ''insurance'' to refer to costs incurred by Part D plans, including supplemental coverage. Commenters suggested that the best reading of the statutory text is that only ''wrap-around'' benefits should be added to the definition of incurred costs, and that the statute's reference to costs ''reimbursed'' through insurance implies a focus on costs covered through other insurance rather than costs covered directly by the Part D benefit. A commenter asserted that if Congress intended to include basic Part D coverage in the scope of ''reimbursed by insurance,'' the same logic should apply to enhanced alternative coverage, on the grounds that enhanced alternative coverage is merely a variant design of the same underlying Part D benefit structure.

Response: CMS thanks the commenters for their input. CMS disagrees that enhanced alternative supplemental benefits are not included in the calculation of TrOOP under section 1860D–2(b)(4)(C)(iii) of the Act. The statute does not draw a distinction between non-Part D commercial insurance and coverage under Part D when it uses the term ''reimbursed through insurance' in this provision. 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 plain 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.'' If the provision only included EGWP supplemental coverage in the definition of costs ''reimbursed through insurance,'' the statutory text would have done so by explicitly including EGWP supplemental coverage in the definition of ''costs reimbursed through insurance'' and expanding the exclusion clause to apply to both basic prescription drug coverage and enhanced alternative supplemental coverage. However, the statute does not do so and instead enacted a broader provision for which the plain text requires any costs ''reimbursed through insurance'' be treated as incurred unless such costs constitute basic prescription drug coverage provided by a prescription drug plan or an MA–PD plan. We disagree with the assertion that if the statute were intended to exclude basic Part D coverage from the scope of ''reimbursed through insurance,'' the same logic must apply to enhanced alternative coverage, because the statute draws an explicit, meaningful distinction between basic and enhanced alternative coverage. The Part D statute and regulations repeatedly distinguish between basic and enhanced benefits, given that enhanced alternative coverage is optional and sponsor-specific.

Comment: Several commenters expressed concern that the inclusion of supplemental benefits in TrOOP artificially accelerates beneficiaries through benefit phases into catastrophic coverage, increasing plan, federal, and manufacturer liability. These commenters asserted that including supplemental benefits in TrOOP creates distortions in plan design and undermines market stability. Specifically, a few commenters suggested that the inclusion of enhanced alternative supplemental benefits in TrOOP decreases plans' ability to manage beneficiary costs, increases government spending, increases bid pressure, and may cause plans to scale back supplemental benefits or exit the PDP market entirely, ultimately undermining program sustainability.

Response: CMS thanks the commenters for their input. CMS acknowledges that the inclusion of enhanced alternative supplemental benefits in TrOOP may affect the incentives available to beneficiaries enrolled in enhanced alternative plans, including the incentives for beneficiaries to choose higher-cost drugs over lower-cost ones in certain circumstances. When beneficiaries move through the benefit phases more quickly, overall plan liability increases, which may contribute to increased premium costs for enhanced alternative plans and affect sponsors' decisions about enhanced alternative plan offerings. While we cannot definitively attribute these changes to this policy, as other elements of the Part D redesign may also be contributing factors, we have seen a notable decline in standalone Part D-only enhanced alternative plan offerings along with a broader shift from copayments to coinsurance benefit design since the redesign was implemented. CMS recognizes stakeholder concerns that the proposed provision has the potential to increase Part D program costs and government spending and reduce plan offerings. We note that only a statutory change would allow CMS to exclude enhanced alternative supplemental benefits from counting towards TrOOP.

Comment: A couple of commenters requested that CMS clarify whether manufacturer copayment assistance or patient assistance programs are considered to be ''certain other third-party payment arrangements'' included as incurred costs for the calculation as TrOOP.

Response: CMS clarifies that manufacturer copayment assistance and

patient assistance programs do not count as incurred costs for purposes of TrOOP accumulation, as these programs operate outside of the Part D benefit.

Comment: Several commenters requested that CMS clarify whether the proposed provision changes the treatment of supplemental benefits provided by Puerto Rico Platino plans for the purposes of calculating TrOOP, and requested that CMS codify current guidance related to the treatment of supplemental benefits provided by Platino plans in regulation.

Response: CMS appreciates commenters' request for clarity regarding the treatment of Puerto Rico Platino wrap-around coverage for purposes of calculating TrOOP. The proposed changes do not alter the longstanding treatment of Platino wrap-around coverage funded by the Commonwealth of Puerto Rico. Platino plans continue to submit Part D bids with only basic benefits. Under section 1860D–42(a) of the Act and § 423.859(c), which permits CMS to waive or modify applicable Part D requirements if CMS determines that waiver or modification is necessary to secure access to qualified prescription drug coverage for Part D eligible individuals residing in the territories, Platino wrap-around coverage count towards the beneficiary's TrOOP. Note that no other Medicaid assistance counts towards TrOOP, only those payments for residents of territories that substitute for low-income cost-sharing subsidies in accordance with the statute. CMS believes that existing statutory provisions and guidance provide sufficient clarity and additional rulemaking to codify current guidance related to supplemental benefits provided by Platino plans is not warranted given the longstanding nature of the section 1860D–42(a) waiver in place for Platino wrap-around coverage.

Comment: A few commenters disagreed with the proposal to codify the exclusion of negative values in the field on the PDE representing supplemental coverage from the calculation of TrOOP. A commenter stated that disregarding negative PDE values overstates the value of supplemental benefits. Another commenter suggested that it could lead to beneficiary confusion.

Response: CMS thanks the commenters for their input. CMS acknowledges 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 OOP threshold, which could also lead to beneficiary confusion and could potentially violate the statutory requirement for an enrollee to have $0 cost sharing once their incurred costs exceed the OOP threshold.

Comment: Some commenters supported CMS' proposal to codify the inclusion of supplemental coverage provided by enhanced alternative Part D plans in the calculation of TrOOP. These commenters stated that aligning the regulatory definition of incurred costs with the statutory amendments provides needed clarity and consistency for beneficiaries, plans, and other stakeholders.

Response: We thank the commenters for their support.

After considering the comments we received and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to comments, we are finalizing the proposed amendments to §§ 423.100 and 423.464 without modification.

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.

In the Contract Year 2027 proposed rule, we explained that 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.

We described the policy established in the Final CY 2025 Part D Redesign Program Instructions for drugs not subject to the defined standard deductible, which addresses situations where a beneficiary has not satisfied their plan deductible but has incurred sufficient TrOOP-eligible costs to satisfy the defined standard deductible, or 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. We explained that, as established in the Final CY 2025 Part D Redesign Program Instructions, manufacturer discounts are not available until cumulative TrOOP-eligible costs meet the defined standard deductible. Plans that offer a non-defined standard plan deductible are responsible for the portion of costs that would otherwise be covered by the discount when 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. Additionally, we noted that in the Final CY 2026 Part D Redesign Program Instructions, we stated that this policy also applied in CY 2026 and established that for CY 2026 the policy for drugs not subject to the defined standard deductible also applies to the selected drug subsidy

with respect to selected drugs during a price applicability period. In the Contract Year 2027 proposed rule, we proposed 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 proposed to codify the policy for drugs not subject to defined standard deductible at a new § 423.104(j).

Comment: A commenter supported the proposal to codify the policies outlined in the Final CY 2025 and CY 2026 Part D Redesign Program Instructions regarding the application of the Manufacturer Discount Program to drugs that are not subject to the defined standard deductible. The commenter stated that codifying these policies ensures clarity, consistency, and effective implementation.

Response: We thank the commenter for their support.

Comment: A commenter recommended that CMS use the beneficiary's plan deductible as the threshold for becoming an applicable beneficiary under the Manufacturer Discount Program to alleviate potential beneficiary confusion, stating that the current approach favors some beneficiaries over others and ignores plan terms.

Response: Section 1860D–14C(g)(1)(C) 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 Part D 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. As such, once a beneficiary has incurred sufficient TrOOP-eligible costs to satisfy the defined standard deductible, they will be an applicable beneficiary under the Discount Program. Because the threshold for when a beneficiary becomes an applicable beneficiary is defined in statute, CMS cannot choose an alternative threshold.

After considering the comments received and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to comments, we are finalizing the proposed amendments to § 423.104 without modification.

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 accordance with the statute and corresponding regulation, the following Part D benefit parameters are updated annually using the API: the standard Part D benefit deductible, the initial coverage limit, the OOP threshold, maximum copayments below the OOP threshold for low-income full subsidy eligible enrollees with income less than 150 percent, but greater than 100 percent of Federal Poverty Level (FPL) not including institutionalized individuals, the RDS cost threshold, and the RDS cost limit. The CPI is used to update maximum copayments below the OOP threshold for low-income full subsidy eligible enrollees with income less than 100 percent of FPL.

In the Contract Year 2027 proposed rule, we explained that 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 the Contract Year 2027 proposed rule, we proposed to codify these methodologies in regulation. Although we proposed to codify the calculation methodology for the API and CPI, 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.

Calculation of the Annual Percentage Increase in Drug Expenditures

In the Contract Year 2027 proposed rule, we described the calculation of the API for Part D as the product of the annual percentage trend (APT), which is the year-over-year change in total per capita Part D covered drug expenditures based on PDE data, and a multiplicative update (MU) factor that incorporates updated data for prior years into the calculation.

We proposed 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

In the Contract Year 2027 proposed rule, we described the calculation of the annual percentage increase in the CPI as the product of an annual percentage trend, which is a year-over-year comparison of the CPI–U for all items, ending in September, and a multiplicative update factor that incorporates revisions when estimated CPI values are replaced with actual BLS data. We explained that this CPI-based update applies to copayments for the lowest-income dually eligible beneficiaries (with incomes not exceeding 100 percent of the FPL) to preserve purchasing power relative to general inflation.

To implement the CPI calculation described previously in our regulations, we proposed to revise § 423.782(a)(2)(iii)(A) to include a reference to a new paragraph (d), which we proposed to add at the end of § 423.782. New § 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 also proposed two technical changes to § 423.782(b).

Comment: A commenter expressed support for CMS' proposal to codify the methodologies for calculating the API and CPI used to update Part D benefit parameters. The commenter stated that the proposal ensures uniform application of Part D parameter updates across plan sponsors and benefit years.

Response: CMS thanks the commenter for their support.

After considering the comments we received, we are finalizing the proposed provisions at §§ 423.104 and 423.782 without modification.

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 (GCPDC) and allowable reinsurance costs for the purpose of describing the methodology for calculating the reinsurance payment amount. In the Contract Year 2027 proposed rule, we explained that GCPDC is defined as the costs incurred under a Part D plan, excluding administrative costs but including deductible and dispensing-related costs, regardless of payer, while allowable reinsurance costs are limited to amounts actually paid net of discounts and rebates. We further explained that consistent with the statutory and regulatory definition of GCPDC, manufacturer discounts under the Coverage Gap Discount Program were included in GCPDC, but the IRA amended the statute to require inclusion of manufacturer discounts under the new Manufacturer Discount Program in both GCPDC and allowable reinsurance costs beginning in 2025. CMS implemented these statutory changes through the Final CY 2025 Part D Redesign Program Instructions and Final CY 2026 Part D Redesign Program Instructions.

In the Contract Year 2027 proposed rule, we proposed 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 proposed 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 proposed 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).''

We received no comments on this proposal and are finalizing the proposed revision at § 423.308 without modification.

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.

Beginning in 2025, the IRA reduced the reinsurance payment amount for a Part D beneficiary from 80 percent to 20 percent for applicable drugs or 40 percent for drugs that are not applicable drugs. As we explained in the Contract Year 2027 proposed rule, we make reinsurance payments to Part D plan sponsors based on the GCPDC that were actually paid during the coverage year, meaning that the costs must be actually incurred by the Part D sponsor and must be net of any direct and indirect remuneration (DIR). In the Final CY 2025 Part D Redesign Program Instructions, we established a methodology to calculate reinsurance subsidies separately for applicable drugs 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. In the Final CY 2026 Part D Redesign Program Instructions we updated the methodology to account for selected drugs, which are grouped with non-applicable drugs for purposes of calculating the reinsurance subsidy. We explained that the Final CY 2026 Part D Redesign Program Instructions established the process for calculating reinsurance separately for applicable and non-applicable or selected drugs, allocating DIR based on each category's share of gross drug costs in the catastrophic phase, and reconciling the adjusted reinsurance amounts against prospective payments using NDC-level drug classifications.

In the Contract Year 2027 proposed rule, we proposed 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 proposed 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.

We received no comments on this proposal and are finalizing the proposed revisions to § 423.329 without modification.

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. In the Contract Year 2027 proposed rule, we described the selected drug subsidy program, under which the Secretary provides Part D plan sponsors with a subsidy equal to 10 percent of the negotiated price for selected drugs during a price applicability period dispensed to applicable beneficiaries below the annual out-of-pocket threshold after the deductible is met. We further explained that because of the intertwined structure and wording of the Manufacturer Discount Program and selected drug subsidy program provisions in the Act, we proposed 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. Finally, we described our proposal to make monthly prospective payments for the selected drug subsidy program, based on Part D plan sponsors' estimates of selected drug subsidy amounts submitted with their annual bids, and reconciled using the actual selected drug subsidy amounts that Part D plan sponsors report on PDE data.

In the Contract Year 2027 proposed rule, we proposed 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 proposed to codify at new § 423.315(h) that we would provide prospective selected drug subsidy payments on a

monthly basis. We also proposed to codify at new § 423.329(e) the determination of selected drug subsidy payments. Finally, we proposed 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.

We received no comments on this proposal and are finalizing the proposed additions at §§ 423.265, 423.315, 423.329, and 423.343 without modification.

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

In the Contract Year 2027 proposed rule, we noted the need for a technical correction at § 423.343(d)(2). The final sentence of this paragraph is incorrectly placed in § 423.343 and should instead be placed in § 423.336. Thus, we proposed to revise § 423.343 to remove this sentence and revise § 423.336(c) to add this sentence in its proper context.

We received no comments on this proposal and are finalizing the proposed revisions at §§ 423.336 and 423.343 without modification.

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 Contract Year 2027 proposed rule, we explained that 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 Contract Year 2027 proposed rule, we proposed to codify the statutory amendments to section 1860D–13(a) of the Act. Specifically, we proposed 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).

We received no comments on this proposal and are finalizing the proposed changes to § 423.286 without modification.

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 Contract Year 2027 proposed rule, we proposed to 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 proposed 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 proposed 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.

Comment: A commenter expressed support for CMS's proposal to align LIS eligibility criteria with the IRA by updating the FPL limit to 150 percent for plan years beginning January 1, 2024.

Response: CMS thanks the commenter for their support.

After considering the comments we received, we are finalizing the proposed revisions to § 423.782 without modification.

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 Contract Year 2027 proposed rule, we explained that, although the IRA amended the parameters of the standard prescription drug coverage and makes other changes to the Part D benefit, it did not change the requirements for qualified retiree prescription drug plans.

Although the majority of the IRA policies in effect for CY 2027 and subsequent years do not require updates to Subpart R, we explained in the Contract Year 2027 proposed rule that there are certain conforming edits required. Specifically, we proposed 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 proposed 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.''

We received no comments on this proposal and are finalizing the proposed revisions to §§ 423.882 and 423.884 without modification.

14. Medical Loss Ratio (§ 423.2420)

In the Contract Year 2027 proposed rule, we explained that the medical loss ratio (MLR) requirements established under section 1857(e) of the Act require Part D contracts to report 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. We described longstanding policy that pass-through payments for which plans retain no liability, such as low-income cost-sharing subsidies and Coverage Gap Discount Program payments, are excluded from both the numerator and denominator of the MLR. We further explained that new federal payments created by the IRA, including Manufacturer Discount Program payments, the Inflation Reduction Act Subsidy Amount (IRASA), and the selected drug subsidy, are treated similarly as pass-through amounts and therefore excluded from the MLR calculation. This was established in the Final CY 2025 Part D Redesign Program Instructions and applied in CY 2026 through the Final CY 2026 Part D Redesign Program Instructions.

In the Contract Year 2027 proposed rule, we proposed 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 proposed 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.

We received no comments on this proposal and are finalizing the proposed revisions at § 423.2420 without modification.

15. Severability

We proposed that the Medicare Part D redesign provisions finalized herein would be separate and severable from one another. Further, we proposed that if any of these provisions 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.

We received no comments on this proposal and are finalizing without modification.

B. Medicare Coverage Gap Discount Program

Section 1860D–14A of the Act established the Medicare Coverage Gap Discount Program, which began on January 1, 2011. Coverage Gap Discount 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 Inflation Reduction Act of 2022 (Pub. L. 117–169) (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 proposed 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 proposed 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 proposed to add the new text at § 423.2300(b). We also proposed to revise § 423.2315(c)(2) to reflect the sunset of the Coverage Gap Discount Program by 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 proposed 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.

To address programmatic differences between the Coverage Gap Discount Program and the Manufacturer Discount Program, which are discussed in more detail in section II.C. of this final rule, we proposed to revise § 423.2305 to clarify that the definitions at § 423.2305 apply only for purposes of the Coverage Gap Discount Program. Further, we proposed 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. Lastly, we proposed technical changes throughout subpart W to replace the shorthand term ''Discount Program'' with ''Coverage Gap Discount Program.''

Comment: A few commenters were in support of the proposed changes. Commenters acknowledged the proposals as important and consistent with statutory requirements.

Response: We thank the commenters for their support and are finalizing the changes to the subpart that were proposed.

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).[14]

In the proposed rule, we proposed to codify the Manufacturer Discount Program Final Guidance, with limited refinements and changes, 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. 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 and adjusts the payments through an annual reconciliation.

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

Discounts under the Manufacturer Discount Program generally reduce the amount the Part D sponsor pays for the drug, 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. Discounts are 10 percent of the negotiated price of the applicable drug in the initial coverage phase and 20 percent in the catastrophic coverage phase, and 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 proposed to codify 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.

Comment: We received several comments supportive of our proposal to codify existing Manufacturer Discount Program policies. Commenters appreciated that CMS implemented the Manufacturer Discount Program in a manner similar to the former Coverage Gap Discount Program.

Response: We thank the commenters for their support. We are finalizing the regulatory policies for the Manufacturer Discount Program largely as proposed, with limited modifications, which are described in greater detail below.

2. Basis and Scope (§ 423.2700)

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

We received no comments on this section and we are finalizing § 423.2700 as proposed.

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

We proposed 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 consistent with the policies we are finalizing in this rule.

Several of these terms are also used for purposes of the Coverage Gap Discount Program. Because some of the terms are applicable to both subpart W and proposed subpart AA, we proposed to revise certain definitions in existing §§ 423.100, 423.1002, and 423.2305, move certain definitions from § 423.2305 to § 423.100 with revisions 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 proposed to revise a number of existing definitions as discussed below.

• ''Applicable beneficiary'';

We proposed 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.

• ''Applicable drug'';

We proposed 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 from the definition. As stated in the proposed rule, this change would codify both longstanding CMS policy under the Coverage Gap Discount Program as well as policy established in section 40.1 of the Manufacturer Discount Program Final Guidance. Whereas 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, because compounds as a whole are not approved under a New Drug Application (NDA) or Biologic Licensing Application (BLA), CMS has established that compounds do not meet the definition of an applicable drug.

For the purposes of the Manufacturer Discount Program, we proposed 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. As stated in the proposed rule, 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 proposed to specify 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 proposed to add definitions for the following terms at § 423.100:

• ''Applicable discount'';

We proposed 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 proposed 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 proposed 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 proposed to remove the existing definition of ''date of dispensing'' from § 423.2305 and add it, with revisions, at § 423.100. Specifically, we proposed 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.''

• ''Labeler code'';

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

• ''Manufacturer'';

We proposed 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''.

• ''Manufacturer Discount Program'';

We proposed 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 proposed to define ''Manufacturer Discount Program agreement'' as the

agreement described at section 1860D–14C(b) of the Act.

• ''Medicare Coverage Gap Discount Program'';

We proposed 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 proposed 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 proposed 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''.

• ''Non-applicable drug'';

We proposed 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 proposed 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 proposed to define ''selected drug'' as having the meaning given such term in section 1192(c) of the Act and any applicable regulations and guidance.

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

We proposed to add at § 423.100 the definition of ''Third Party Administrator'' that we proposed to remove from § 423.2305, with revisions. Specifically, we proposed 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 proposed 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 proposed 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 proposed to remove the following definitions from § 423.2305 because, as noted previously, we proposed 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 proposed to define the following terms for purposes of proposed subpart AA and the Manufacturer Discount Program:

• ''Agreement holder'';

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

• ''Applicable LIS percent'';

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

• ''Applicable small manufacturer percent'';

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

• ''Covered Part D drug'';

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

• ''Dispute submission deadline'';

We proposed 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 proposed 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, the negotiated price includes any dispensing fee and, if applicable, any vaccine administration fee and sales tax.

• ''Network pharmacy'';

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

• ''Part D drug'';

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

• ''Primary manufacturer'';

We proposed 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 proposed 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 proposed 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 proposed 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.

Comment: We received a few comments regarding our proposed definitions, specifically in support of our proposed definitions of ''applicable drug'' and ''date of dispensing.'' Both commenters noted that the proposed definitions will provide clarity for stakeholders, including plans, pharmacies, enrollees, and manufacturers. A commenter applauded CMS's recognition that transition fills and emergency supplies are ''applicable drugs'' and may be necessary for long term care residents to ensure uninterrupted access to medications that can be lifesaving. Another commenter appreciated CMS ensuring that definitions are consistent across the agency's guidance documents, policies, and programs.

Response: We thank the commenters for their support and are finalizing the proposals discussed in this section without modification our proposed definitions at §§ 423.100, 423.1002, 423.2305, and 423.2704.

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.

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.

At § 423.2708(a), we proposed to codify existing Manufacturer Discount Program policy 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 that chooses 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 did not propose to prohibit this practice, provided all other requirements of the Manufacturer Discount Program are met. As discussed in the preamble to the proposed rule, 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 proposed to codify this requirement at § 423.2708(b).

While a manufacturer may participate in the Manufacturer Discount Program in accordance with proposed § 423.2708(b)(2), 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 proposed 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 proposed 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.

At § 423.2708(d), we proposed that non-applicable drugs, as we proposed 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.

Comment: We received a comment on the proposals in this section. The commenter expressed concern about limitations on enrollee access to drugs of a manufacturer that does not participate in the Manufacturer Discount Program, and recommended that CMS specify criteria for making a determination that an applicable drug is essential to the health of Part D enrollees.

Response: CMS appreciates and shares the commenter's concern about

enrollee access to applicable drugs of manufacturers that choose not to participate in the Manufacturer Discount Program. However, we decline to codify specifications for the exception provision at § 423.2708(c) at this time. Based on experience under the Coverage Gap Discount Program and the Manufacturer Discount Program to date, CMS does not anticipate using this exception, which has not been used to date under either program. We are concerned that proactive exemptions for certain drugs, or categories and classes of drugs, from the required conditions for Part D coverage would result in higher costs to Part D sponsors, beneficiaries, and the government because manufacturers of those drugs would have no incentive to participate in the Manufacturer Discount Program. Manufacturers should not expect to get their applicable drugs covered under Part D as a result of this exception.

CMS is finalizing the regulation text at § 423.2708 without modification.

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

Consistent with the definition in § 423.100 that we are finalizing in this final rule, ''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 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 proposed 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 final 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 proposed to codify this policy at § 423.2712(g).

In accordance with section 1860D–14C(c)(1)(C) of the Act, we proposed 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 proposed 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 proposed 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 proposed 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 proposed to codify the policy for straddle claims at § 423.2712(e).

d. Claims Not Subject to Discount

Since CMS is unable to ascertain from the PDE how much liability, if any, the Part D sponsor has on Medicare Secondary Payer (MSP) claims, we proposed to codify our policy under the Manufacturer Discount Program that discounts are not applied to MSP claims. In addition, since 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 proposed to codify our policy that discounts are not paid on Medicaid subrogation claims involving an applicable drug. We proposed to codify those policies at § 423.2712(f)(1) and (2), respectively.

We proposed 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.

Lastly, at § 423.2712(f)(4) we proposed 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.

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

CMS received no comments on proposed § 423.2712 and we are finalizing this provision without modification.

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

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.

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 proposed 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; [15]

• 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 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.

We proposed to codify this eligibility criteria for specified manufacturers at § 423.2716(a).

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 final rule.

[15] 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.

We proposed to codify the aggregation rule 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.

We proposed to codify this eligibility criteria for specified small manufacturers at § 423.2716(b).

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 final rule.

We proposed to codify the aggregation rule at § 423.2716(c).

c. Determination of Phase-In Eligibility

As discussed in section 50.1 of the Manufacturer Discount Program Final Guidance and the preamble to the proposed rule, 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. The methodology used by CMS 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 proposed to codify the methodology at § 423.2720.

Specifically, we proposed 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 proposed 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 proposed 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 proposed 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.

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,[16] 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

[16] We use 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.*

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 this calculation, 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 proposed to codify this part of the methodology at § 423.2720(a)(2).

Next, CMS will determine 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 proposed to codify this part of the methodology at § 423.2720(a)(3).

The last value that must be determined for each specified manufacturer is the total expenditures under Part D for any one of the manufacturer's specified drugs covered under a Coverage Gap Discount Program agreement(s) for 2021, and covered under Part D in 2021. This 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,[17] 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,[18] 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[19] 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 proposed to codify this part of the methodology at § 423.2720(b).

Finally, at paragraph (c)(1) of § 423.2720, we proposed 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 proposed 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 treats 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 proposed 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 acquisitions under the Manufacturer Discount Program thus far, we proposed 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

[17] As described in section 505(c) of the FD&C Act.
[18] As described in section 351(a) of the PHS Act.
[19] As described in 21 CFR 300.50.

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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed to codify this policy at § 423.2728(c).

Finally, at § 423.2728(d), we proposed 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.

CMS received two comments regarding the phase-in methodology and summaries of the comments with our responses are below.

Comment: A commenter was opposed to aspects of our proposed methodology to determine specified small manufacturer eligibility. Specifically, the commenter objected to our proposal to calculate total expenditures under Part D for each applicable drug of a manufacturer based exclusively on PDE records and urged CMS to instead use PDE data as prima facie evidence, rather than the sole determinant of Part D total expenditures, and to consider, as part of CMS's recalculation process, other sources of evidence for Part D total expenditures, including data submitted to CMS by the manufacturer. The commenter argued that CMS must include all costs directly related to the dispensing of a covered drug when determining Part D total expenditures, even if those costs are not included in the PDE data set. The commenter also argued that, because of supposed flaws in the PDE data set and because PDE data is not relied on exclusively in certain other contexts, it cannot be relied on exclusively to determine the Part D total expenditures for applicable drugs of a manufacturer.

Response: CMS acknowledges that certain aspects of our Manufacturer Discount Program phase-in methodology as set forth in applicable guidance are the subject of recent litigation, including *Servier Pharmaceuticals LLC* v. *Becerra,* No. 1:24–cv–02664 (D.D.C.) and related appeal *Servier Pharmaceuticals LLC* v. *Kennedy,* No. 25–5054 (D.C. Cir.) (hereafter referred to as *Servier*) and *PharmaEssentia USA Corp.* v. *HHS,* No. 1:24–cv–03346 (D.D.C.) (hereafter referred to as *PharmaEssentia*). The district court in *Servier* upheld CMS's determination that Servier fails to qualify as a specified small manufacturer. Servier appealed the district court's decision, which appeal is pending in the U.S. Court of Appeals for the D.C. Circuit. The district court in *PharmaEssentia* vacated CMS's determination that PharmaEssentia failed to qualify as a specified small manufacturer and remanded the matter back to CMS after expressly recognizing that CMS might reach the same conclusion after further proceedings.

CMS appreciates the comment, but we will continue to use PDE data as the basis for calculating total expenditures under Part D because PDEs are the

records used to capture Part D expenditures. CMS created the Medicare Drug Data Processing System (DDPS) to collect and maintain records for all Part D claims, and the agency requires Part D sponsors to submit a PDE for every claim. The PDE contains information about payment liability of the plan and the enrollee. As discussed in more detail in section II.C.13 of this final rule, PDEs are subject to a robust editing process to verify their accuracy. PDE records are used to pay Part D sponsors for administering the prescription drug benefit and to calculate manufacturer discounts under the Coverage Gap Discount Program and the Manufacturer Discount Program. We note that while PDEs, like any data set, may contain errors, Part D sponsors have significant financial incentive to submit timely and accurate PDE records, in addition to being legally required to do so. As a result, we continue to believe that it is appropriate and consistent with the statute to calculate Part D total expenditures based on PDE data when determining a manufacturer's phase-in eligibility under the Manufacturer Discount Program.

Nevertheless, consistent with the district court's opinion in *PharmaEssentia,* we are clarifying that a manufacturer may provide additional information, as part of a timely recalculation request under the process described at § 423.2728, that the manufacturer asserts is evidence of Part D total expenditures that were not reported on PDEs. CMS will evaluate the information to determine if it is sufficient to merit consideration and what, if any, further investigation of the information provided is necessary to determine if there were actually paid Part D claims. If CMS determines based upon the additional information, and any additional investigation, that there were paid Part D claims that were not reported on PDEs that constitute Part D total expenditures under section 1860D–14C(g)(4)(D) of the Act, CMS will include those expenditures in the recalculation, consistent with the requirements of this section.

For clarity and precision, we are making a minor change in the regulation text at § 423.2728(b) to specify that supporting documentation for recalculation requests must be included with the recalculation request.

Comment: Another commenter also opposed aspects of CMS's proposed methodology for determining specified small manufacturer phase-in eligibility. Specifically, the commenter disagreed with our proposal to attribute 2021 total expenditures under Part D to a manufacturer based on the labeler code for purposes of identifying each specified drug of a manufacturer and calculating the Part D total expenditures for such drugs under § 423.2720(b). Instead, the commenter recommended that CMS attribute total expenditures for a drug to the holder of the New Drug Application (NDA) for that drug. The commenter stated that in other CMS programs that utilize similar statutory definitions of manufacturer as the definition found in section 1860D–14C(g)(5) of the Act, the NDA holder is identified as a manufacturer. The commenter further recommended that even if CMS were not to attribute expenditures based on the entity that holds the NDA for the applicable drug, the agency should consider evidence in addition to the labeler code when attributing total expenditures. The commenter stated that, while the labeler code may accurately reflect the manufacturer in many cases and can be used as a first step, the agency should consider additional evidence where appropriate to identify the manufacturer.

The commenter also opined that, if CMS alters the methodology used to determine phase-in eligibility, the changes should be applied retroactively to phase-in determinations made for manufacturers that have already entered into agreements to participate in the Manufacturer Discount Program or at least to those phase-in determinations that manufacturers have previously challenged as erroneous. Relatedly, the commenter further recommends that CMS establish a mechanism to adjust manufacturer liability on previously invoiced discount amounts of a manufacturer affected by an erroneous determination that the manufacturer is not a specified small manufacturer, and suggests that the dispute resolution framework at § 423.2764 should be used for this purpose.

Response: While we recognize that the statutory definition of manufacturer at section 1860D–14C(g)(5) of the Act may be similar to the statutory definition of manufacturer used in other programs, we decline to adopt the commenter's suggestion that such similarities in manufacturer definitions indicate that for purposes of the Manufacturer Discount Program, CMS should attribute Part D expenditures for a specified drug to the entity that holds the NDA of such drug. We continue to believe that the labeler code provides the most appropriate basis by which to attribute Part D expenditures to a manufacturer for purposes of making phase-in eligibility determinations under the Manufacturer Discount Program and that this methodology is consistent with section 1860D–14C of the Act, including CMS's longstanding practices of entering into the agreement for participation in the Coverage Gap Discount Program and Manufacturer Discount Program with the entity that meets the statutory definition of manufacturer based on such entity being the holder of the FDA-assigned labeler code(s) for the applicable drugs to which the agreement will apply.[20] As explained in the Manufacturer Discount Program Methodology, CMS identifies each Part D expenditure for a drug using the unique NDC reported on the PDE record for the expenditure and attributes that expenditure to the one manufacturer uniquely assigned the labeler code for that drug as reflected in the first five digits of the NDC.

CMS agrees with the commenter's recommendation that there should be a mechanism to adjust previously invoiced discounts of a manufacturer impacted by an erroneous determination about the manufacturer's phase-in eligibility. Prior to any correction of PDE records or discounts, a determination would have to be made that the phase-in eligibility status was incorrect. The process established in the Manufacturer Discount Program Final Guidance and codified at § 423.2728 for requesting such corrections is the recalculation process. CMS has also made a small number of corrections to manufacturer phase-in status in the first year of the program through own-motion review.

Retrospective adjustment of previously invoiced discounts or previously submitted PDE records can occur for reasons not limited to a retrospective change to or correction of a manufacturer's phase-in status. While retrospective application of a correction would depend on the specific situation, and may involve adjustments of overpayments or underpayments by a manufacturer, CMS has already established a process for adjusting previously invoiced manufacturer discounts, which is the PDE outlier process described in the January 17, 2025 HPMS memorandum, *Prescription Drug Event (PDE) Analysis website for CMS Data Quality Review Outliers, Withheld and Invoiced Outliers, and Reviews of Invoiced Data Disputed by Manufacturers.*

After consideration of the comments received on these sections of our

[20] As discussed earlier, such agreements may also include the labeler codes assigned by the FDA to another manufacturer, but only when such manufacturers have entered into an arrangement whereby the agreement holder lists such labeler codes on its agreement and all other applicable requirements are met.

proposal, and for the reasons described, we are finalizing the regulation text at §§ 423.2716 through 423.2728 as proposed, with minor modifications at § 423.2728(b) to further clarify our expectation that such supporting documentation must be included with the timely recalculation request.

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

We proposed to codify the agency's engagement of a TPA at § 423.2732. Specifically, we proposed at § 423.2732(a) that CMS will engage a TPA to assist in the administration of the Manufacturer Discount Program, which may include and is not limited to facilitating Manufacturer Discount Program invoicing, the receipt and distribution of funds of a manufacturer, and the dispute resolution process described in § 423.2764.

We proposed 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 further proposed 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.

We received no comments on proposed § 423.2732 and are finalizing this provision as proposed.

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. We proposed 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, which we are finalizing in this final rule).

Part D regulations at part 423 subpart K set forth the requirements for Part D contracts between Part D sponsors and CMS. We proposed 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 proposed codifying this policy at § 423.2736(b). As we explained in the proposed rule, 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.

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 proposed 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 claim for reimbursement.

d. Prescription Drug Event Requirements

We proposed to codify at § 423.2736(d) a requirement 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. We explained that this information is later 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 proposed to codify this policy at § 423.2736(e).

Comment: We received a comment in support of our proposal at § 423.505 to require Part D sponsors to provide applicable discounts on applicable drugs at the point of sale on behalf of the manufacturer, in alignment with the process that has been used under the Coverage Gap Discount Program since 2011.

Response: CMS appreciates the commenter's support.

Comment: We received several supportive comments on our proposal at § 423.2736(c) to require Part D sponsors to reimburse a network pharmacy the amount of the applicable discount no later than the applicable number of calendar days after the date of dispensing of an applicable drug. These commenters stated that clear prompt payment requirements promote consistent administration of the Manufacturer Discount Program, reduce payment delays that can create operational burdens at the pharmacy counter, support continuity of care for Part D enrollees, and strengthen the integrity of the redesigned Part D benefit.

Response: We thank the commenters for their support of our prompt payment proposals.

Comment: A commenter requested that CMS ensure Manufacturer Discount Program discounts are applied correctly at the point of sale so that increased out-of-pocket costs do not result in access disruptions. Another commenter recommended that enrollees be provided with real-time data regarding the impact of discounts under the Manufacturer Discount Program on the enrollee's progress toward the Part D out-of-pocket maximum.

Response: We thank the commenters for their feedback but decline to make the requested changes. Because manufacturer discounts generally do not impact the amount of enrollee cost sharing, are applied at the point of sale, and reduce plan liability for the cost of Part D drugs, we do not expect the

Manufacturer Discount Program to have any negative impact on enrollee access or out-of-pocket costs. As noted in section II.C.15 of this final rule, beneficiary protections established under subpart M of part 423 continue to apply and are separate from the Manufacturer Discount Program. Enrollees maintain the right to request a coverage determination from their plan or file a grievance.

Consistent with section 1860D–14C(g)(4) of the Act, applicable discounts under the Manufacturer Discount Program are not counted toward an enrollee's incurred costs. Thus, while we agree that it is important to provide enrollees with accurate and timely information about their benefits and liabilities with respect to their Part D coverage, we are not making any changes to existing policies related to enrollee notification requirements. Part D enrollees will continue to receive information about Part D coverage of their medications through existing vehicles, including the Part D explanation of benefits as required under § 423.128(e).

Comment: A commenter requested that CMS establish timing requirements for plans to submit PDE records.

Response: CMS established deadlines for the timely submission of PDE records at the start of the Part D program, which were recently codified at 42 CFR 423.325. We are finalizing changes to those requirements that are unrelated to the Manufacturer Discount Program in this final rule, which are described in section IV.K.

Comment: A commenter noted the unique integrated financing structure of PACE and urged CMS to monitor implementation of the Manufacturer Discount Program carefully to ensure PACE organizations have the technical support and guidance needed to administer manufacturer discounts.

Response: We appreciate the commenter's feedback and agree that it is important for CMS to monitor implementation of the Manufacturer Discount Program and provide guidance and technical support to PACE organizations. Recognizing that implementation of the Manufacturer Discount Program necessitated significant operational changes for PACE organizations, including reporting an expanded set of data elements on PDE submissions and understanding and developing capabilities related to the dispute resolution process for the Manufacturer Discount Program, CMS issued guidance specific to PACE organizations in HPMS memoranda, titled ''PACE Participation in the Manufacturer Discount Program beginning January 1, 2025,'' issued on January 26, 2024, and ''2025 Prescription Drug Event (PDE) File Layout Updates for all Part D Plan Sponsors, and Additional 2025 Changes to PDE Reporting for PACE Organizations'' issued on March 8, 2024. In addition, CMS held multiple technical assistance and training sessions to help PACE organizations prepare for changes related to implementation of the Manufacturer Discount Program.[21]

We will continue to issue guidance and support, as needed, regarding the Manufacturer Discount Program, and we encourage interested parties to monitor for additional guidance or information issued through HPMS or posted on our Manufacturer Discount Program web page at *https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-information-pharmaceutical-manufacturers.* Part D sponsors with questions regarding the Manufacturer Discount Program can reach out to their CMS account manager or submit questions to *PartDManufacturerDiscountProgram@cms.hhs.gov*.

After consideration of the public comments we received on this section, we are finalizing without modification our proposals at §§ 423.505 and 423.2736.

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

In certain instances in the quarterly Manufacturer Discount Program invoicing process (described in section II.C.13.a of this preamble) 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 the PDE adjustment or deletion. We proposed at § 423.2740 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 received no comments on this section of our proposal. We are finalizing § 423.2740 as proposed.

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

a. General Rule

As discussed in more detail in the preamble to the proposed rule, at § 423.2744(a), CMS proposed to codify existing policies to provide monthly prospective Manufacturer Discount Program payments to Part D sponsors so that sponsors can advance applicable discounts at the point of sale under § 423.2736(a) and reimburse network pharmacies within the timeframe required under § 423.2736(c).

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 proposed 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 proposed 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.

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

[21] CMS provided training sessions for PACE Organizations at two User Group Calls held on February 14, 2024 and May 22, 2024, and also provided training via a presentation and question and answer session at the National PACE Association Spring Policy Forum, on March 11, 2024.

pay all invoiced amounts due under the requirements of proposed § 423.2756(a), we proposed 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 proposed 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.

Comment: We received a comment on our proposals regarding prospective payments to Part D sponsors. The commenter requested additional guidance on the prospective payment process and the related documentation plans should maintain for tracking, submission for payment, and potential reconciliation. In addition, the commenter encouraged CMS to consider the potential impact of these requirements and stated that it is critical for plan sponsors to receive clear guidance to minimize administrative burden and ensure EGWPs remain a viable option for plan sponsors.

Response: CMS thanks the commenter for their feedback. As described in our proposed rule, prospective Manufacturer Discount Program payments to Part D sponsors will be based on the projections included in each plan's bid and on 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. As we explained in the proposed rule, 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. Document retention requirements for Part D sponsors are specified at § 423.505(d) and described in section IV.D. of this final rule. At this time, we do not believe additional CMS guidance is necessary. We encourage interested parties to monitor for additional guidance or information issued through HPMS or posted on our Manufacturer Discount Program web page at *https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-information-pharmaceutical-manufacturers.* Part D sponsors with questions regarding the Manufacturer Discount Program can reach out to their CMS account manager or submit questions to *PartDManufacturerDiscountProgram@cms.hhs.gov.*

CMS acknowledges the commenter's concern regarding the impact of requirements on Part D sponsors generally and EGWPs more specifically. With respect to prospective Manufacturer Discount Program payments and the exception for EGWPs, because EGWPs are not subject to typical Part D bidding requirements due to a longstanding waiver by CMS, they do not submit Part D bids. As such, CMS lacks the information necessary to estimate the cost of applicable discounts for these plans.

After consideration of the comments received, we are finalizing proposed § 423.2744 without modification.

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

At § 423.2748, we proposed to codify requirements related to use of the Health Plan Management System (HPMS) that were included in the Manufacturer Discount Program Final Guidance. Specifically, we proposed that agreement holders are required to maintain HPMS access and 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.

We did not receive any comments regarding this section of our proposal. We are finalizing § 423.2748 without modification.

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. 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) through December 31, 2028. We proposed to codify the requirements for the Manufacturer Discount Program agreement at § 423.2752.

a. Requirements of Agreement

As discussed in more detail in section II.C.4. of this preamble, CMS is finalizing at § 423.2708(b) the requirement 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, 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. As discussed in the preamble to the proposed rule, 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 proposed 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 proposed at § 423.2752(a) 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.

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 final rule. Consistent with the policies CMS established in the Manufacturer Discount Program Final Guidance, we proposed to codify the requirements related to 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 proposed to codify the policies for termination by CMS at § 423.2752(c)(1).

Consistent with applicable guidance for the Medicare Drug Price Negotiation Program,[22] a manufacturer that is a primary manufacturer, as defined 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.[23] CMS also will terminate coverage for all of the drugs of the

[22] 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.*

[23] 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.

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 proposed 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 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's 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 proposed 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 proposed 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 under this provision 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 proposed to codify this requirement at § 423.2752(c)(1)(v)(A)(*2*).

At § 423.2752(c)(1)(v)(B), we proposed 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.

We proposed to codify these existing policies 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 proposed 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 proposed to codify this policy at § 423.2752(c)(4).

(5) Automatic Assignment Upon Change of Ownership

At § 423.2752(d) we proposed 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 proposed 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.

CMS did not receive any comments on our proposals in this section. We are finalizing the provisions of § 423.2752 with a minor clarifying change at paragraph (c)(1)(v)(A)(*2*) to clarify that the termination of coverage described in paragraph (c)(1)(v)(A)(*2*) is specific to the termination of coverage ''under paragraph (*2*)''.

13. Manufacturer Requirements (§ 423.2756)

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

a. Manufacturer Invoicing

At § 423.2756(a), CMS proposed that we 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 an agreement holder's Manufacturer Discount Program agreement and will invoice the agreement holder quarterly. We also proposed that CMS will invoice manufacturer discount amounts from accepted PDE data for 37 months following the end of the benefit year.

As we explained in the preamble to the proposed rule, 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

At § 423.2756(b) CMS proposed to codify the requirements for timely payment of manufacturer discounts. Specifically, at § 423.2756(b)(1) we proposed that agreement holders must pay each Part D sponsor invoiced amounts no later than 38 calendar days from receipt of the relevant invoice, with limited exceptions in proposed paragraphs (b)(2) and (b)(3). At § 423.2756(b)(2), we proposed 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 proposed 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. We further proposed that 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.

As discussed in the preamble to the proposed rule, 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 strikes 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 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 proposed 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 proposed 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.

At § 423.2756(c)(2), we proposed requirements related to providing information to CMS about manufacturer ownership. Specifically, at paragraph (c)(2)(i), we proposed 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 proposed to codify at § 423.2716. Likewise, at paragraph (c)(2)(iii), we proposed 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.

As we explained in the proposed rule, it is also imperative that CMS be notified promptly of any ownership changes of a manufacturer participating in the Manufacturer Discount Program so that we 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 proposed to codify our longstanding policy that agreement holders notify us 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 proposed 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 us 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 proposed requirements related to labeler codes. Consistent with the Manufacturer Discount Program Final Guidance, section 80.5.2, we proposed 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 proposed 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 manufacturer has not executed and does not have in effect its own Manufacturer Discount Program agreement in accordance with § 423.2708(b)(1).

We proposed that agreement holders must provide to CMS and maintain all required labeler code information as instructed by CMS. Specifically, we proposed 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 proposed 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 proposed 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 proposed 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 proposed 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. 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 proposed 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. This includes 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 proposed 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 proposed 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. As explained in the proposed rule, 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 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.

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.

Comment: We received a few comments regarding the data elements CMS provides on Manufacturer Discount Program invoices. The commenters thanked CMS for expanding the data provided to manufacturers compared to what was provided under the Coverage Gap Discount Program. A few commenters supported codifying the Manufacturer Discount Program invoice data elements.

The commenters also recommended that CMS expand the set of data elements currently provided on manufacturer invoices, arguing that additional data fields are necessary for manufacturers to accurately verify Manufacturer Discount Program discounts. In combination, these commenters asked that CMS add the following additional data elements to Manufacturer Discount Program invoices: Part D contract and Part D plan benefit package identifiers; a de-identified Part D beneficiary identifier; the prescriber's National Provider Identifier; the date the Part D plan paid the pharmacy; claim status (*i.e.,* whether the claim was paid or reversed); a Medicare Prescription Payment Plan participation identifier; information about the indication for which the drug was prescribed; and various cost accumulator fields to identify an enrollee's actual out-of-pocket costs and where the enrollee falls in the phases of the Part D benefit.

Response: We appreciate the commenters' support and acknowledgement of CMS's decision at the start of the Manufacturer Discount Program to include additional data elements on manufacturer invoices. As commenters recognized, the current data elements included on invoices provide manufacturers with more data than they received on invoices under the Coverage Gap Discount Program. However, we disagree with the commenters that additional data elements are necessary or would be beneficial. We are not persuaded by the comments to add any of the additional data elements requested. We believe the current data elements included on invoices appropriately balance important beneficiary privacy protection and sufficient information for agreement holders to meet their statutory obligation to provide discounted prices for applicable drugs under section 1860D–14C(b)(1)(A) of the Act. We further clarify that we did not propose to enumerate in the regulation text which specific data elements are included on Manufacturer Discount Program invoices.

As discussed in the Manufacturer Discount Program Final Guidance and the preamble to the proposed rule, in providing the invoice data, CMS seeks to limit the disclosure of claim-level information to the minimum necessary for an agreement holder to verify payment. Pursuant to section II(l) and section (b)(1) of Exhibit C of the Manufacturer Discount Program agreement, information sent from CMS or the TPA to the agreement holder with each quarterly invoice may be used only for evaluating the accuracy of the invoiced discounts and resolving disputes concerning the manufacturer's payment obligations under the Manufacturer Discount Program.

Manufacturers should consider that prior to invoicing under the Manufacturer Discount Program, CMS performs extensive editing on PDE records and conducts outlier analyses to check for duplicate claims, applicable national drug codes (NDCs), and incorrect discount calculations, among other checks. Detailed information on the PDE submission process, including on CMS's robust PDE editing process, can be found on the Customer Service and Support Center (CSSC) website.[24]

After consideration of the comments received, we are finalizing § 423.2756 as proposed.

14. Audits (§ 423.2760)

We proposed to codify at § 423.2760 the Manufacturer Discount Program audit processes established in section 90 of the Manufacturer Discount Program Final Guidance.

Regarding manufacturer audits of TPA data, we proposed 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. We proposed at § 423.2760(a)(2) that 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.

As discussed in the preamble to the proposed rule, 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.

We proposed limits on audits of TPA data and information at § 423.2760(a)(3). Specifically, we proposed 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. At § 423.2760(a)(3)(ii), we proposed 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.

At § 423.2760(a)(3)(iii), we proposed that audits must occur on site at a location specified by the TPA, and with the exception of work papers, audit data cannot be removed from the audit site. Additionally, we proposed 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 proposed 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 proposed at § 423.2760(b)(2) that CMS must provide agreement holders with 60

[24] *https://www.csscoperations.com/internet/csscw3.nsf.*

calendar days' notice of the reasonable basis for the audit and a description of the information required for the audit. We further proposed 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.

Comment: A commenter requested that CMS remove the requirement that audits be conducted on site only, because the requirement imposes a significant burden on the manufacturer, including travel time and expenses. The commenter suggested that CMS allow manufacturers to access audit data through a secure online portal overseen by the TPA.

Response: We thank the commenter for their feedback. Regarding allowing manufacturer audits of TPA data to be conducted remotely, CMS intends to continue exploring with the TPA ways in which remote audits might be conducted in the future. While we do not expect remote auditing of the TPA to be in place by CY 2027, in order to allow for the possibility of remote audits in the future, we are striking the words ''on site'' and ''the audit site'' from the proposed regulation text at § 423.2760(a)(3)(iii) that specified that audits must occur on site at a location specified by the TPA and that data cannot be removed from the audit site. As modified, the regulatory text requires that audits must occur at ''a location specified by the TPA'' and that data cannot be removed from ''such specified location''. CMS and the TPA may specify through future guidance whether an audit will be conducted on site or remotely at a virtual location. Until CMS establishes and operationalizes a secure method for allowing manufacturers to conduct remote audits of TPA data, audits will continue to occur on site at a physical location specified by the TPA.

Comment: The same commenter urged CMS to clarify the limitation on an auditor sharing information beyond its opinion of the audit results with its client and specifically permit the manufacturer to review all data underlying an audit conducted on its behalf. The commenter also requested that CMS permit manufacturers to audit CMS records and the records of Part D sponsors beyond the data provided to the TPA, including any data CMS would use to audit the selected drug subsidy under proposed § 423.329(e) .

Response: We disagree with these comments. As previously noted, CMS believes that the limitations on distribution of audit data strike the appropriate balance between supporting beneficiary privacy and ensuring manufacturer access to data relevant to the calculation of discounts.

Regarding manufacturer audits of information beyond the data provided to the TPA, we note that section 1860D–14A(d)(3)(D) of the Act permitted manufacturers to conduct periodic audits ''of the data and information used by the third party to determine discounts'' under the Coverage Gap Discount Program. There is no statutory requirement under the Manufacturer Discount Program to permit manufacturers to audit any data or information used to determine discounts. We chose to carry over this policy because we continue to utilize a TPA to facilitate administration of the program. While manufacturers can dispute invoiced discounts through the process described at § 423.2764, which may involve CMS review of data beyond what is provided by the TPA, including consultation with Part D sponsors, we believe that data available to manufacturers under our proposed rule is sufficient for manufacturers to validate invoiced discounts. We decline to permit manufacturers to audit information beyond the data provided to the TPA.

After consideration of the comments received, we are finalizing § 423.2760 with modification, as described in our response to comments. Specifically, we are striking the words ''on site,'' ''such,'' and ''the audit site'' from the proposed regulation text at § 423.2760(a)(3)(iii), and we are modifying the regulatory text to specify that ''audit'' data cannot be removed from ''such specified location''. We are also adding the word ''calendar'' to convey 60 calendar days at § 423.2760(a)(2), which was inadvertently left out of the regulation text in the proposed rule.

15. Dispute Resolution (§ 423.2764)

At § 423.2764, CMS proposed a 3-level dispute resolution framework through which agreement holders can dispute applicable discounts that they were invoiced via the invoicing process at § 423.2756(a). Specifically, we proposed 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. We proposed at § 423.2764(a)(1) that the initial dispute must be filed in the manner specified by CMS no later than the dispute submission deadline, which is defined 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 proposed at § 423.2764(a)(2) that CMS will issue a written determination on such initial dispute no later than 60 calendar days from the dispute submission deadline.

At § 423.2764(b), we proposed 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. We proposed 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 proposed 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 sources.

We proposed at § 423.2764(b)(3) that the IRE will issue a written decision to the agreement holder and to CMS no later than 90 calendar days from receipt of the request. At § 423.2764(b)(4), we proposed that 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. At § 423.2764(b)(5), we proposed that 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 proposed that an agreement holder or CMS may

request review by the CMS Administrator following receipt of an unfavorable determination from the IRE. We proposed at § 423.2764(c)(2) that such request must be filed in the manner specified by CMS, no later than 30 calendar days from the date of the IRE decision. We proposed at § 423.2764(c)(3) that after completing the review and making a decision, the CMS Administrator will issue a written decision to both parties. Such decision by the CMS Administrator is final and binding under proposed § 423.2764(c)(4). At § 423.2764(d), we proposed that CMS will adjust future invoices, or implement an alternative reimbursement process if determined necessary, if a dispute is resolved in favor of the agreement holder. We further proposed 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).

We proposed at § 423.2764(e) that 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. 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).

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.

We received no comments on this section and are finalizing § 423.2764 as proposed.

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 proposed codifying this general rule at § 423.2768(a), in alignment with processes established in section 120 of the Manufacturer Discount Program Final Guidance.

CMS proposed at § 423.2756(b)(1) to require agreement holders to 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). As we stated in the proposed rule, 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 proposed 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), and that the agreement holder has 5 business days to respond to CMS.

Consistent with section 1860D–14C(e)(1) of the Act, we proposed 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. We stated in the proposed rule that 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 proposed 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 proposed at § 423.2768(e) to apply existing appeal procedures for CMPs in 42 CFR part 423, subpart T to agreement holders appealing a CMP imposed under the Manufacturer Discount Program. Specifically, we proposed to amend paragraph § 423.1000(a)(3) by replacing it with new paragraphs (a)(3)(i) and (a)(3)(ii) to codify 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 proposed conforming changes to the definition of ''affected party'' at § 423.1002 to revise the definition to refer to ''for purposes of the Coverage Gap Discount Program, any manufacturer (as defined in § 423.100)'' and ''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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed to codify this requirement at § 423.2768(g).

At § 423.2768(h), we proposed 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.

Comment: We received a comment on our proposed regulations related to CMPs. The commenter argued that the language in our proposed CMP regulation fails to recognize the agency's flexibility and enforcement discretion. Pointing to language in proposed § 423.2768, which states that CMS ''must impose a civil money penalty,'' the commenter asserted that CMS's proposed regulation does not take into account factors in section 1128A(d) of the Act when determining the scope or amount of CMP. The commenter also stated that CMS procedures should allow for discussion and explanation between CMS and the manufacturer and should include an opportunity for the manufacturers to confer with the agency prior to imposition of CMPs and without requiring a manufacturer to request a formal hearing. The commenter stated generally that this would be consistent with government agencies issuing pre-enforcement notification letters or pursuing other informal means to give regulated parties an opportunity to respond before the agency initiates formal proceedings.

Response: We appreciate the commenter's feedback on the proposed CMP regulations. We believe our proposed CMP regulations at §§ 423.1000, 423.1002, and 423.2768 are consistent with statutory requirements under the Manufacturer Discount Program, and that the clarity provided in our CMP regulation text is important for enforcement purposes. Section 1860D–14C(e) of the Act states that if a manufacturer fails to provide discounted prices for applicable drugs of the manufacturer dispensed to applicable beneficiaries in accordance with the Manufacturer Discount Program agreement in effect, such manufacturer ''shall'' be subject to a CMP for each such failure. Further, section 1860D–14C(e) of the Act explicitly provides the formula that must be used to determine the amount of such CMP.

We agree with the commenter that CMS may exercise enforcement discretion in our imposition of CMPs. Our proposed regulation text does not preclude the agency from exercising discretion and allows an opportunity for dialogue prior to the agency making a determination to impose a CMP under the Manufacturer Discount Program, using the same process used under the Coverage Gap Discount Program. Proposed § 423.2768(b) provides that 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, and the agreement holder will have five business days from the date of the notice to respond to CMS. As we stated in response to similar comments in the Manufacturer Discount Program Final Guidance and in the preamble to the proposed rule, this gives the agreement holder an opportunity to provide additional context, evidence refuting the violation, or other factors CMS may consider when determining whether to impose a CMP. Part D sponsors advance applicable discounts at the point of sale on behalf of manufacturers, and it is essential that manufacturers, in turn, provide timely reimbursement. Accordingly, such discretion is generally limited to a situation where the manufacturer demonstrates that the non-compliance is due to a technical or other reason beyond the manufacturer's control.

After consideration of the public comments we received, we are finalizing without modification our proposals at §§ 423.1000, 423.1002, and 423.2768.

17. Severability

We proposed that the Manufacturer Discount Program provisions finalized herein would be separate and severable from one another. Further, we proposed that if any of these provisions 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.

We received no comments on this section of our proposal and are finalizing without modification.

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.[25] 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

[25] 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.*

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 [26] 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.

++ 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 prescription drug 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 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 for CY 2025 to continue to permit use of the creditable coverage simplified determination methodology, without modification to the existing parameters, 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

[26] 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.

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.
- 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. 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 for 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 proposed 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 proposed 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 proposed 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 stabilizing thereafter. Accordingly, we proposed a minimum of 73 percent instead of 72 percent for 2027. We further proposed that we would 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. We intend to update the percentage 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 Part D bid submission deadline for non-RDS group health plans to take into account as they prepare for the following year.

As described previously, the proposed changes to § 423.56 would retire the simplified approach presented in the ''Updated Creditable Coverage Guidance'' that we released on September 18, 2009, and generally proposed 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.

Comment: Several commenters stated their support for the proposed creditable coverage methodology, citing that it appropriately balances a few considerations: the need to have standards that accurately capture the value of Part D coverage; the need to let patients make informed decisions about whether they have adequate prescription drug coverage; the need to minimize paperwork burdens on non-Medicare plans; and the need to protect taxpayers from the increase in the cost of Medicare Part D that would occur if eligible individuals were able to wait to enroll until they had high prescription drug expenses without any penalty.

Response: We thank commenters for their support.

Comment: A commenter asked whether we account for the selected drug subsidies under section 1860D–14D of the Act and federal reinsurance under 1860D–15(b)(1)(B) of the Act with respect to selected drugs in the determination of creditable coverage. They requested that CMS treat selected drug subsidies under sections 1860D–14D of the Act and federal reinsurance under 1860D–15(b)(1)(B) with respect to selected drugs analogously to manufacturer discounts under section 1860D–14C and exclude them from the creditable coverage methodology. The commenter stated that excluding these amounts from the creditable coverage methodology would be consistent with the approach established for the Manufacturer Discount Program and help employer-sponsored group health plans continue to provide creditable prescription drug coverage, including retiree drug coverage through the Retiree Drug Subsidy (RDS) program, as more drugs become selected over time.

Response: CMS thanks the commenter for their input. As stated in the Final CY 2025 Part D Redesign Program Instructions, CMS determines actuarial equivalence based on plan liability and does not include subsidies such as low income cost sharing (LICS). Consistent with the existing policy, federal reinsurance in the catastrophic phase is included in the plan paid amount. The value of any selected drug subsidy under section 1860D–14D of the Act is not included in the determination of actuarial value.

To clarify the existing policy that the selected drug subsidy is excluded from the determination of actuarial equivalence, we have revised § 423.56(a) to state that the actuarial value of creditable prescription drug 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 **or of any selected drug subsidy under section 1860D–14D** of the Act'' (bold indicates new text).

Comment: A few commenters were supportive of codifying the revised simplified determination methodology but requested a delay in moving to the 73 percent of prescription drug costs that a plan must cover for it to be considered creditable. A couple commenters requested a 1-year delay and another commenter suggested starting to phase in 66 percent of prescription drug expenses in 2027 and move to 73 percent in 2028. The commenter questioned if CMS does not adopt a phase-in approach, to allow a 1-year grace period of allowing plans to continue to use the existing simplified determination methodology.

Response: We appreciate the support of codifying the revised simplified determination methodology and do not believe that further delay or grace periods for adopting this methodology are justified at this time. In the Final CY 2026 Part D Redesign Program Instructions, we provided a grace period that permitted non-RDS group health plans to use either the existing simplified determination methodology or the revised simplified determination methodology to determine whether their prescription drug coverage is creditable. In those instructions, we emphasized that the grace period was for CY 2026 only and that for CY 2027 and subsequent years, CMS intended to propose to no longer permit use of the existing simplified determination methodology. As explained in the Final CY 2025 Part D Redesign Program Instructions and Final CY 2026 Part D Redesign Program Instructions, there were significant changes to the Part D program that took effect in those years under the IRA's Part D redesign that warranted a transitional delay to a revised simplified determination methodology. We believe that plans now have adequate experience under the new benefit design to incorporate the changes we proposed and are finalizing in this rulemaking. Additionally, as discussed above, plans have been on notice that we intended to retire the existing simplified determination methodology in favor of transitioning to one that more accurately reflects the actuarial value of a defined standard Part D plan in accordance with section 1860D–13(b)(5) of the Act. For 2027, we are finalizing the percent value at 73 percent. For 2028 and going forward, we will release the percentage of prescription drug costs to use in the creditable coverage methodology with enough time for group health plans to take into account when designing their plan benefits.

Comment: A commenter highlighted the timing of releasing guidance in future years that would, as needed, update the percentage value of prescription drug expenses and requested that it be released in a timely manner—ideally at the same time the

Part D Defined Standard benefit parameters are released.

Response: We thank the commenter and agree. We would release this guidance in advance of the yearly bid submission deadline for Part D plan sponsors so that they may consider the guidance as they prepare their bids and group health plans to design their plan benefits. This timing would align with the release of the Part D Defined Standard benefit parameters as the commenter suggests.

We appreciate all of the comments on this proposal and are largely finalizing this provision as proposed, with one modification to specify in § 423.56(a) that the value of any selected drug subsidy under section 1860D–14D of the Act is not included in the determination of actuarial value.

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 proposed 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 proposed and sought public comment on what criteria should apply for designation as a persistent outlier prescriber of opioids. We proposed to establish a threshold to identify persistent outlier prescribers of opioids as those outlier prescribers who receive three consecutive outlier prescriber notifications from us 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 sought comments on this threshold.

Specifically, we proposed 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 proposed 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.

We received public comments on these provisions in the proposed rule. The following is a summary of the comments we received and our responses.

Comment: Several commenters suggested that the statistical identification of outlier prescribers may disproportionately affect those prescribers that treat patients with chronic pain or complex diagnoses and ultimately affect proper pain management and palliative care of beneficiaries. A commenter suggested that the use of a statistical methodology could identify prescribers whose prescribing is clinically appropriate and suggests identifying outliers by considering beneficiary specific clinical factors, comorbidities, and treatment history.

Response: CMS appreciates the commenters' insights and considerations for the prescribers of our beneficiaries with chronic pain and complex care. CMS agrees with commenters that statistical analyses may identify outlier prescribers that care for patients with unique circumstances that result in prescribing patterns that vary from the norm, yet are still clinically appropriate. As such, CMS acknowledges this point in the annual outlier prescriber notifications and encourages prescribers to utilize the information to review their current prescribing habits and take advantage of educational resources and programs to remain current on treatment guidelines. While CMS notes that utilizing

beneficiary specific clinical factors, comorbidities, and treatment history would allow for a robust review of individual prescriber habits, it is unrealistic for CMS to do that on a broad scale for all prescribers as part of an educational analysis and would require the review of medical records. CMS would encourage prescribers notified as outliers to internally review their medical records to ensure that they are prescribing appropriately based on their patients' individual health and care plans.

Comment: Several commenters supported the current excluded patient groups within CMS's methodology. Some commenters suggested that beneficiaries in palliative care should be excluded. Another commenter recommended that in addition to beneficiaries with cancer pain, those beneficiaries with cancer treatment related pain should also be excluded.

Response: CMS, beginning with the 2027 letters is aligning the exclusion criteria for beneficiaries with other CMS initiatives and the definition of an exempted beneficiary at § 423.100, including beneficiaries in hospice or receiving palliative or end of life care; residing in a long-term care facility; being treated for cancer-related pain; or with sickle cell disease. Of note, in a CMS final rule (89 FR 30448) the definition at § 423.100 shifted the terminology from 'active cancer-related pain' to 'cancer-related pain' effective January 1, 2025. CMS currently utilizes a year look-back period to identify beneficiaries with past cancer treatment.

Comment: Several commenters recommended maintaining a standardized statistical methodology to improve transparency and prevent variation, in addition to a standardized notification letter and prescriber education materials. These commenters recommended CMS refine the methodology to keep up with changing opioid practice and consider accounting for intermittent benzodiazepine use.

Response: CMS currently maintains both a methodology and aggregate data summary for public consumption found at *https://www.cms.gov/about-cms/story-page/prescribing-opioids.* The methodology and aggregate data are updated annually to align with the latest outlier prescriber notifications. CMS does refine the methodology regularly and considers changes to guidelines and will continue to do so going forward, including appropriate thresholds for being identified as an outlier. Annually, in each notification to prescribers identified as an outlier, CMS provides standardized language, including educational resources for the prescriber to reference for up-to-date opioid prescribing best practices. In identifying outlier prescribers, CMS currently only considers beneficiaries receiving a benzodiazepine that overlaps with an opioid for a consecutive 30 days but thanks the commenters for their suggestion and will continue to refine the methodology, as necessary.

Comment: Commenters noted that guidelines no longer set thresholds as these limited access to care for beneficiaries in the high-risk groups. A commenter recommended CMS limit the prescribing threshold to the top 5 or 10 percent as a 25 percent threshold is overly-broad.

Response: CMS acknowledges the Centers for Disease Control and Prevention (CDC) 2022 opioid guideline update and shift from morphine milliequivalent (MME) thresholds. CMS does not utilize a single MME threshold for this analysis but rather uses a comparative analysis of prescriber habits according to specialty and state to determine outlier prescribers of opioids. CMS also notes that the annual outlier prescriber letters are based on a statistical methodology, and CMS clearly recognizes that an outlier may be prescribing within clinical norms for certain patient populations and still be identified as an outlier. CMS does refine the methodology regularly and considers changes to guidelines and will continue to do so going forward, including appropriate thresholds for being identified as an outlier.

Comment: A commenter also recommended that CMS establish an appeals process for being identified as an outlier.

Response: CMS takes no administrative action based on the outlier prescriber identification. These letters are solely an identification that the identified prescribers are statistically different than other prescribers in their same specialty and state in an effort to provide education on prescribing practices. As such, no appeals process is necessary.

Comment: Several other commentors were in support of the proposals and definitions for identifying outliers and persistent outliers but a commenter expressed that CMS's support is critical as plan sponsors may not have all information necessary to identify potential outliers on a provider and beneficiary level. It was recommended that CMS continue to release the methodologies and updates on the website.

Response: CMS thanks the commenters for their support and will continue to release the methodologies and updates on the website, *https://www.cms.gov/about-cms/story-page/prescribing-opioids.*

Comment: A few commenters questioned the utilization of NPPES for prescriber specialty as it is dependent on a prescriber updating their taxonomy and using an appropriate taxonomy code. A commenter suggested CMS consider the order of taxonomy codes in NPPES. A few commenters recommended the need for consideration of subspecialties as some complex patients are treated by physicians of a subspecialty under a more general primary specialty. A commenter recommended that CMS consider different thresholds for different specialties.

Response: CMS thanks the commenters for their suggestions on further refining the taxonomy of a prescriber by subspecialty. CMS will consider this going forward. CMS encourages prescribers to update NPPES accordingly when taxonomy changes occur to ensure they are up to date and accurate.

Comment: A commenter opposed CMS's proposed methodology and recommended that CMS work collaboratively with physician groups and other stakeholders to develop alternative approaches that ensure continued access to care, eliminate arbitrary prescribing thresholds, and avoid targeting physicians treating complex patients. A commenter suggested that the proposal to report persistent outliers would lead Part D plan sponsors to refuse patient prescriptions from the prescribers and lead to patient harm. Additionally, a commenter suggested that CMS clarify what the Part D plan sponsors' expectations were for the information received on persistent outliers. Another commenter suggested that CMS provide plan sponsors with flexibility in overseeing the appropriate use of opioid therapies and to collaborate with plan sponsors. One commenter suggested that CMS and plan sponsors review for outlier prescribers prescribing based on specialty-specific norms and allow for clinical review before adverse actions are imposed.

Response: Section 6065 of the SUPPORT Act requires CMS to identify outlier prescribers of opioids based on specialty and geographic area and provide notification annually to such providers. CMS collaborated with external stakeholders to establish the thresholds CMS utilizes to determine a prescriber is an outlier and continuously works with plan sponsors and other stakeholders to ensure oversight of the Part D program and provide the best outcomes for Medicare

beneficiaries. Consistent with section 1860D–4(c)(4)(D)(v) of the Act, CMS will issue a persistent outlier prescriber report to plan sponsors in an effort for increased transparency and provide investigative leads. CMS understands the concerns from commenters regarding the potential for unsubstantiated penalties on the prescribers identified as persistent outliers; however, this report will identify outliers across the Medicare Part D program and assist plan sponsors that may have limited views of trends and schemes within their own data. CMS will direct plan sponsors to not act solely on the information in the report without performing their own internal fraud, waste, and abuse efforts that substantiate their actions, thereby allowing plan sponsors to maintain autonomy to review any persistent outliers for specialty norms and conduct clinical review in accordance with their organizations policies and procedures. CMS will continue to clarify in each outlier prescriber notification letter that each prescriber's unique circumstances may result in prescribing patterns that vary from the norm yet are still clinically appropriate.

Comment: A few commenters recommended CMS identify persistent outliers more frequently than annually to ensure proper oversight. Another commenter suggested that CMS provide a list of all outliers to Part D plan sponsors, not just those that are classified as persistent. One commenter recommended reviewing outlier prescribing behavior every 6 months to not only identify prescribers by statistical comparison but also percent increase in their prescribing. Additionally, a commenter recommended CMS look at prescribing trends.

Response: CMS appreciates the feedback and clarifies that alternative options have been considered. Providing persistent outlier letters more frequently than annually is allowable in accordance with section 1860D–4(c)(4)(D)(v) of the Act; however, CMS believes prescribers should have the opportunity to make prescribing adjustments, if necessary, prior to being identified as an outlier on subsequent notification. Annual outlier notifications allow prescribers identified as an outlier to have approximately 6 months of time to make prescribing changes after receiving the outlier letter. CMS also disagrees with releasing all outlier prescribers to plan sponsors annually as the statutory requirement, section 1860D–4(c)(4)(D)(v) of the Act, applies to only those outliers identified as persistent. CMS believes that one annual identification does not establish a pattern of behavior. In response to a commenter recommending that CMS look at prescriber trends, CMS does evaluate trends internally and externally posts a data summary chart for outliers identified by state each year on the CMS website.[27]

Comment: A commenter suggested that plan sponsors have additional requirements to offer education, peer consultation, pain management, and addiction specialists, as well ensure beneficiaries have access to medication-assisted therapy and a variety of counseling options. Another commenter recommends CMS consider additional steps to deter persistent outlier prescriber behavior beyond technical assistance and Medicare provider enrollment.

Response: CMS appreciates the suggestion to have plan sponsors provide additional education and services to both outlier providers and their beneficiaries. CMS will consider recommending to plan sponsors that they offer services that align with their current organization's contracts with both prescribers and beneficiaries in their networks. CMS will also continue to review and assess other steps that can be taken to address outlier prescribers.

After consideration of the public comments we received, we are finalizing the provisions as proposed. Section 6065 of the SUPPORT Act (Pub. L. 115–271) and section 1860D–4(c)(4)(D)(v) of the Act requires CMS to notify outlier prescribers based on specialty and state and provide information about persistent outliers to plan sponsors annually. While CMS received comments and feedback on specific methodology considerations, CMS is not adopting these comments in this final rule. Considerations and recommendations for exclusion criteria, thresholds, postings of methodology and other documents, and frequency of reporting will all be considered by CMS annually through program instruction or otherwise as we continue to refine the methodology and enhance our oversight of the Medicare Part D program.

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 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.[28] 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 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 proposed to amend § 423.308 to add the definition of Inflation Reduction Act Subsidy Amount (IRASA).

We proposed 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 proposed to update the existing regulation concerning the reopening of final payment determinations and the existing payment appeals regulation by

[27] See: *https://www.cms.gov/files/document/opioid-benzodiazepine-prescribing-patterns.pdf.*

[28] 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*).

adding the Manufacturer Discount Program reconciliation, selected drug subsidy reconciliation, and IRASA reconciliation payment determinations. We also proposed 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 proposed 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.

We did not receive comments on this section of the proposed rule and are finalizing the definition of Inflation Reduction Act Subsidy Amount (IRASA) at § 423.308 as proposed.

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, 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 established the reopening provision at § 423.346, which allows CMS, at its discretion, to reopen and revise initial or reconsidered specified payment determinations. Section 423.346(a) 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 7936), we added the Coverage Gap Discount Program reconciliation payment to the list of payment determinations that we may reopen and revise.

We proposed 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 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.[29] 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.

We did not receive comments on this section of the proposed rule and are finalizing the amendments to § 423.346(a) as proposed.

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 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

[29] 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.*

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 7938), we added the reconciled Coverage Gap Discount Program payment to the list of payment determinations that could be appealed under § 423.350.

We proposed 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.[30] We proposed 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 proposed 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 proposed 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 submission of information necessary to determine that payment determination.

We did not receive comments on this section of the proposed rule and are finalizing the amendments to Payment appeals at § 423.350(a)(1) and (a)(2) as proposed.

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 proposed two amendments to § 423.350(b)(1) to reflect actual practice. First, we proposed to amend 15 days to 15 calendar days. Second, we proposed 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 proposed 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.

We did not receive comments on this section of the proposed rule and are finalizing the amendments to payment appeals at § 423.350(b)(1) as proposed.

The provisions described in this section of the final rule are consistent with our current guidance and requirements. The changes are updates that do not place additional requirements on Part D sponsors, nor do they 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.

We did not receive comments on this proposal and are finalizing this provision without modification.

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 [31]), added a definition of ''hemp'' to the Agricultural Marketing Act of 1946. Under this definition, ''[t]he term

[30] 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*).

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

'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.[32] The Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026, amended 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 under current law as of the time of this rulemaking. 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 proposed 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.

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.[33] 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.[34] CMS also noted in the Contract Year 2027 proposed rule [35] (90 FR 54940) that while the prescription drug Epidiolex meets the definition of hemp under the 2018 Farm Bill, because it is covered under Medicare Part D, it would not be permitted to be offered as a Part C supplemental benefit.

Therefore, this regulation will 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 the time of this rulemaking, 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. Barring subsequent legal changes, 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 substance and therefore will be illegal under federal law [36] 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.[37] 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 should 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 § 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 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.

CMS solicited comment on the proposed amendments and thanks commenters for their input. In the following section, CMS describes the comments received and CMS's corresponding responses.

Comment: Several commenters expressed support for the proposal.

Response: CMS appreciates this support of the proposal.

Comment: Many commenters found the proposal to be overly restrictive. Several commenters urged CMS to allow plans to cover all hemp-derived THC or CBD products that meet federal hemp standards under the 2018 Farm Bill (0.3 percent delta-9 THC dry-weight threshold), while others expressed concern that overly restrictive THC limits would eliminate full-spectrum products. Commenters also requested CMS distinguish between non-psychoactive industrial hemp grain products and hemp-derived cannabinoid products, noting that the proposed 0.4 mg per-container THC threshold was operationally unworkable for bulk agricultural commodities.

Response: CMS appreciates commenters' feedback and would like to take this opportunity to provide additional clarification regarding certain aspects of the proposal, including CMS's role in the regulation of cannabis-derived products. CMS's authority does not extend to the direct regulation of cannabis-derived products. Moreover, given the regulation of cannabis-derived products is relatively nascent at both the federal and state levels, CMS does not address the specific technical applications of such laws directly in the regulation text to provide maximum flexibility for MA plans to be able to adapt their SSBCI offerings as the legal landscape changes.

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

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

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

[35] Medicare Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program (90 FR 54894).

[36] 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).

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

As outlined in the Contract Year 2027 proposed rule and this final rule, current regulations prohibit all cannabis products from being offered as SSBCI. Here, CMS acknowledges that not all cannabis products are illegal under federal law and is amending the regulation to accurately reflect this distinction. At the time of this rulemaking, there are only three products that are permissible under applicable state and federal law and therefore may be covered as SSBCI. Those products are hulled hemp seed, hemp seed protein powder, and hemp seed oil. However, should additional products become allowable as the law continues to evolve, this regulation would allow MA plans in a subsequent plan year the option to increase their offerings without requiring additional rulemaking from CMS. Therefore, should other cannabis-derived products become allowable as SSBCI due to changes in state or federal law, MA plans must wait until their next bid submission for the following plan year to add these items to their list of covered SSBCI.

CMS notes that the reference to the FFDCA in the text of the regulation is not necessary because the regulation's reference to current applicable federal law includes the FFDCA. Therefore, CMS is finalizing the regulation with a modification to read as follows, ''Cannabis products that are illegal under applicable State or Federal law.''

Comment: Multiple commenters emphasized the therapeutic benefits of hemp-derived CBD and other cannabinoid products for various medical conditions including chronic pain, cancer, and dementia. Some commenters argued that further investment in cannabinoid products could improve health outcomes and reduce healthcare costs. Others indicated a need for further research.

Response: CMS appreciates these recommendations, however given that CMS does not regulate cannabis and hemp-derived cannabis products, many of these comments were outside the scope of this proposal. CMS would like to note that while the current list of products that are available to be offered as SSBCI is limited, should additional products become allowable in the future CMS will accept a variety of evidence from MA plans to meet the bibliography requirement set forth at 42 CFR 422.102(f)(3), including randomized control trials, case studies or internal analyses to demonstrate that the proposed benefits meet the ''reasonable expectation'' that the benefit improves or maintains the overall health or function of the enrollee. CMS encourages MA plans that wish to offer these products as SSBCI to monitor emerging studies regarding the efficacy of these products.

Comment: A commenter recommended that CMS conduct a cost-benefit analysis of hemp coverage, specifically examining potential Medicare savings from reduced hospitalizations and emergency room visits if hemp were covered by MA plans.

Response: CMS thanks the commenter for their input, however this comment is outside the scope of this proposal. The amendment to the regulation text is meant to ensure conformity with federal and state law. CMS did not propose to evaluate the clinical benefit or cost of hemp coverage in MA but will consider it as laws evolve.

Comment: Another commenter recommended that CMS clarify how its proposals regarding treatment of cannabis and hemp products as SSBCI would apply if the Administration finalizes policies to reschedule marijuana from Schedule I to Schedule III of the Controlled Substances Act.

Response: CMS appreciates this comment and the opportunity to clarify, especially in light of Executive Order (E.O.) 14370, ''Increasing Medical Marijuana and Cannabidiol Research,'' which was issued on December 18, 2025. The E.O. directs the Attorney General to expedite the rulemaking process to reschedule marijuana from Schedule I to Schedule III under the Controlled Substances Act, among other things. Should cannabis be rescheduled to Schedule III, this would change its status under the Controlled Substance Act. However, rescheduling alone would not automatically make cannabis products allowable SSBCI unless the relevant products also meet other applicable State and Federal laws, including the FFDCA.

Comment: Another commenter noted that in light of possible changes to acceptable SSBCI benefits, CMS should have a clear process and timeline to solicit feedback and receive public input on permissible SSBCI and ensure that plans have sufficient time to analyze this information for their advanced planning for annual submissions of bid and benefit packages.

Response: CMS appreciates this comment, and as CMS did here, any changes to SSBCI requirements will be made by requesting public comment on a proposed regulation through a Notice of Proposed Rulemaking (NPRM). However, CMS regulations do not include an exhaustive list of every qualifying item or service that meets the requirements for CMS approval as SSBCI. CMS will ensure that updates to bid instructions and other relevant sub-regulatory guidance are timely and provide sufficient advance notice to MA plans. As a reminder, CMS releases guidance every spring regarding standards for bid review and evaluation prior to the bid submission. In these memos and other guidance, CMS includes references to resource mailboxes for MA benefit questions and MA policy questions. These mailboxes are open year-round for plans and other stakeholders to submit questions, including questions regarding supplemental benefits. MA organizations that are looking to cover new or novel benefits are strongly encouraged to raise those to CMS well in advance of bid submission to allow ample time for the MA organization to provide, and for CMS to review, information explaining how the applicable statutory and regulatory standards are met for the proposed benefits without the time pressures of the bid review process. This is especially true regarding cannabis and cannabidiol products, as the legal landscape continues to quickly evolve.

CMS notes that MA plans are prohibited from making mid-year benefit changes pursuant to 42 CFR 422.254(a)(5), which prohibits MA plans from changing benefits, cost-sharing and premiums for an MA plan after they begin marketing for the prospective plan year. Therefore, should other cannabis-derived products become allowable as SSBCI due to changes in state or federal law, MA plans must wait to add these items to their list of covered SSBCI in their next bid submission for the following plan year.

CMS appreciates commenters' input in this area and is finalizing the proposed amendment to regulation text with a modification. CMS is finalizing that 42 CFR 422.102(f)(1)(iii)(G) be amended as follows: ''Cannabis products that are illegal under applicable State or Federal law.''

A. 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)) provide 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 proposed 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 proposed 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 proposed 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. We proposed to 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 were proposed to be codified at §§ 422.62(b)(3), (b)(5), (b)(20), (b)(23), (b)(27), and 423.38(c)(2), (c)(8), (c)(12), and (c)(36). Language was added to each SEP we proposed to limit to require CMS approval. The language indicates that CMS approval is required and references how CMS approval will 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 proposed 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, in the Contract Year 2027 proposed rule, we concluded that the changes to the regulatory text would not adversely impact plan sponsors, individuals, or agents/brokers, nor would the changes have any impact on the Medicare Trust Funds or result in a paperwork burden. We also stated that 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 solicited comments on this proposal as well as comments on how these SEPs can be further improved for beneficiaries. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for the proposal to codify limits to certain SEPs that would require prior CMS approval, via receipt of a notice or election through a CMS-operated mechanism.

Response: We thank the commenters for their support.

Comment: A commenter opposed this proposal and recommended CMS allow agents and brokers to assist individuals to enroll directly with a new election mechanism instead of limiting elections to existing CMS-operated mechanisms.

Response: We thank the commenters for their suggestion to create a new election mechanism that would allow agents and brokers to assist individuals more directly. However, we disagree that a new mechanism is necessary to maintain the ability for agents and brokers to assist individuals. As we stated in the proposal, agents and brokers are still able to assist individuals making elections using these SEPs and have their involvement captured by 1–800–MEDICARE and the OEC by providing their National Producer Number, which is transmitted to the plan along with the enrollment request. We believe that the existing process allows agents and brokers to actively guide individuals with their plan options and during their election request and results in no additional burden to the plan.

Comment: A commenter opposed this proposal and stated that these SEPs are not used regularly but broadening the SEPs could lead to more churn. The commenter also suggested that educational materials on these SEPs be updated and designed with the reader's health literacy level in mind.

Response: We thank the commenter for their suggestion to improve educational materials and will bear in mind the readability of materials when updating guidance and education materials regarding codification of this proposal. We disagree with the commenter's statement that these SEPs are being broadened by the proposed changes and could lead to enrollment churn. This proposal codifies existing restrictions on these SEPs, which puts guardrails on them, and does not broaden their availability. Therefore, codifying these requirements is likely to result in no change or reduce enrollment churn.

Comment: A commenter opposed the inclusion of the SEP for other exceptional circumstances in this proposal. The commenter stated that requiring CMS approval would place an undue burden on beneficiaries wishing to make an election, particularly for individuals looking to enroll in a C–SNP.

Response: We thank the commenter for this perspective on how the SEP for other exceptional circumstances might be used by individuals wishing to enroll in a C–SNP. However, we disagree with the suggestion that the SEP for other exceptional circumstances not be limited to situations in which CMS approval is provided via notice or use of a CMS-operated election mechanism. As stated previously, we proposed to codify these limitations in order to better oversee the use of SEPs that may not be appropriate for plans to use without prior CMS eligibility determination and approval. This is especially true for the SEP for other exceptional circumstances, which covers situations not otherwise captured in the SEPs in regulation and is determined on a case-by-case basis. We believe that CMS is the only party that

can reasonably make these SEP determinations. We remind the commenter that this limitation does not apply to an SEP that is relevant to enrollment in a C–SNP, the SEP for individuals who are eligible or are found ineligible to enroll in a C–SNP (§ 422.62(b)(13)), which is designed to allow for an enrollment in a C–SNP that serves individuals with specific severe or disabling chronic conditions.

Comment: A commenter opposed this proposal and stated that the change would have significant operational impacts on plans. Additionally, the comment stated that beneficiaries may not understand the enrollment process through CMS-operated mechanisms, which may delay enrollments and result in continuity of care issues. The commenter stated that plans would need to implement systems changes to validate these SEPs, update workflows, and train staff and agents to prevent enrollment errors.

Response: We appreciate the commenter's perspective on potential impacts of this proposal. However, we disagree that this change would result in additional burden. As stated previously, the limitation on these SEPs is already implemented and long-standing. Additionally, the procedural steps plans must take to receive and process election requests and its impacts have already been accounted for in existing burden calculations and plans should not need to make procedural changes in response to this proposal if they are currently following long-standing enrollment guidance.

Comment: A commenter in support of this proposal also suggested that CMS similarly limit the SEP for individuals affected by a government-entity declared disaster or other emergency to only CMS-operated election mechanisms.

Response: We thank the commenter for their support and their suggestion. We will consider limiting the SEP for individuals affected by a government-entity declared disaster or other emergency to only CMS-operated election mechanisms in future rulemaking.

Comment: Several commenters in support of this proposal requested clarification on whether individuals will be expected to provide a copy of a notice of SEP eligibility or otherwise provide documentation to prove their eligibility for these SEPs. The commenters also recommended that the availability of State Health Insurance Assistance Programs (SHIPs) should be promoted whenever individuals need assistance with the SEPs.

Response: We thank the commenters for their requests for clarification and recommendations. Individuals will not be expected to provide a copy of a notice of SEP eligibility when enrolling through a CMS-operated mechanism, or other mechanism when allowed. Currently, only the SEP for individuals who disenroll in connection with CMS sanction requires receipt of a notice for SEP eligibility, in which case they will not be expected to provide the notice or other documentation to establish eligibility, they must only attest that they received the notice about SEP eligibility; the other SEPs are approved through the use of a CMS-operated mechanism, eligibility in these cases is established through attestations made to CMS during the election, such as verbal attestations of the conditions of eligibility made to a 1–800–MEDICARE customer service representative. We will consider the commenters' suggestions about referring individuals to SHIPs when developing guidance and educational materials for these SEPs.

Comment: A commenter in support of this proposal recommended that CMS improve existing guidance and educational materials on these SEPs and mention the availability of agent/broker assistance.

Response: We thank the commenter for their support and recommendations. We will update our guidance and educational materials to reflect the codification of this proposal and explain the availability of agent/broker assistance where appropriate.

Comment: A commenter asked for clarification on whether current regulations allow CMS to create SEPs in response to plans providing false information related to provider networks.

Response: This comment is outside of the scope of the final rule as this proposal did not discuss creating new SEPs.

After consideration of the public comments we received, we are finalizing this proposal without modification.

B. 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 more than 50 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, and reduce waste. The changes to the use and release regulations described in section IV.C of the proposed rule 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, hereafter referred to as Original Medicare (OM) 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.[38] [39] 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 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,[40] 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 regulatory 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

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

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

[40] 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.*

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 OM utilization data, to support the administration of the Medicare program and to more 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 proposed 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 OM 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 OM 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 required to be established between CMS and the requesters prior to disclosing the data. Data sharing agreements include, but are not limited to, information exchange agreements (IEA),[41] memoranda of understanding (MOU), and data use agreements (DUAs),[42] 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

[41] 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.*

[42] 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.*

improve health care delivery. As outlined in section IV.C of the proposed rule, we 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 will 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 will 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 OM claims. The 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.

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

CMS proposed 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 OM 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 OM 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 proposed 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 updates provide for the stipulation that this regulation does not limit CMS disclosure of data as authorized under separate statutory authority.[43] We proposed to repeal the nine specified uses currently listed in § 422.310(f)(1) that would be encompassed under the revised paragraph (f) text. We also proposed 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 data necessary and on the release of dollar amounts at the encounter level, which were moved to § 422.310(f). We noted in the proposed rule, however, that protections to the beneficiary identifying information would be encompassed under the data sharing procedures in the revised paragraph (f) text.

Though CMS proposed 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.

In the Contract Year 2027 proposed rule, CMS discussed 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

[43] 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).

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. In the Contract Year 2027 proposed rule, CMS stated it was 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 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 in the Contract Year 2027 proposed rule, this change 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.[44] Consistent with our proposed changes to remove the list of permissible uses and conditions for release of risk adjustment data, CMS also proposed to remove the detailed list of exceptions for release of risk adjustment data prior to reconciliation in paragraph (f)(3). The 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 in section IV.C of the proposed rule, because MA plans have a window of time in which they should submit data corrections for a given payment year (typically January 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 update allows 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 will 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 updates 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 sought 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. Summaries of and responses to the public comments on CMS's proposal to revise § 422.310(f) are presented below.

Comment: The majority of commenters supported CMS's proposal to revise 42 CFR 422.310(f) to ease restrictions on the use and release of MA risk adjustment data. These commenters emphasized that increased transparency is necessary given the continued growth of the MA program and that the proposed revisions would better align MA risk adjustment data availability with OM data, noting that current regulations constrained research, oversight, and program evaluation. Commenters asserted that broader access to MA risk adjustment data would result in greater transparency and support improved program integrity, research, innovation, and accountability, including analyses of coding practices, care delivery, and utilization trends.

Response: CMS thanks the commenters for their support.

Comment: Many commenters supported the flexibility provided with the proposed regulatory revision to relax restrictions regarding the timing of release of MA risk adjustment data. Some commenters noted that delays and gaps in MA data have limited timely evaluation of MA program impacts on patient outcomes and costs, and emphasized that, given the growth of MA enrollment, MA data should more closely match OM data in timeliness, completeness, and quality. Several commenters urged CMS to ensure the data released is accurate and complete, requesting that CMS improve the completeness of encounter data to prevent inaccurate or misleading conclusions. A couple of commenters opposed the release of pre-reconciled data or urged CMS to maintain restrictions on pre-reconciled data, warning that incomplete or unvalidated data could be misinterpreted and result in inaccurate analysis.

Response: CMS appreciates the thoughtful comments and acknowledges the concerns raised regarding timeliness and completeness of MA risk adjustment data. While the proposed revision allows for release of MA risk adjustment data prior to reconciliation more broadly, CMS understands that it is not always necessary or appropriate for risk adjustment data to be used or released prior to the final risk adjustment data submission deadline, which is when data are considered reconciled for payment purposes for a given payment year. However, over time and as encounter data has matured, the

[44] § 422.310(f)(3)(ii) through (f)(3)(v).

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. As reflected in the recent changes to § 422.310(f)(3), CMS has identified purposes for which use of the data prior to reconciliation may be appropriate, such as emergency preparedness and care coordination, and CMS believes other purposes may include those for program integrity, emerging health situations, to support beneficiaries in managing their health by allowing them to access and share their current data, for example, through the CMS Blue Button 2.0 Application Programming Interface (API), or for research initiatives that necessitate timelier data. Having flexibility to release risk adjustment data prior to reconciliation when necessary and appropriate reduces regulatory burden and removes barriers that slow progress and limit opportunities to effectively and efficiently administer, oversee, and improve Federal programs.

CMS will continue to review requests for pre-reconciled MA risk adjustment data to ensure that pre-reconciled data are necessary and appropriate for the requester's purpose. The completeness and validity of the data will be considered during the review process. An example of a necessary and appropriate use of pre-reconciled data would be for the care coordination of beneficiaries participating in State Medicaid programs. However, since plans have at least 13 months after the end of the service year to submit diagnoses for payment, relying on diagnosis information for research or program operations may not always be appropriate before the final risk adjustment data submission deadline.

CMS continues to employ a range of activities aimed at improving the completeness and validity of encounter data including submission outreach, technical assistance, data analysis, and monitoring. These activities continue to improve the completeness and validity of encounter data. CMS continues to see evidence in the data that the efforts by the agency and MA organizations to improve accuracy and completeness of encounter data have been effective. Specifically, CMS's analysis conducted in 2023 found that the utilization data are complete in a similar time frame as OM claims. Further, a recent CMS analysis of encounter data records with 2021 dates of services submitted for payment year 2022 found that 97.7 percent of all encounter data records submitted by the risk adjustment reconciliation deadline (July 31, 2023) had been submitted by August 2022—8 months after the end of the service year.

Comment: Several commenters stressed the importance of maintaining appropriate beneficiary privacy protections and enforcing robust safeguards through data sharing agreements and privacy and security requirements with expanded data sharing to ensure confidentiality and compliance with applicable Federal laws. A couple of commenters called for additional privacy protections, de-identification standards, and controlled-access environments.

Response: As noted in the proposed rule, CMS will maintain existing guardrails that protect beneficiary information in accordance with applicable Federal laws such as the Privacy Act of 1974, section 1106(a) of the Act, and CMS information disclosure regulations at 42 CFR part 401, subpart B. CMS will be able to release an individual's risk adjustment data when authorized by that individual. For other kinds of requests for release of MA risk adjustment data, CMS will release such information in accordance with CMS data sharing procedures that reflect applicable Federal laws and agency privacy and security policies, 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 CMS data and enters into data sharing agreements with data requesters for disclosures of MA risk adjustment data to ensure that data requesters agree to comply with CMS privacy and security requirements and data release policies. CMS maintains that this process contains the necessary checks and safeguards to appropriately protect beneficiary identifying information.

Comment: Some commenters requested transparency and clarity on what MA data fields are available for release and when data would be released, including requests for publication of a comprehensive data-element inventory, release cadence, and context notes to avoid misinterpretation or inaccurate analysis given the complexity of MA risk adjustment data. A few commenters requested clarity on which external entities or third parties may receive access to the data, under what terms or agreements and for what purposes. A commenter requested CMS retain explicit regulatory language noting that MA risk adjustment data may be released to States to avoid implying that CMS might bypass longstanding state partnerships as it broadens authority for external releases.

Response: MA risk adjustment data can be requested by external stakeholders, such as an individual, a group, an organization, a State, or Federal Agency, for a variety of purposes including, for example, for program administration and oversight, care coordination, research initiatives, public health preparedness, program integrity, and quality improvement. CMS does not intend to bypass longstanding state partnerships as it broadens authority for external releases.

As discussed in the proposed rule, CMS has long-standing data sharing procedures and pathways for entities to request and obtain approval for access to CMS data, including risk adjustment data. This includes an evaluation by CMS to ensure that data requests comply with applicable Federal laws, regulations, and CMS data sharing policies. 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 that documents the terms and conditions under which CMS data may be released and used to ensure that data requesters agree to comply with CMS privacy and security requirements and data release policies, including safeguards to protect beneficiary identifying information and confidentiality. In addition, data sharing agreements provide for potential enforcement mechanisms and penalties. Requesters of CMS data are responsible for abiding by applicable federal and state law, as well as the policies and restrictions of the data sharing agreements.

General information on data products and data files available to external stakeholders can be found at the following link: *https://www.cms.gov/data-research/cms-data/learn-more-about-cms-data.* Detailed information on research requests, including the Research Data Use Agreement (DUA) and datafiles (including variables) available for request can be found at: *https://resdac.org/.*

Comment: Several commenters appreciated that CMS maintained the regulatory language restricting the release of plan-submitted dollar amounts, with a few of those commenters stating that this restriction preserves safeguards on commercially sensitive information and minimizes the risk of potentially anticompetitive harm. A few commenters urged CMS to expand transparency by releasing the plan-submitted dollar amounts at the encounter level, arguing that the

continued restriction on dollar amounts limits the ability to evaluate MA spending, provider payment methodologies, and enrollee cost-sharing, and is inconsistent with broader federal price transparency initiatives. These commenters asserted that increased disclosure could improve understanding of MA program performance, value of care, and benefit beneficiaries without causing competitive harm.

Response: CMS thanks commenters for their comments and acknowledges concerns regarding the restriction of plan-submitted payment data. At this time, CMS will maintain the restrictions that currently exist such that we will not release plan-submitted dollar amounts associated with the items or services for which data is submitted to CMS pursuant to § 422.310(b) to 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, 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 at the level of the encounter record without taking steps to protect the information through aggregation. While changes in federal laws and regulations, such as the Transparency in Coverage Final Rule (CMS–9915–F), and Executive Order 14221 ''Making America Healthy Again by Empowering Patients With Clear, Accurate, and Actionable Healthcare Pricing Information'' (February 25, 2025) are making plan pricing information for specific services more widely available in the group and individual health insurance markets, CMS believes the dollar amounts plans report at the encounter data record level are not ready for release at this time. CMS has not provided extensive guidance for the wide range of payment scenarios that exist in the MA program. As a result, plan practices for reporting service level payment amounts vary widely. CMS's research suggests that the data are a valid representation of MA spending on services in aggregate, but more research and guidance is needed before more detailed data can be made available. Consequently, CMS is maintaining the guardrails for payment data at the level of the encounter as they were originally finalized in the August 2014 final rule, with the inclusion of language to clarify that, as stated previously, these updates do not limit or supersede separate statutory authority that requires CMS disclosure of the data. We look forward to working with stakeholders to continue improving the reliability of plan-submitted payment data and may consider reassessing the restriction on its release in the future.

Comment: A commenter raised concerns about commercial use of MA risk adjustment data, particularly with AI/machine learning companies, and urged CMS to limit or prohibit ''profit-driven'' reuse of such risk adjustment data.

Response: In the August 2014 final rule CMS stated our intention to have consistent policies for the release of data across the OM (Parts A and B) program, the Part D prescription drug program, and the Part C Medicare Advantage program. We noted that in the event policy regarding the release of Parts A, B, and D data for commercial purposes were to change, we would also revise our Part C risk adjustment data sharing policies to be consistent with that change. Since 2014, CMS has established an innovator research program that allows a researcher associated with a for-profit organization to request data for research, or anyone to conduct research with the intent to create a product or tool to be sold. For example, an innovator could use CMS data to develop care management or predictive modeling tools. There are a number of additional protections in place to access data through the innovator research program. First, innovators provide information on the research that will be conducted. This is reviewed and approved by the CMS Privacy Board.[45] Second, innovators are required to provide information on the product, tool, or analyses that will be created using the CMS data. This information undergoes an extensive review to ensure that the data is not used to exploit beneficiaries or to create fraud or abuse in the CMS programs. CMS data cannot be used for marketing purposes. Finally, innovators are only permitted to access CMS data that are approved for their research protocol within the CMS Chronic Condition Warehouse Virtual Research Data Center (CCW VRDC). The CCW VRDC is a virtual research environment for securely accessing and analyzing CMS data. All individual-level data are stored in the CCW VRDC and cannot be downloaded. Innovators only have the ability to download aggregated and de-identified reports and results to their own personal workstation. CMS maintains that these protections provide sufficient safeguards on the commercial use of MA risk adjustment data.

Comment: We received some comments that were out of the scope of this regulation including broader transparency for MA data beyond risk adjustment data such as plan-level metrics, the cost of MA encounter data, more timely reporting requirements, additional reporting requirements, updates to the Part C and Part D risk adjustment models, and improvements to condition specific data. Additionally, some commenters requested CMS ensure plans receive risk adjustment data as early as possible for beneficiaries that move into their plan and others voiced concern regarding plan-initiated medical record requests.

Response: We thank the commenters for their feedback; however, we note that these comments are out of scope for the changes proposed to § 422.310(f). This provision concerns the use and release of the risk adjustment data MA organizations are required to submit to CMS. This provision does not address arrangements between plans and providers, risk adjustment methodology, or plan submission requirements.

After consideration of the public comments we received, we are finalizing the provisions at § 422.310(f) as proposed.

C. 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.

[45] The CMS Privacy Board is an internal CMS panel that reviews research requests for compliance with CMS data policies, but does not act as a HIPAA Privacy Board.

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.[46] 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).[47]

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 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. Provisions

We proposed standardized, detailed documentation requirements for coverage determinations and POS claim adjudications, used for purposes of determining coverage under the Part D benefit. We proposed 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,

[46] 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*).

[47] 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*).

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 proposed 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.

We received public comments on these provisions in the proposed rule. The following is a summary of the comments we received and our responses.

Comment: Numerous commenters were in support of the proposed provision to require standard documentation for coverage determinations and POS edits that determine coverage. Of note, commenters acknowledged this was critical to effective auditing, promoting compliance, improving consistency, enhancing beneficiary understanding of coverage, reducing administrative burden, and enhancing program integrity. One commenter also expressed support for the provision as it levels the playing field for smaller health plans and increases transparency for health plans that are vertically integrated. In addition, a few commenters noted that they are in support of documentation standards as long as they avoid duplicative and prescriptive requirements, and one commenter suggested providing documentation templates.

Response: CMS appreciates commenters' support on its efforts to strengthen program integrity. It is CMS's intention to standardize documentation standards for all Part D plan sponsors to ensure proper oversight of the program while not increasing burden for plan sponsors. CMS understands the commenter request for documentation templates; however, given the vast array of systems and flexibilities for plan sponsors and the varying information needed for different requests, CMS cannot create one singular template that would be applicable universally.

Comment: A few commenters requested clarification on the meaning and intent of ''original format documentation,'' particularly as it pertained to audio recordings. Commenters expressed concern for the administrative and financial burden of maintaining audio recordings, especially on small health plans. Another commenter requested examples of original format documentation and if call notes or transcripts would suffice. It was further recommended that retention of transcripts be permitted in lieu of recordings. A few commenters suggested it would create a great burden especially for plan sponsors to obtain communications between pharmacists, prescribers, enrollees, or other stakeholders that plan sponsors do not currently collect or have direct access to, such as pharmacies that cannot transmit their internal call notes to plans. One commenter recommended that CMS clarify if scanned or digitized copies of documents are considered original records for purposes of compliance.

In addition, a commenter expressed concern that this requirement may read as retention beyond the 10-year standard, effectively increasing costs, annual coverage determinations and burden. It was noted by another commenter that CMS already can request the original coverage determination documentation during audit and that no new documentation requirement is needed.

Another commenter supported the requirement for plan sponsors to maintain original format documentation.

Response: CMS understands the commenters' concerns and requests for clarification surrounding ''original format documentation.'' In regard to audio recordings, we do not expect the retention of the actual audio recording; a transcript or call note(s) of the call will be sufficient documentation. The maintenance of transcripts or call notes should not increase burden on plan sponsors because this information should already be maintained. However, the information in a transcript or call note(s) of an audio recording must include sufficient information to allow CMS to fully evaluate the appropriateness of coverage under the Part D program in accordance with § 423.505(d)(ii). Additionally, a scanned or digitized copy of a request will be considered original format documentation.

Regarding the comments about obtaining communications between pharmacists, prescribers, enrollees, or other stakeholders and the worry that plan sponsors do not have access to those calls or communications, CMS agrees with the commenters' concerns and did not intend to suggest that those communications be collected. Rather, the proposed provisions related to

expectations of Part D plan sponsors, including that plan sponsors maintain communications that *they* have with these different entities, not communications that those entities have with one another. CMS is therefore modifying the language of the proposed rule to clarify that the communications that must be maintained are between the plan sponsor and those entities.

Plan sponsors must have documentation to support Part D coverage determinations and POS edits that determine coverage, including when an authorization is reauthorized for an extended period or original approved for a timeframe greater than 10 years. If the authorization is still ongoing, documentation must be available to support it.

CMS agrees that original coverage determination documentation is already expected upon audit; however, we disagree with the commenter that no new documentation standards are necessary. As stated in the proposed rule, the documentation CMS receives during an audit varies greatly among plan sponsors. An example would be a call note stating ''approved Part D'' instead of documentation reflecting the questions asked and answers provided during the call. For this reason, CMS believes it is imperative to establish standards for strengthening oversight and ensuring all plan sponsors are being held to the same standards.

Comment: A few commenters requested clarification on what is meant by both the ''entity who submitted the request'' and the ''name and title (as applicable) of the individual the Part D plan sponsor contacted to verify the request,'' including what is meant by ''verify the request.'' One commenter questioned how the name and title of the requester applied to a POS claim. A few commenters requested that CMS clarify the expectation for handling requests when information is unavailable to the plan sponsor, including the expectation for documenting the name and title of an individual when additional information is not required to verify a request. It was also noted that plan sponsors, especially PDPs, do not have contracts with the providers and cannot enforce the information being provided. A commenter also questioned the ability of plan sponsors to obtain this information, especially from large provider groups. Additionally, a commenter noted that these requirements will extend adjudication processing time to ensure documentation retrospectively while not providing any real-time clinical decision-making benefit, while another noted that the requirements proposed goes far beyond what is reasonable or necessary for effective program oversight.

A few commenters expressed concern over providing the information CMS proposed to require, as the NCPDP standard for coverage determinations does not allow for the collection of this information. A commenter noted that plan sponsors often have no mechanism to capture this information, especially the identity of the individual submitting the pharmacy claim and verbal discussions between the prescriber, pharmacist and patient. Another commenter noted that plans are prohibited from requiring submission(s) on a specific form and must accept any format.

Another commenter supported the requirement to document the identity and title of the individual submitting a coverage determination or POS request, as well as the individual contacted to verify it as it establishes accountability, improves the accuracy and efficiency of follow-up when documentation is incomplete or inconsistent, enables identification of aberrant or high-risk submission patterns, and supports CMS's ability to validate that drugs were paid for medically accepted indications (MAIs).

Response: The ''entity who submitted a request'' refers to the person who submitted the coverage determination request. CMS's Part C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance [48] states that an individual or entity authorized to request a coverage determination include: (1) enrollee, (2) enrollee's appointed representative, (3) prescribing physician or other prescriber, or (4) any individual representative authorized under state or other applicable law. This information is important to CMS for determining that an appropriate entity requested the coverage determination and allows CMS to monitor for potential fraud, waste, and abuse in instances where an entity is requesting determinations on their own behalf to increase utilization and payment.

In regard to the ''name and title (as applicable) of the individual the Part D plan sponsor contacted to verify the request,'' CMS is referring to those situations in which plan sponsors conduct further follow up with an individual or entity to clarify a coverage determination. For example, in the case of conflicting or missing information needed to approve coverage, CMS would want to ensure that the individual contacted would be able to provide the information necessary to determine coverage. For instance, a beneficiary may not have the necessary information to determine if a drug or service was covered by Medicare. CMS believes this information is still relevant, when available, for a POS edit that determines coverage. In accordance with the Prescription Drug Benefit Manual (PDBM), a plan sponsor that approves or denies a drug through application of a POS edit has made a coverage determination and is subject to all applicable coverage determination standards, timelines, and requirements. As such, plan sponsors maintain some level of information or automation that allowed the POS edit to make an appropriate coverage determination. In these instances, CMS would expect to see what in their system determined that the drug was covered under the Part D program and make that information available to CMS upon audit.

However, CMS does understand that this information may not be available in all instances and/or may be unobtainable by the plan sponsors within authorization timeframes due to a variety of reasons, such as unresponsive entities or format of the coverage determination, including the NCPDP standard. CMS did not intend to require plan sponsors to reject a claim based on the lack of this information, but to include it when reasonable and obtainable. CMS does not expect plan sponsors to perform additional outreach if the information available to the plan sponsor clearly illustrates how a decision for Part D coverage was made.

Based on the comments received, CMS is modifying the proposed regulatory text to make it clear for plan sponsors that the identity of the individual requiring the coverage determination be provided when available. CMS already had proposed ''as applicable'' language for the name and title of the individual the plan contacted to verify the request, but is modifying the proposed language to better clarify that the identity of the individual the plan contacted to verify the request refers to who was contacted in instances when additional information is needed to complete a request.

Comment: A few commenters questioned the need for a diagnosis code to establish a MAI, as this information is captured in different manners, such as ICD–10 codes, provider attestations and medical record review. Other

[48] Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, (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*).

commenters questioned if widespread Part D coverage of drugs is a significant driver of improper payments, especially in cancer treatments and questioned if gathering the MAI at the POS is warranted given risks of imperfect, insufficient, or delayed coding especially in oncology and ultra rare disease. A commenter suggested that CMS clarify how a plan sponsor should adjudicate and document coverage determinations, including when both coverable and non-coverable diagnoses are listed and clarification cannot be obtained within adjudication timeframes.

Response: CMS appreciates the commenters' discussion on the requirement to provide a diagnosis code for coverage determinations reviewing for a MAI. CMS agrees that a diagnosis code itself may be limiting in some instances as suggested by commenters in oncology or rare disease, and CMS is modifying the language in the proposed rule to remove the terminology ''code.'' This will provide the plan sponsors with flexibility in instances where the diagnosis is provided by ICD–10 code, prescriber attestations, or medical records.

CMS does expect plan sponsors to ensure that drugs are only covered under the Medicare Part D program when they are prescribed and dispensed or administered for an MAI in accordance with the section 1860D–(2)(e)(4) of the Act. CMS does recognize that not all drugs can be monitored for MAI at the POS, specifically as it relates to routine drugs. However, plan sponsors do make formulary decisions for their organization as it relates to coverage determinations, such as prior authorization, for drugs that have a high likelihood of being utilized for a non-MAI. In these instances, CMS expects that plan sponsors document a diagnosis used by the plan sponsor in making a coverage determination under the Part D benefit. In instances where there is conflicting information, CMS expects plan sponsors to make a reasonable determination within the adjudication timeframes but notes that plan sponsors should retrospectively be getting clarification to ensure proper coverage for the drug.

Under the rule as proposed, plan sponsors would be required to supply a diagnosis on any coverage determination or POS edit that determines coverage for only those coverage determinations reviewing a drug for a MAI. Based on the commenters' feedback, CMS is modifying the proposed language to clarify and be more explicit that the requirement for a diagnosis is only for those reviews of a MAI.

Comment: A commenter noted that plan sponsors may feel compelled to require a diagnosis on all prescriptions for a likelihood of non-Part D covered uses, even though CMS does not explicitly propose this. The commenter further noted that prescribers are not required to include diagnosis codes on all scripts and NCPDP standards do not require pharmacies to submit them.

Additionally, a commenter noted that CMS should establish that coverage determinations made via ePA transactions conforming to adopted standards (for example, NCPDP SCRIPT or successor standards) are compliant with documentation requirements when the structured transaction data is retained, as this includes clinical criteria responses, attestations, and decision outcomes.

Response: CMS agrees with the commenter that requiring a diagnosis on all prescriptions was not proposed by CMS and is, therefore, outside the scope of this provision.

Further, CMS disagrees with the commenter that CMS should establish that coverage determinations made via an adopted standard are compliant with the documentation standards. CMS recognizes that different authorizations require different information, and CMS cannot state that any one standard will fulfill all requirements of all request types.

Comment: A commenter supported CMS's proposal for standardization but suggested that CMS coordinate audit methodologies and create standard requirements and protocols across Centers for consistency, to minimize duplication and improve understanding and compliance. The commenter noted that the proposal only affects CMS Part D Self-Audits, which would cause misalignment between auditing programs and increase burden. It was also noted by a commenter that currently, plan sponsors are not told why a PDE failed and not offered the opportunity to rebut, which is inconsistent with other program audits in CMS. A few commenters questioned the interplay between CMS's expectations for plan sponsors to approve coverage determinations timely and utilize information available while also expecting detailed documentation retrospectively.

Response: CMS thanks the commenters for their feedback. CMS currently coordinates internally on upcoming audits and methodologies. CMS will continue to work internally to enhance program auditing by reducing any audit duplication, minimizing burden for plan sponsors, and creating consistency when able. CMS also clarifies that these requirements would apply to any program integrity PDE record review audit, which currently would include CMS's Part D Self-Audits and National Audits. CMS believes that these proposed standards will streamline auditing and ultimately make it easier for plan sponsors to provide case files upon audit, as well as create consistency across plan sponsors. CMS appreciates the commenters' concern for the current audit methodology in which plan sponsors are not provided why a specific PDE record failed and subsequently no mechanism to appeal. The audit methodology, including determination rationale, is not a part of this rule and is outside the scope of this specific provision; however, CMS will take this comment into consideration for audit enhancements.

In addition, CMS notes that it proposed to create a mechanism for appeal elsewhere in the proposed rule, which is being finalized at 42 CFR part 423 subpart Z (90 FR 54962). CMS also recognizes that plan sponsors have expectations to approve or deny determinations within adjudication timeframes set by CMS using the best available information. However, if a plan sponsor utilizes the best information available and knows that information was missing or conflicting, plan sponsors should be retrospectively performing outreach to ensure appropriate coverage of its drugs, items or services.

Comment: Several commenters supported the proposed documentation standards but noted that CMS's formulary oversight lacks transparency. Of note, stakeholders have limited insight into how CMS evaluates submissions and utilization management criteria. Specific criteria to increase transparency were recommended including quarterly or annual summaries of Part D formulary review, structured process for stakeholder input, standardized reporting and transparency for a variety of indicators such as coverage determinations by drug category, approval and denial rates, average turnaround times and the clinical criteria applied, and auditing to identify patterns of inappropriate denials and denial appeals.

Response: CMS thanks the commenters for their concerns over CMS's formulary oversight; however, that subject is outside the scope of the proposed provisions.

Comment: A few commenters noted that there is no differentiation between coverage determinations and POS

determinations. One commenter expressed that POS decisions are not coverage determinations and should be exempted from the more extensive documentation CMS is proposing, as at the pharmacy level it could disrupt efficient real-time coverage authorization processes.

Response: CMS agrees with the commenters that not all POS decisions are coverage determinations, such as those triggered based on an approved formulary criteria such as quantity limits. However, in accordance with the PDBM, a plan sponsor that approves or denies a drug through application of a POS edit has made a coverage determination and is subject to all applicable coverage determination standards, timelines, and requirements. As such, plan sponsors maintain some level of information or automation that allowed the POS edit to make an appropriate coverage determination. In these instances, CMS would expect to see what in their system determined that the drug was covered under the Part D program and make that information available to CMS upon audit. For these reasons, CMS proposed that only coverage determination and those POS edits utilized to determine coverage are subject to these requirements.

Comment: A few commenters expressed concerns over the implications for pharmacies and pharmacists. It was noted that pharmacists work in fast-paced environments and verbal exchanges are not recorded, and therefore, mandating capture would disrupt workflow, reduce patient care time, and add administrative burden. A commenter suggests that CMS ensure Part D plan sponsors are solely responsible for recording these interactions.

Response: CMS clarifies that pharmacists and pharmacies are not subject to the requirements proposed at § 423.505 and would not be held accountable for capturing exchanges with the plan sponsors. The requirements proposed are applicable to the plan sponsors contracted by CMS and subject to the requirements at § 423.505.

Comment: A few commenters expressed concern over PDE records, upon audit, being subject to deletion for not having all information documented and the implications it could have on timely decision making, conflicting with CMS's beneficiary-first approach to coverage determinations. It was noted that plan sponsors may hesitate to approve coverage for high-cost drugs, impose stricter internal evidence requirements than medically necessary, or require additional documentation slowing access. Another commenter expressed that the requirement to maintain ''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'' is broad and unclear especially when tied to PDE record deletion upon audit. Commenters recommended that CMS provide alternative oversight approaches that leverage existing documentation requirements and improved audit methodologies. Alternatively, another commenter recommended that CMS soften the terminology from ''will'' to ''may'' in regard to marking a PDE record as improper.

Response: CMS, through previous comment responses, clarifies that not all information in the documentation standards is required for every coverage determination and POS edit that determines coverage. For CMS to provide oversight and ensure that plan sponsors are meeting their requirements to only provide coverage for Part D when it meets the definition of a Part D drug, CMS must be able to review the information utilized by the plan sponsor. When not documented sufficiently, CMS is unable to determine that it was appropriately covered under Medicare Part D, which may lead to an audit finding that the PDE was improper. CMS has modified the proposed regulatory text to clarify that not all requirements are expected for every determination, as not every determination is evaluating the same criteria. The language modifications clarify that some requirements are only necessary when applicable or available, while others like the questions asked and responses received that led to coverage under Part D are required for documentation to be considered sufficient for CMS to evaluate appropriateness. Therefore, documentation provided to CMS upon audit that does not contain each proposed requirement will not automatically mean that a PDE records is deemed improper.

Comment: A commenter recommended that CMS adopt an audit approach to focus on enhanced documentation review on coverage determinations with elevated program integrity risk, drugs with Part B/D coverage, or drugs with unknown fraud or abuse patterns. It was noted that this approach targets resources without imposing uniform burden across all coverage determinations. Another commenter suggested adopting a risk-based audit approach, where plans with strong compliance histories or those in the upper performance quartile are audited less frequently.

Response: CMS clarifies that the program integrity PDE record review audits currently focus on enhanced documentation review for coverage determinations and POS edits that determine coverage, specifically for drugs, items, or services that have a high likelihood that, (1) coverage is available under Parts A or B, (2) the drug is excluded from coverage or otherwise restricted under Part D, or (3) the drug is used for non-medically accepted indications

Comment: A commenter expressed that these requirements may slow prior authorization and coverage determination processes that are in opposition to CMS's efforts to streamline administrative requirements. It was suggested that these requirements could hinder the industry's progress toward automation and electronic prior authorization and could unintentionally undermine both beneficiary access and the modernization goals shared by CMS and plan sponsors. It was recommended that CMS consider not finalizing the proposed documentation language and instead work with plans to develop documentation standards that support program integrity without creating operational inefficiencies or impeding automation efforts.

Response: CMS thanks the commenter for the suggestions. CMS's intent is not to change the current process for prior authorization and coverage determinations, but rather to have the plan sponsors document the information they are already collecting to determine coverage under Medicare Part D when approving coverage determinations or POS edits that determine coverage. CMS is modifying the proposed language to clarify not all information is required in all situations to address concerns about increasing administrative burden to gather the information proposed.

Comment: Several commenters opposed CMS's provision to standardize documentation requirements. Overall concerns expressed pertain to unintended consequences for beneficiary access, increased administrative burdens, and financial risk.

Response: CMS thanks the commenters for sharing their concerns regarding the proposed provisions. Many of the specific concerns voiced by these commenters that led to the consequences of beneficiary access, increased administrative burdens, and financial risk were addressed in other comments. CMS believes that modifications to the regulatory language

proposed will mitigate many of the commenters' concerns. For example, adding that some of the requirements are ''as applicable'' allows plan sponsors discretion in the documentation required based on the specific evaluation criteria for each coverage determination and when the information is not obtainable due to outreach going unanswered. CMS does not expect plan sponsors to do additional outreach for coverage determinations but does expect plan sponsors to provide sufficient and clear documentation that shows how a coverage determination or POS edit that determines coverage led to Medicare Part D approval. CMS believes the burden is minimal and the benefits of program oversight and beneficiary safety vastly outweigh the perceived burden by plan sponsors.

After consideration of the public comments we received, we are finalizing the proposal as modified.

D. 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 TPMO 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 proposed 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. When proposing these changes, CMS solicited comment on how the Agency should identify when a ''discussion of benefits'' occurs.

In the Contract Year 2027 proposed rule, CMS only proposed changes to the TPMO disclaimer provision at §§ 422.2267(e)(41)(ii) and 423.2267(e)(41)(ii). Thus, the proposal did 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 also proposed to remove SHIPs as a source of information from the disclaimer. CMS recognized 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 for beneficiaries. SHIP volunteers may not always have the expertise to help beneficiaries navigate increasingly complex MA and Part D programs. CMS stated 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. CMS also recognized 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 stated 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.

In summary, and for reasons previously discussed, CMS proposed to revise introductory text in §§ 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 proposed 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 solicited comments on this proposal and appreciates stakeholders' input on the proposed changes. The Agency received the following comments and provided responses as follows:

Comment: CMS received several comments supporting the proposal to adjust the timing of when TPMOs are required to verbally convey the disclaimer during a call. A few commenters noted that the first minute of the sales call is not the most effective place to present the TPMO disclaimer. These commenters agreed that conveying the disclaimer before benefits are discussed ensures beneficiaries understand the role and affiliation of the marketing organization before receiving substantive information that could influence decision-making. Additionally, some commenters noted that relaxing the existing requirement for the disclaimer to be conveyed within the first minute of the call is a common-sense change that would retain important beneficiary safeguards and reduce confusion while preserving disclosure objectives.

Response: CMS thanks commenters for supporting this proposal.

Comment: CMS received several comments disagreeing with the proposal to adjust the timing of when TPMOs are required to verbally convey the disclaimer during a call. A commenter expressed concerns that delaying the disclaimer would permit TPMOs to harvest personal information from callers who would not share their information if they knew the limits of the plans the TPMO offers. Others were concerned that beneficiaries would not have immediate awareness of the scope of the conversation they are having before being lured into any kind of discussion about plan choices, and that beneficiaries largely do not understand how MA plans' networks work, so it is essential to immediately provide the disclaimer. A commenter also noted that maintaining the current requirement would maintain transparency and consistency in MA plan marketing.

Response: CMS appreciates the concerns raised by commenters. The Agency is committed to ensuring the protection of beneficiaries' personal data. However, CMS respectfully disagrees with the assertion that altering the requirements for when TPMOs verbally convey the disclaimer puts beneficiaries' personal information at risk. There are other data-focused beneficiary protections still in place to prevent the unauthorized sharing of beneficiary information, such as those found under §§ 422.2274(g)(4) and 423.2274(g)(4) that prohibit personal beneficiary data collected by TPMOs for marketing or enrolling a beneficiary into an MA or Part D plan to be shared with other TPMOs, unless prior express written consent is given by the beneficiary.

CMS also disagrees that this change would diminish beneficiaries' understanding of the call's scope or impact transparency and consistency in MA plan marketing. As previously discussed in this preamble, CMS has determined that many calls typically begin with the TPMO obtaining basic demographic information from the beneficiary. As such, it is CMS' position that the change to the timing of the disclaimer will enhance the effectiveness of the disclaimer. The Agency also believes that conveying the disclaimer before a discussion of benefits occurs will promote clear communication with the beneficiary and mitigate beneficiary confusion. CMS does not anticipate that changing the timing of when the disclaimer is verbally conveyed will have a negative impact on the transparency and consistency of MA plan marketing.

Comment: CMS received several comments about how the Agency

should identify when a ''discussion of benefits'' occurs to mitigate any confusion over when the disclaimer should be read and to ensure consistency in interpretation. Commenters suggested that a ''discussion of benefits'' occurs when the specificity of benefits is being discussed with the intent to draw a beneficiary's attention to an MA or Part D plan or to influence a beneficiary's decision-making process, when discussing plan options, or whenever a TPMO representative begins to discuss unique benefits, premiums, or cost sharing of a particular MA or Part D plan. Another commenter urged CMS to align ''discussion of benefits'' with the current regulatory definition of marketing.

Response: CMS appreciates these recommendations. As previously discussed in this preamble, 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), 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, consistent with 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. Thus, the Agency agrees that a ''discussion of benefits'' can align with the definition of marketing in §§ 422.2260 and 423.2260. Additionally, the examples previously provided establish a framework that agents and brokers can use to judge when the disclaimer should be read. In addition, as this final rule is implemented, CMS will continue to gauge industry's need for more examples or other means of operational guidance for these requirements.

Comment: CMS received numerous comments from stakeholders who submitted similar, and in some cases identical, comments regarding the TPMO disclaimer. The commenters asserted that the TPMO disclaimer, as currently framed, forces independent agents to make statements that are untrue and confuses beneficiaries. The comments included that the disclaimer operates under the flawed assumption that insurance agents, particularly independent ones, do not or cannot represent all plans available in a given area. The commenters further stated that it is common for experienced independent agents, especially in less saturated markets or those committed to extensive certifications, to represent every single plan available to a beneficiary. These commenters further urged CMS to eliminate the entire TPMO disclaimer requirement.

Response: CMS disagrees with the commenters' assertion that the disclaimer requires them to make statements that are untrue or confusing to the beneficiary. The current disclaimer already addresses the commenters' concerns and provides disclaimer language for instances where the agent offers all plans in a service area. Additionally, the TPMO disclaimer is currently designed to ensure that agents provide beneficiaries information about the scope of plans that they represent, inform beneficiaries that there are a variety of plans in their service area to consider when picking a plan, and provide beneficiaries with additional resources for information. The modifications to the current requirements in this final rule are a practical step in refining the rules around the disclaimer to alleviate TPMO burden without a negative impact to the beneficiary. While the elimination of the TPMO disclaimer was not proposed, and hence this comment is out of scope, CMS appreciates these commenters' input and will take it under advisement.

Comment: CMS received several comments strongly disagreeing with the proposal to remove SHIPs from the TPMO disclaimer. These commenters asserted that SHIPs are the only federally-funded source of independent, individual-level counseling available to Medicare beneficiaries and are a critical source of unbiased information for Medicare beneficiaries. Commenters also noted that 1–800–MEDICARE customer service representatives often refer to SHIPs because SHIPs have expertise in state programs, can meet with people in person, and provide a higher level of advocacy and assistance than 1–800–MEDICARE.

Response: CMS agrees that SHIPs can be a source of unbiased information about plan choices. For the purpose of the of the TPMO disclaimer, CMS prefers that TPMOs direct beneficiaries to 1–800–MEDICARE. As previously mentioned in this preamble, this is based on the fact that 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. When appropriate, 1–800–MEDICARE representatives may refer beneficiaries to their local SHIP.

Comment: Some commenters acknowledged the complexity of the MA and Part D programs and suggested that, instead of removing the SHIPs from the TPMO disclaimer, SHIPs should be provided with additional resources. Other commenters noted that increased support for SHIPs, both from a staffing and training perspective, and receiving similar training to 1–800–MEDICARE staff, could help SHIP volunteers better navigate the MA and Part D programs.

Response: While out of scope to this provision, CMS appreciates these comments and will take them under advisement.

After consideration of the public comments CMS received, CMS is finalizing as proposed revisions to the introductory text of §§ 422.2267(e)(41) and 423.2267(e)(41) and revisions to §§ 422.2267(e)(41)(ii) and 423.2267(e)(41)(ii).

E. 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 Medicare Advantage (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 final 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 the Contract Year 2027 proposed rule, CMS proposed several changes to requirements regarding the time and manner of plans' outreach to beneficiaries. The primary proposals included 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 proposed a few other regulatory changes to add specificity and clarify policy. As CMS stated in the Contract Year 2027 proposed rule, in total, these proposals and clarifications were 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, CMS noted that these proposals align with the January 31, 2025, Executive Order 14192, ''Unleashing Prosperity Through Deregulation'' (hereinafter referred to as E.O. 14192).[49] 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 proposed are deregulatory and therefore support the Administration's policy goals.

CMS solicited comment on the proposed changes to §§ 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), including on the accuracy of CMS's assumptions regarding information collection requirements. CMS did not receive comment on the information collection requirements. CMS thanks commenters for their input on the proposed amendments and removal of rules regarding time and manner of beneficiary outreach. In the following sections, CMS describes each proposal, along with the comments received and CMS's corresponding responses.

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

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

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. Thus, CMS proposed that plans and agents/brokers should be able to hold an educational event and a marketing event back-to-back and in the same location.

For these reasons, in the Contract Year 2027 proposed rule, CMS proposed 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 aligned 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. CMS also noted that this proposal, permitting marketing events to follow educational events, provided there is an appropriate break, is consistent with the statutory requirement. CMS proposed 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. CMS provided examples of appropriate beneficiary notification, such as 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 proposed 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. CMS noted that 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. CMS stated in the Contract Year 2027 proposed rule that this deregulatory change is expected to significantly reduce burden and cost for plans and agents/brokers in terms of event planning, and it would also likely ease burden on beneficiaries when they attend an educational event and subsequently want to obtain more plan-specific information at a marketing event. CMS underscored that, 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, CMS expressed in the Contract Year 2027 proposed rule that this proposal would provide greater convenience for beneficiaries and enhance the beneficiary experience in shopping for a plan.

CMS received the following comments on this proposal, and CMS's response follows:

Comment: Many commenters supported eliminating the 12-hour delay between an educational event and a marketing event, viewing it as overburdensome and confusing. They noted that beneficiaries attending educational events often wanted immediate personalized guidance and that forcing them to wait disrupted natural inquiry flow, leading to disengagement or frustration. Commenters viewed the delay as serving no protective purpose when beneficiaries actively requested assistance. In addition, commenters emphasized that agents/brokers should be empowered to respond to beneficiary-initiated questions without fear of regulatory violation.

Response: CMS appreciates the support for this proposal and agrees with commenters' sentiments regarding potential implications of the 12-hour delay on beneficiaries and agents/brokers.

Comment: Some commenters highlighted practical benefits of CMS permitting marketing events to follow educational events, noting that the change would reduce transportation burdens (especially for dually eligible individuals), allow multiple meetings in a single day, increase outreach efficiency, and better utilize limited staffing resources, which is particularly important for smaller plans serving geographically dispersed populations. Commenters also stated the change would reduce unnecessary delays and administrative burden while preserving beneficiary protections. The proposal was viewed as a practical, beneficiary-friendly improvement that promoted timely access to information, reduced confusion, and improved the beneficiary experience while maintaining appropriate safeguards.

Response: CMS agrees that there are many practical benefits to allowing marketing events to follow educational events, including those related to transportation and administrative burden relief, time saving, and efficiency. CMS also agrees that this proposal would help beneficiaries while also preserving safeguards.

Comment: A commenter stated that the proposal would allow plans and agents/brokers to provide education followed by enrollment at the same event, enabling in-person discussion of unique situations. A commenter noted that the change would allow tailored outreach aligned with beneficiary preferences, enable quicker and more responsive communication, and result in better beneficiary experiences and improved health outcomes.

Response: CMS appreciates commenters' support for the promotion of in-person, tailored beneficiary communications that this provision invites. CMS also believes that the provision may improve beneficiaries' experiences and ultimately health outcomes in the long run.

Comment: Other commenters opposed eliminating the 12-hour delay, warning it would merge educational and marketing events into sales seminars that pressure beneficiaries into hasty decisions. Commenters claimed a brief restroom or snack break was inadequate separation between the two event types. These commenters described the waiting period as essential for beneficiaries to digest information, access SHIP resources, conduct research, discuss with families, and make informed choices. Commenters believed that without meaningful separation, the statutory prohibition against sales activities at educational events would become meaningless, particularly given the vulnerabilities of the Medicare-eligible population.

Response: CMS disagrees with commenters that eliminating the 12-hour delay would result in beneficiary pressure. As discussed in the Contract Year 2027 proposed rule, CMS believes that beneficiaries' support from caregivers is a built-in layer of added protection from any potential undue pressure, coupled with other various beneficiary protections, such as potential SEPs, including retrospective enrollments, if warranted. CMS notes that the provision includes the

important requirement that plans and agents/brokers notify the beneficiary that the educational event is ending and a marketing event will begin shortly. CMS disagrees with commenters and believes that a brief restroom or snack break is indeed an adequate separation between the two types of events. Furthermore, in response to the comment about the statutory prohibition against sales activities at educational events, CMS notes, as stated in the Contract Year 2027 proposed rule, that section 1851(j)(1)(D)(ii) of the Act does in fact prohibit sales and marketing activities at educational events but does not require a specific timeframe between an educational event and a marketing event.

Comment: In other comments opposing this provision, commenters cited extensive experiences with unwitting enrollments, including beneficiaries who did not consent, thought they were enrolling in dental/vision only, did not understand network limitations, or had dementia and were enrolled without family present. Commenters mentioned low-income individuals who were pushed into plans without adequate discussion. The commenters described plan marketing violations and suggested that, if finalized, the rule would foster problematic behaviors in an increasingly commission-based market.

Response: CMS understands commenters' concerns but reiterates that beneficiaries are able to take advantage of certain important beneficiary protections such as potential SEPs, including retrospective enrollments, when appropriate, if a beneficiary makes an adverse enrollment decision based on misrepresentation or otherwise non-compliant sales tactics. However, CMS believes that such instances of plan marketing violations and negative beneficiary enrollment experiences that commenters describe are rare, as CMS does not often receive reports or complaints in this area. Additionally, CMS routinely monitors compliance with MA marketing rules and may take compliance action if CMS determines that a plan or agent/broker is out of compliance with these rules.

Comment: Several commenters believed the proposed changes could increase confusion and high-pressure interactions, especially for beneficiaries with complex medication needs, limited health literacy, cognitive impairment, or limited English proficiency. Commenters stated that relying on family presence or SEPs as safeguards is inadequate because caregivers may not help beneficiaries discern where education stops and marketing starts, and that no one is immune from Medicare system confusion. Commenters asserted that relying on SEPs after misleading enrollment was unacceptable because these remedies were exceedingly difficult to use, and many beneficiaries did not seek help until well after problems emerged (*e.g.,* discovering out-of-network providers). Also, commenters stated that beneficiaries might not successfully obtain SEPs due to lack of knowledge about how to access them, leaving them without options once enrolled.

Response: CMS respectfully disagrees. The various beneficiary protections mentioned have previously served as more than sufficient safeguards to potential beneficiary confusion and pressure during both educational and marketing events, as well as during other enrollment processes. This includes the possibility of CMS processing a retrospective enrollment if warranted. As noted previously, CMS routinely monitors compliance with MA marketing rules and may take compliance action if CMS determines that a plan or agent/broker is out of compliance with these rules, including in instances where plans or agents/brokers engage in high-pressure interactions with and possibly confuse vulnerable beneficiaries with complex medication needs, limited health literacy, cognitive impairment, or limited English proficiency.

Comment: A commenter stated that the change could result in educational presentations being less complete and built solely to support subsequent sales activities.

Response: CMS appreciates the commenter's concern but views this as a hypothetical scenario that is unlikely to occur. Specifically, CMS expects relevant safeguards—such as existing requirements for educational events—will protect beneficiaries from being exposed to partial educational presentations that are designed solely to support subsequent sales activities. For example, §§ 422.2264(c) and 423.2264(c) prohibit plans and agents/brokers from marketing specific plans or benefits and from conducting sales or marketing presentations at educational events. CMS also notes that plans and agents/brokers have the freedom to design educational presentations as they choose, provided that they remain in compliance with CMS's marketing and communication requirements at 42 CFR part 422, subpart V, and 42 CFR part 423, subpart V.

Comment: Some commenters believed the proposed changes would remove beneficiary protections without replacement, and that each time federal protections were removed, states had to navigate the new landscape or create their own rules. They asserted that state staff spent significant time addressing problematic plan growth rather than advancing integration, MA was described as ''the wild west,'' and these rules were necessary to prevent vulnerable populations from being pressured into unsuitable products.

Response: CMS thanks commenters for offering this information regarding the state perspective. However, CMS disagrees that the proposed changes would remove beneficiary protections without replacement; rather, CMS is simply amending the existing beneficiary protections. Furthermore, in response to the reference to states creating their own rules, CMS reminds all parties of the statutory and regulatory framework applicable to MA, and that standards established under federal law preempt state law, other than state licensing laws or state laws relating to plan solvency, with respect to MA plans. These federal standards include communications and marketing standards set forth in 42 CFR part 422, subpart V, and 42 CFR part 423, subpart V. Section 1856(b)(3) of the Act states the following: ''Relation to state laws. The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.'' In turn, CMS's regulation, under § 422.402, closely mirrors this statutory language regarding federal preemption. CMS does note that for D–SNPs, state Medicaid agencies may include communications and marketing requirements in state Medicaid agency contracts as long as the requirements do not conflict with federal requirements.

Comment: Commenters urged CMS to protect PACE enrollments from aggressive MA marketing that might not clearly communicate differences between MA plans and the PACE program, as PACE participants were particularly vulnerable.

Response: While out of scope of the requirements in this final rule, CMS will take this into consideration when evaluating both MA and PACE marketing rules and beneficiary protection rules in the future.

Comment: A commenter asserted that plans, rather than beneficiaries, would benefit from the proposed change and took issue with CMS's reliance on undefined stakeholder input, the presence of others at events, and the availability of corrective measures to support the change.

Response: As previously explained, CMS has received stakeholder input that the 12-hour delay requirement between an educational event and a marketing event makes it difficult for beneficiaries who live far from the events or who lack transportation to access important MA and Part D information. CMS agrees that this input raises legitimate concerns about access challenges. CMS reiterates its stance on the sufficiency of existing beneficiary protections in place and the likelihood of support from beneficiaries' family, friends, and caregivers during education, marketing, and enrollment experiences. CMS believes that eliminating the 12-hour delay between an educational event and a marketing event will foster a better, more convenient plan shopping experience for beneficiaries. For these and other reasons stated in the Contract Year 2027 proposed rule, CMS stands by its reasoning for this change.

Comment: A commenter supported a tailored approach—supporting the change for dually eligible individuals but expressing concern that other MA beneficiaries could be pressured into real-time coverage decisions. Commenters also expressed concerns about potential ''unintentional non-compliance.''

Response: CMS thanks the commenter for the idea, but unfortunately such a tailored approach is not feasible because educational and marketing events are attended by a wide range of beneficiaries, including both dually eligible and non-dually eligible individuals. CMS does not believe it would be practical for the 12-hour delay between events to be eliminated for some attendees and not others. CMS is unclear on what the commenter meant by ''unintentional non-compliance.'' CMS notes that plans are responsible for ensuring compliance with CMS regulations.

Comment: Some commenters recommended that if CMS proceeded with the proposal, it should replace timing guardrails with clear, enforceable standards preventing immediate transitions and ensuring clear beneficiary consent. They suggested, at minimum, there should be sufficient time (30–60 minutes) and space between events so individuals could affirmatively choose whether to attend the marketing event.

Response: CMS appreciates this input and believes that a brief restroom or snack break is a sufficient opportunity for all beneficiaries, including those with mobility concerns, to leave the facility if they wish prior to the beginning of a marketing event.

Comment: Another commenter recommended that if this proposal were finalized, CMS should provide a dedicated office to receive referrals from state departments and SHIP offices, take swift enforcement action, and share complaints with states to enable compliance with state licensing laws.

Response: CMS thanks the commenter for these recommendations. If states or SHIP offices encounter any issues or have questions related to this regulation, they may contact CMS directly through already established channels, including the use of the Complaints Tracking Module and sharing of information as outlined in existing memorandums of understanding (MOUs) that CMS has with states.

After considering all the comments received on allowing marketing events to directly follow educational events in the same location, CMS is finalizing the proposal 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, as long as plans and agents/brokers notify the beneficiary that the educational event is ending and a marketing event will begin shortly and also give the beneficiary a sufficient opportunity to leave the educational event prior to the start of the marketing event.

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.[50]

[50] 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

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, in the Contract Year 2027 proposed rule, CMS proposed 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. CMS noted that 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. CMS also stressed that 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. CMS acknowledged in the Contract Year 2027 proposed rule that, if finalized, it would still require an advance agreement, as statutorily required, but without a specified timeframe, as 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 also proposed a minor technical correction in § 422.2264(c)(3)(i) to add the missing word ''appointment'' after ''marketing.''

In the Contract Year 2027 proposed rule, CMS explained that eliminating the 48-hour SOA rule would benefit all parties, especially beneficiaries, by allowing for a discussion of plan products on the beneficiary's schedule. CMS also stated that, 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, CMS noted that it does not account for other interactions that may take place between the beneficiary and a plan or an agent/broker. In the Contract Year 2027 proposed rule, CMS provided the example of 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, who would be required to come back no less than 48 hours later to meet with that plan or agent/broker again.

CMS acknowledged 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, in the Contract Year 2027 proposed rule, CMS asserted that a different approach may be appropriate now for a similar reason as mentioned for the proposal to eliminate the 12-hour delay requirement. CMS stated that 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. In the Contract Year 2027 proposed rule, CMS stated that the Agency 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, 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 led 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, as stated in the Contract Year 2027 proposed rule, the proposal CMS put forth would also reduce the burden on plans and agents/brokers in addition to beneficiaries and their representatives.

Furthermore, CMS explained that 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 stated that the Agency 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 also proposed a few additional associated regulation changes and

(hereinafter referred to as the December 2022 proposed rule).

clarified 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 so in the Contract Year 2027 proposed rule, CMS deemed these proposed regulation changes and policy clarifications as necessary and responsive to those questions. CMS requested that plans and agents/brokers review the following information carefully and provide feedback through the comment process. CMS also noted that, if this portion of the rule is finalized as proposed, the SOA policy clarifications contained herein will supersede any existing SOA guidance.

First, CMS proposed 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 proposed 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 also clarified in the Contract Year 2027 proposed rule 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, CMS clarified that another example would be a parent and child who are both Medicare-eligible. CMS also explained that 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, CMS noted that §§ 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, in the Contract Year 2027 proposed rule, CMS reminded 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 proposed 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 proposed 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 explained that these regulatory text changes were necessary to avoid ambiguity and prevent misinterpretation.

CMS stated in the Contract Year 2027 proposed rule that, 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. As an example, CMS stated that 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, in the Contract Year 2027 proposed rule, CMS stressed that 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 proposed 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). CMS pointed out that 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 proposed 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 also clarified 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. In the Contract Year 2027 proposed rule, CMS listed instances in which SOAs may be accepted or collected, including: (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—in the case where the proposed changes to §§ 422.2264(c)(1)(ii)(D) and 423.2264(c)(1)(ii)(D) would be finalized as proposed. CMS also listed instances in which SOAs may not be accepted or collected, including: (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 clarified in the Contract Year 2027 proposed rule 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. CMS asserted that this aligns with section 1851(j)(2)(A) of the Act's reference to ''the scope of the marketing appointment'' and provided the following non-exhaustive list of examples of types of products to be discussed: MA plans, MA–PD plans, and standalone PDPs. As a best practice, in addition to the type of product(s) to be discussed, CMS encouraged plans to also include other pertinent information in the SOA, such as the date of the appointment and beneficiary contact information. In addition, CMS stated that 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. As explained in the Contract Year 2027 proposed rule, 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 clarified 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 noted that the Agency currently does not provide a model document for SOAs.

Lastly, in the Contract Year 2027 proposed rule, CMS reminded plans and agents/brokers of and clarified 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. CMS clarified that 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, CMS noted that the signed SOA can be used for multiple telephonic or in-person contacts or appointments. With that said, a plan or agent/broker must respect a beneficiary's request to no longer be contacted, even if that additional contact takes place within the 12-month window.

CMS received the following comments on this proposal, and CMS's response follows:

Comment: The majority of commenters strongly supported eliminating the 48-hour waiting period between obtaining an SOA and conducting a personal marketing appointment. Commenters characterized the requirement as creating unnecessary delays, administrative burden, and paperwork without providing meaningful beneficiary protection. The waiting period was described as preventing timely assistance, particularly for beneficiaries with urgent needs or limited availability, and taking valuable time away from agents/brokers during the short open enrollment window. Commenters believed the 48-hour SOA rule created situations where beneficiaries were available, agents/brokers were available, and questions were time-sensitive, yet agents/brokers could not answer questions, provide quotes, or explain benefits for 48 hours. This was viewed as dismissive, confusing, bureaucratic, and distrust-inducing from the beneficiary perspective. Commenters noted that by the time 48 hours passed, many beneficiaries contacted someone else, enrolled immediately without the help of an agent/broker, or worked with individuals who did not follow the rules.

Response: CMS appreciates the strong support for this proposal and agrees with commenters' sentiments regarding potential implications of the 48-hour SOA rule on the interactions between beneficiaries and agents/brokers.

Comment: Some commenters suggested that the SOA often confused beneficiaries who were eager to understand their options and created unnecessary barriers to access. Commenters believed the cooling-off period assumption that beneficiaries were incapable of requesting information responsibly was both inaccurate and disrespectful. Eliminating the waiting period, commenters believed, would allow beneficiaries to engage with knowledgeable, trained advisors on a timeline that worked best for them and enable same-day appointments.

Response: CMS understands that the SOA could potentially be confusing to beneficiaries or present a barrier to access, and CMS appreciates the commenters' support for removing the 48-hour waiting period.

Comment: A few commenters characterized the 48-hour SOA requirement as a unique administrative burden imposed specifically on agents/brokers that did not apply to other enrollment channels. They stated that this disparity created an uneven playing field and introduced unnecessary friction into the enrollment process.

Response: CMS acknowledges the commenters' implication that they are pleased with CMS's proposal to eliminate the 48-hour SOA requirement to give agents/brokers selling MA and Part D products a more even playing field as compared to agents/brokers selling other insurance products. CMS appreciates this observation and the support for this proposal expressed by commenters.

Comment: Some commenters recommended eliminating the SOA requirement entirely and implementing a uniform post-enrollment rescission period applicable to all channels. They suggested that this would allow beneficiaries a designated timeframe after enrollment to review their decisions and change their minds if necessary, providing more robust and beneficiary-centric safeguards. If CMS retained the SOA requirement, commenters suggested allowing one universal SOA at first contact, permitting immediate discussion of benefits once completed, eliminating the 48-hour waiting period, and allowing SOAs to remain valid for ongoing discussions.

Response: CMS is not eliminating the SOA requirement entirely, as it is a statutory requirement under section 1851(j)(2)(A) of the Act, as well as out of the scope of CMS's proposal. The concept of a uniform post-enrollment recission period is also outside of the scope of what CMS proposed, but CMS may take this suggestion under consideration for future rulemaking. However, there are various existing beneficiary safeguards already in place, as previously mentioned, such as potential SEPs, including retrospective enrollments, if warranted. Finally, regarding the suggestion to allow one universal SOA at first contact, CMS is not in favor of this approach because requiring a new SOA for each appointment is an important beneficiary protection that ensures common agreement and clarity regarding the intended scope of each individual personal marketing appointment prior to the appointment taking place.

*Comment: S*everal commenters opposed eliminating the 48-hour waiting period and urged CMS to retain it. Commenters stated that the waiting period was designed to protect

beneficiaries from high-pressure sales tactics and provide time for them to consult with family or caregivers before making enrollment decisions, and that removing this safeguard would increase the risk of rushed and uninformed enrollments, further undermining trust in the Medicare enrollment process. Some commenters believed the 48-hour cooling-off period already struck the appropriate balance by reducing the likelihood that beneficiaries would be subject to undue pressure and giving beneficiaries the opportunity to consider their options fully before making key decisions. Regarding other safeguards that CMS identified in the Contract Year 2027 proposed rule, such as potential availability of assistance from family and availability of SEPs in the event of certain marketing or enrollment improprieties, some commenters deemed these as inadequate on their own to ensure beneficiaries had the opportunity to engage in well-informed decision-making during enrollment.

Response: CMS acknowledges commenters' concerns with eliminating the 48-hour waiting period before a beneficiary's personal marketing appointment. However, as stated in the Contract Year 2027 proposed rule, 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. In the time since the 48-hour delay went into effect, CMS has received multiple email inquiries from agents/brokers who have provided real-world examples of how this rule has had unintended negative consequences for the beneficiary. For example, if a beneficiary calls an agent to discuss MA plan options but does not immediately connect and instead leaves a message for the agent to call back, when the agent does call back, the agent must complete the SOA with the beneficiary, and then inform the beneficiary that they are unable to discuss MA plan options until 48 hours later. Another example is a beneficiary completes an SOA to discuss Part D options, meets with an agent, and during the conversation, the beneficiary asks about MA. In this scenario, the agent must complete a new SOA, but based on the current regulation, must then wait an additional 48 hours before the discussion about MA options can continue. In eliminating such a delay, CMS is enabling beneficiaries to learn about plan products in real time, rather than having to come back for a personal marketing appointment 48 hours later. Additionally, CMS reiterates its stance on the sufficiency of existing beneficiary protections in place and the likelihood of support from beneficiaries' family, friends, and caregivers during education, marketing, and enrollment experiences. CMS believes such safeguards offer appropriate beneficiary protection in the absence of the 48-hour SOA rule.

Comment: Commenters believed that having no waiting period presented the possibility of agents/brokers pressuring beneficiaries to sign an SOA directly before an appointment. Commenters asserted that this would be wholly inappropriate in light of ongoing pressure tactics deployed in MA marketing. Commenters urged CMS to, at a minimum, prohibit the SOA from being signed simultaneously with the beginning of a personal marketing appointment.

Response: Any pressure tactics deployed during MA marketing events would be considered non-compliant and subject to potential compliance or enforcement action by CMS. Moreover, concerns about potential pressure tactics could be mitigated by existing beneficiary safeguards already in place, as previously mentioned, such as potential beneficiary support from caregivers and potential SEPs, including retrospective enrollments, if warranted. Such safeguards offer appropriate and sufficient beneficiary protection in the absence of the 48-hour SOA rule. Plans and agents/brokers will still be required to complete an advance agreement (an SOA form) as statutorily required, just without a specified timeframe, giving beneficiaries the flexibility to fill out an SOA just prior to discussing plan products or in advance of a future personal marketing appointment.

Comment: A commenter expressed that community health centers routinely assisted patients who later discovered high-cost sharing, restrictive networks, or prior authorization barriers, with no recourse until the next enrollment period. Thus, in this commenter's opinion, removing the 48-hour SOA safeguard would increase rushed and uninformed enrollments.

Response: CMS thanks the commenter for sharing these unfortunate beneficiary experiences at community health centers. CMS notes that beneficiaries are always encouraged to contact 1–800–MEDICARE if they believe that they have been misled or steered into a plan that does not meet their needs as a result of plans or agents/brokers engaging in misrepresentation or otherwise non-compliant sales tactics. As previously noted, CMS has the ability to grant SEPs, when warranted, including the potential for retrospective enrollments. Finally, CMS takes such beneficiary complaints seriously and will take compliance or enforcement actions as appropriate, including in such cases of rushed and uninformed enrollments per the commenter's concerns.

Comment: Commenters encouraged CMS to prioritize protecting beneficiaries from abusive marketing practices over the interests of marketing and brokerage firms or MA plans. Commenters characterized the proposal as primarily benefiting agents/brokers rather than beneficiaries, despite CMS's stated rationale. Commenters stated that the proposed change seemed to remove guardrails previously put in place to protect beneficiaries.

Response: CMS agrees with commenters' sentiment that protecting beneficiaries from abusive marketing practices is of utmost importance. CMS assures commenters that the Agency is committed to ensuring existing important beneficiary protections remain in place. As previously mentioned, there are a range of such beneficiary protections, and CMS engages in active oversight of plans, holding plans accountable for complying with CMS rules and ensuring that their contracted agents/brokers also comply. In light of the beneficiary safeguards outlined here, CMS does not believe the 48-hour SOA guardrail is necessary. In instances of beneficiary harm, CMS will take compliance or enforcement actions as appropriate.

Comment: A few commenters supported eliminating the 48-hour waiting period after signing an SOA but emphasized it was critical that CMS maintain strong structural safeguards. For example, commenters believed that SOAs must still be required before any personal marketing discussion, clear definitions around what constituted a personal marketing appointment were helpful, and consistency across guidance was essential. Commenters also noted that simplification was beneficial, but any relaxation of oversight would inevitably be exploited by bad actors. Commenters recommended that CMS should streamline the process but not weaken the protections that kept beneficiaries safe. While not opposed to administrative simplification and finding the right ways to safeguard and protect beneficiaries in a competitive landscape, commenters stated that they would have liked to see new or different proposals rather than simply removing existing protections.

Response: SOAs are still required before personal marketing appointments. CMS's removal of the

word ''scheduled'' means that an SOA will be required for all appointments that meet the definition of personal marketing appointments. As an example, an SOA will 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 for purposes of discussing marketing topics. To be clear, this means that an SOA is required regardless of whether the personal marketing appointment is initiated by the plan, an agent/broker, or the beneficiary. CMS thanks commenters for their praise of the clear definition, simplification, and streamlining the process. CMS also agrees on the importance of consistency across guidance, oversight, and beneficiary protections, as stated previously. Regarding the recommendation for new or different proposals, CMS will consider new ideas for future rulemaking in this area.

After considering all the comments received on the timing of a personal marketing appointment after SOA completion, CMS is finalizing the proposal to eliminate the 48-hour waiting period required between the SOA completion and a personal marketing appointment, as well as eliminating the two corresponding exceptions to the 48-hour SOA rule.

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.

In the Contract Year 2027 proposed rule, CMS proposed 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. As CMS noted in the Contract Year 2027 proposed rule, 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. CMS also pointed out that 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.

In the Contract Year 2027 proposed rule, CMS acknowledged 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, in the Contract Year 2027 proposed rule, CMS recognized 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, CMS highlighted that 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 proposed 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 proposed 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 noted 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.

CMS received the following comments on this proposal, and CMS's response follows:

Comment: Many commenters supported CMS's proposal to allow the collection of SOA forms at educational events. They noted that current restrictions create unnecessary barriers preventing beneficiaries from receiving timely assistance, as beneficiaries often attend these events seeking help understanding how information applies to their situations and requesting next steps. Commenters believed the change would improve the beneficiary experience by reducing confusion, improving access to guidance, alleviating transportation burdens, streamlining processes, enabling quicker and more responsive communication, and providing greater flexibility for decision-making at convenient times.

Response: CMS appreciates the support for this proposal and agrees with commenters' sentiments regarding the benefits, including improving the beneficiary experience and communication, alleviating transportation burdens, and providing flexibility.

Comment: Commenters also highlighted that the change would enhance workflow efficiency for plans and agents/brokers, modernize Medicare outreach rules, reduce administrative burden, lower costs, and improve resource allocation. Commenters characterized the change as practical, consumer-friendly, and balanced, stating it would support informed decision-making while preserving beneficiary protections.

Response: CMS agrees that this change will result in administrative efficiencies, reduce burden, and result in practical improvements to the beneficiary decision-making process.

Comment: Some commenters opposed CMS's proposal, emphasizing that existing rules protect vulnerable populations from pressure tactics and inappropriate products. They expressed concerns that the change would increase

confusion, high-pressure interactions, and misleading encounters during plan selection, especially for beneficiaries with complex medication needs, limited health literacy, cognitive impairment, limited English proficiency, or those relying on local counseling resources.

Response: As stated in the Contract Year 2027 proposed rule, these concerns regarding beneficiary pressure appear to be outweighed by the importance of maximizing timely 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.

Comment: Commenters questioned characterizing SOA collection as educational rather than as a marketing activity, noting that procuring a signature on an SOA form relates to a sales appointment.

Response: As stated in the Contract Year 2027 proposed rule, CMS reiterates that 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 because it does not meet the definition of marketing at §§ 422.2260 and 423.2260, which requires the activity to meet specific standards for intent and content. Rather, the collection of an SOA form is simply 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.

Comment: A few commenters asserted that when federal protections are removed, states must either navigate the new landscape or create their own rules, and states lose contractor attention to beneficiary protection. Some commenters urged CMS to withdraw the proposal, establish a dedicated office to receive referrals from state insurance departments and SHIP offices, take swift enforcement action against violations, share complaints with state insurance departments, and retain existing standards for beneficiary outreach.

Response: CMS thanks the commenters for these recommendations. If states or SHIP offices encounter any issues or have questions related to this regulation, they may contact CMS directly through already established channels, including the use of the Complaints Tracking Module and sharing of information as outlined in existing MOUs that CMS has with states.

As to the comment that states must create their own rules, CMS reminds all parties of the statutory and regulatory framework applicable to MA, and that standards established under federal law preempt state law, other than state licensing laws or state laws relating to plan solvency, with respect to MA plans. These federal standards include communications and marketing standards set forth in 42 CFR part 422, subpart V, and 42 CFR part 423, subpart V. Section 1856(b)(3) of the Act states the following: ''Relation to state laws. The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.'' In turn, CMS's regulation, under § 422.402, closely mirrors this statutory language regarding federal preemption.

Comment: Some commenters requested clarity regarding compliant educational environments for SOA collection, ''standardized scripts,'' clear guidance, and guardrails to prevent beneficiary confusion and promote industry consistency.

Response: Compliant educational environments for SOA collection include any educational events that meet the requirements outlined at § 422.2264(c)(1). CMS is unsure what commenters mean by ''standardized scripts,'' however, CMS notes that the Agency currently does not provide a model document for SOAs, nor any SOA scripts. CMS will consider the need for any sub-regulatory guidance regarding the finalized policy.

Comment: Some commenters also noted the importance of ongoing oversight and evaluation to ensure changes meaningfully advance beneficiary understanding and trust without unintended consequences and emphasized ensuring discussions are clear about plan benefit offerings. Commenters commended CMS for recognizing the evolving marketing and communications landscape and encouraged the Agency to work proactively to empower beneficiaries to make informed choices.

Response: As stated previously, CMS engages in active oversight and evaluation of plans and their contracted agents/brokers. CMS agrees with commenters that beneficiary understanding and trust are important. CMS also appreciates commenters' commending the Agency's recognition of the evolving MA landscape and proactive work to help beneficiaries. CMS remains committed to improving MA marketing and communications policies.

After considering all the comments received on allowing the SOA at educational events, CMS is finalizing the proposal 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.

4. Summary of Regulatory Changes

In summary, in the Contract Year 2027 proposed rule, CMS proposed 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 included: (1) allowing a marketing event to directly follow an educational event in the same location (provided there is appropriate beneficiary notification and opportunity to leave); (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 received a range of comments pertaining to these proposals, the majority of which reflected support for the regulations. After considering the comments received and for the reasons outlined in the Contract Year 2027 proposed rule and in responses to comments, CMS is finalizing all provisions under *Removing Rules on Time and Manner of Beneficiary Outreach* as proposed. As finalized, these regulatory changes will 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.

F. 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. In the April 2023 final rule, CMS asserted that 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). In the Contract Year 2027 proposed rule, CMS explained that, after years of implementation and oversight, including one revision to the requirement, the current restrictions regarding use of superlatives at §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) were 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 (90 FR 54956). Although CMS proposed 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 noted that the Agency would 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 (90 FR 54956). CMS also explained that it would continue to encourage MA organizations and Part D sponsors to make available to beneficiaries and the public data, reports, or other documentation that supports the superlative to promote informed enrollment decisions (90 FR 54956).

As described in the Contract Year 2027 proposed rule, 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 (90 FR 54956). 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. CMS also explained that, 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 (90 FR 54957). CMS noted, however, that if this proposed change to CMS's regulations was finalized, MA organizations and Part D sponsors could still choose to make data available to beneficiaries as they determine appropriate, which may reduce the administrative burden (90 FR 54957).

CMS stated it would 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 CMS is investigating a complaint regarding a misleading, confusing, or materially inaccurate material, CMS may request the plan provide documentation that supports a superlative used, per the Agency's oversight authority at §§ 422.504(f)(2) and 423.505(f)(2).

In the Contract Year 2027 proposed rule, CMS provided examples of quantifiable superlatives that would be acceptable if this provision was finalized, such as ''highest rated providers in Chester County,'' ''largest provider network in Florida,'' or ''highest rated plan in Virginia'' (90 FR 54957). Further, CMS noted that MA organizations and Part D sponsors would need to be able to factually support such superlatives through data, surveys, studies, or other type of information, and when requested, provide that information to CMS (90 FR 54957). 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. CMS explained that the use of a superlative such as ''The most popular Medicare Prescription Drug plan in Montgomery County in 2023'' would be acceptable (90 FR 54957). Conversely, CMS noted that the Agency would generally find the same statement to be misleading if the date was missing (90 FR 54957).

CMS recognized 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'' (90 FR 54957). CMS explained that both examples would be permissible, 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 (90 FR 54957).

Consistent with Executive Order 14267,[51] 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

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

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 proposed to delete current paragraphs at §§ 422.2262(a)(1)(ii) and 423.2262(a)(1)(ii) in their entirety to remove the prohibition of using superlatives in marketing and communications materials without providing supporting documentation. With this revision, CMS explained that the Agency would renumber current paragraphs §§ 422.2262(a)(1)(iii)-(xix) and 423.2262(a)(1)(iii)–(xviii) (90 FR 54957).

Consistent with Executive Order 14192,[52] Unleashing Prosperity Through Deregulation, issued on January 31, 2025, CMS also proposed deleting the current paragraphs at §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(i), which reiterated the prohibition on MA organizations and Part D sponsors providing misleading and inaccurate information to beneficiaries (90 FR 54957). 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 solicited comments on this proposal and appreciates stakeholders' input on the proposed changes. The Agency received the following comments and provided responses as follows.

Comment: Many commenters expressed support for this proposal. They stated that the marketing landscape is currently so restrictive that the actual benefits of plans are often unable to be effectively and clearly communicated to beneficiaries, which can be harmful.

Response: CMS thanks the commenters for their support.

Comment: Many commenters urged CMS to reconsider or revise this proposal as they believed it may result in increased complaints, and a few added that the Agency may not have the bandwidth to adequately oversee all those complaints. Many expressed that this proposal would allow for exaggerated, subjective, and misleading information that beneficiaries may not be able to verify themselves, which the industry has previously experienced. Some commenters underscored examples of past beneficiary complaints related to marketing, including several that highlighted the current substantial marketing of supplemental benefits, which already creates frequent beneficiary confusion. Some commenters requested additional guidance on superlatives that CMS would consider permissible.

Another commenter suggested that CMS maintain the requirement to include supporting documentation for a material with a superlative but modify it to allow exceptions for media formats with limited time and space. Another suggested that CMS adopt limitations with this proposal, such as prohibiting the use of superlatives when marketing materials describe benefits or prices of a plan.

Response: CMS appreciates the feedback on this proposal and acknowledges the commenters' concerns and suggestions. However, CMS maintains that the existing marketing and communications requirements at §§ 422.2262 and 423.2262 uphold beneficiary protections against misleading, confusing, and inaccurate information. CMS will continue oversight of marketing materials, as statutorily required, and will adjust resources accordingly if there is an increase in the volume of complaints. As such, the Agency will consider the use of superlatives and may request supporting documentation when conducting marketing material reviews or investigating beneficiary complaints.

CMS acknowledges that some supplemental benefits can be complex and challenging for beneficiaries to understand. CMS expects the majority of superlatives that mention benefits, including supplemental benefits, to be quantifiable, as they can be reasonably measured. To offer some examples of superlatives about supplemental benefits, CMS would consider ''we have the best supplemental benefits in Texas'' to be misleading and confusing as the ''best'' supplemental benefits are entirely subjective to the health needs of each beneficiary. However, when describing mandatory supplemental benefits as, ''we have the most comprehensive dental benefits in Michigan'' and ''we offer the cheapest over the counter benefits in Beaverhead County,'' CMS would not consider those misleading, confusing, or materially inaccurate, provided ''most comprehensive'' and ''cheapest'' can be factually supported through data, surveys, studies, or other types of information, and when requested, the plan can provide that information to CMS.

Moreover, during a review of a material that uses a superlative, whether it be a routine prospective review or a retrospective review in response to a complaint, CMS will focus on the use of the superlative in tandem with other regulatory requirements to determine if the overall material is misleading, confusing, or inaccurate. For example, if a material markets an optional supplemental benefit by saying, ''we offer the most rides to medical appointments in Oregon,'' CMS would consider the use of the superlative ''most'' acceptable provided it can be factually supported with data, but would consider the statement in its entirety misleading and confusing because it does not include information informing the beneficiary that they must opt into the optional benefit to access it, such as ''. . . for those who elect our optional transportation benefit.'' That is, CMS would still consider a marketing material misleading, confusing, or inaccurate unless the statement clearly references that the beneficiary must pay for, elect, or opt in to the optional benefit mentioned. Additionally, for superlatives focused on special supplemental benefits for the chronically ill (SSBCI), for example, CMS would consider ''we offer the most meal deliveries in Massachusetts for those who qualify,'' to not be misleading, confusing, or inaccurate provided the use of the superlative ''most'' can be factually supported and the statement clarifies that a beneficiary must qualify for the special supplemental benefit. As a reminder of an additional beneficiary protection, if a marketing material includes any information or statements about SSBCI, that material must include the SSBCI disclaimer as required at § 422.2267(e)(34).

Comment: Numerous commenters urged CMS to continue or increase oversight and monitoring efforts to ensure beneficiaries are protected from misleading, confusing, and inaccurate information. Proactive oversight recommendations included issuing significant civil money penalties or temporary suspension of marketing for repeated non-compliance, requiring correction and re-education campaigns to affected beneficiaries. Another commenter requested clarification on how this proposal will be enforced.

Response: CMS reiterates that the Agency will continue to conduct oversight and monitoring of marketing and communications materials to ensure beneficiaries receive accurate information. In addition, beneficiaries or their caregiver can report misleading marketing to 1–800–MEDICARE. As

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

noted previously, when investigating a marketing or communications material for accusations of the material being misleading, confusing, or materially inaccurate, such as from a complaint reported to 1–800–MEDICARE, if the material includes the use of superlatives, CMS may request supporting documentation from MA organizations and Part D sponsors per the Agency's oversight authority. Also, CMS reminds MA organizations and Part D sponsors to maintain adequate oversight of entities marketing on their behalf as they are ultimately responsible for ensuring their first tier, downstream, and related entities, as well as TPMOs, comply with CMS's requirements, per §§ 422.504(i), 423.505(i), 422.2274(g)(1) and 423.2274(g)(1).

Comment: Some commenters noted that this proposal will not responsibly increase competition and will only lead to greater beneficiary confusion, with a commenter stating that beneficiaries will no longer be able to easily verify the recency of the supporting data.

Response: CMS thanks these commenters for sharing their concerns. CMS disagrees that this rule will create confusion for beneficiaries because MA organizations will continue to be prohibited from providing misleading, confusing, or inaccurate information in marketing and communications materials. As described previously, if a superlative is based on supporting documentation that uses data from before the current or prior contract year, the statement should directly refer to the relevant contract year to not be considered misleading, confusing, or materially inaccurate.

Comment: A few commenters noted that this proposal will not reduce administrative burden, with some stating that it will shift the burden away from plans and onto beneficiaries, with another commenter stating that this signals CMS's intent to neglect its oversight of marketing. Another commenter remarked that this proposal may result in higher operational costs, yet a different commenter stated that this proposal will be especially beneficial for small plans.

Response: CMS respectfully disagrees that this provision will shift administrative burden onto beneficiaries, nor does this proposal impede CMS's oversight of marketing. MA organizations and Part D sponsors will still remain responsible for complying with the robust beneficiary protections that remain at §§ 422.2262 and 423.2262. This includes that MA organizations and Part D sponsors are still required to ensure their materials do not include misleading, confusing or inaccurate information and the Agency will continue oversight of all marketing and communication materials for compliance with these requirements. In addition, CMS reiterates here that MA organizations and Part D sponsors remain ultimately responsible for entities marketing on their behalf and should maintain adequate oversight of said entities. While a quantifiable superlative must be able to be substantiated by supporting documentation, CMS reiterates that this provision could reduce administrative burden, depending on plans' internal processes, as the supporting documentation must no longer be provided directly in the material. The Agency appreciates the feedback that this provision may be especially beneficial for small MA organizations and Part D sponsors that may have less administrative capacity.

Comment: Another commenter stated that this proposal might negatively impact Make America Healthy Again (MAHA) priorities.

Response: Without any examples of how or why, CMS does not see how this proposal negatively impacts MAHA priorities.

Comment: A commenter asked CMS to specify what types of supporting documentation would be acceptable for substantiating superlative statements.

Response: CMS has similar expectations for supporting documentation as the Agency did previously. CMS expects supporting documentation data to reflect data, reports, studies, or other documentation that applies to the current year. If the supporting documentation includes data that is not from the current or prior contract year, as described previously, it would be permissible if the older contract year is referenced in the superlative. In the Contract Year 2027 proposed rule, CMS provided examples of permissible superlatives supported by data from prior contract years, which CMS will include in the Agency's review of marketing materials and requests for supporting documentation when necessary.

Comment: Another commenter wrote that CMS should allow descriptive language such as superlatives and terms like ''free'' when the statements are substantiated by facts. Another commenter noted that advertising rides to medical appointments as ''free'' could be misleading if there are only a limited number of rides.

Response: As noted in this rule, CMS agrees that superlative statements should be permitted in marketing and communications materials provided they can be factually supported, when applicable, as previously discussed. However, CMS also notes that the use of the term ''free'' is outside the scope of this proposal as ''free'' is not a superlative. Currently, § 422.2262(a)(1)(xiii) prohibits the use of ''free'' in certain scenarios, and § 422.2262(a)(2)(iii) explains when the term ''free'' may be used.

Comment: A couple of commenters urged CMS to reinstate the ''meaningful difference'' requirement, which would limit plans to only benefit packages that are ''substantially different'' from other plans offered by the same parent organization in a service area.

Response: CMS appreciates these comments and will take them into consideration. However, the ''meaningful difference'' requirement that was previously in place is outside the scope of this proposal.

After consideration of the public comments CMS received, CMS is finalizing these provisions as proposed.

G. 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)

In the Contract Year 2027 proposed rule, CMS proposed to codify the revision of 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 presently expected to retain the sales and marketing call recordings described in §§ 422.2274(g)(2) and 423.2274(g)(2) for 10 years. CMS proposed 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 only modified 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 the proposal did 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 are still 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 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, such as the Department of Justice (DOJ) 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. The recordings were reviewed to determine if the claims against the agent or broker were supported by the call recording. 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 notifies the MA organization or Part D sponsor of the Agency's findings and requests 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. When CMS proposed revisions to these regulations in the Contract Year 2027 proposed rule, there were over 68 million Medicare beneficiaries, of which 51.1 percent are enrolled in MA and other health plans.[53] Of the approximately 34 million beneficiaries enrolled in an MA plan or other health plan, 31 percent use agents to assist with plan choices,[54] 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,[55] resulting in approximately 3.1 million beneficiaries using agents or brokers to review their plan choices. Based on these data, CMS conservatively estimated 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

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

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

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

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 proposed 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. The 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 stated that a 6-year record retention requirement for the marketing and sales portion of calls is sufficient for the purpose of enabling CMS to review 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 for CMS to review the marketing and sales portion of audio recordings when the Agency receives complaints from beneficiaries related to being misled into choosing a plan and 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.

When CMS proposed a revised 6-year record retention requirement for the marketing and sales portion of calls, in the Contract Year 2027 proposed rule, CMS also said that the Agency would consider several other alternatives for finalization as described below. CMS considered alternatives based on the cost and burden of recording and storing calls.

One alternative to the proposed 6-year retention requirement was to reduce the 10-year retention requirement for the marketing and sales portion of calls to a 3-year retention requirement. In the Contract Year 2027 proposed rule, CMS noted that a 3-year retention would 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, CMS also noted in the Contract Year 2027 proposed rule that a 3-year retention requirement would result in a more significant decrease in burden as compared to the proposed 6-year retention requirement.

In the Contract Year 2027 proposed rule, CMS also considered 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 considered 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 the remainder of the retention period would be sufficient to achieve the purpose articulated by CMS in the Contract Year 2027 proposed rule. An important factor to this alternative that CMS considered was the ability of current technology to automate the transcription with sufficient accuracy. CMS stated the Agency was considering that 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. However, CMS also stated that, on the other hand, transcripts would not capture the tone by which the agent or broker interacted with the beneficiary. The Agency also acknowledged that 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 considered as an alternative whether maintaining a recording, 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 acknowledged there are differences between MA, Part D, Marketplace, Medicaid, and commercial insurance, however, CMS noted 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.

CMS solicited comments on all aspects of the proposal and requested comments on other alternatives for consideration in the final rule. CMS thanks commenters for their input. In the following section, CMS describes the comments received and CMS's corresponding responses.

Comment: Numerous commenters supported the proposal to change the call recording requirement from 10 to 6 years, mentioning that auditing recorded calls is a necessary practice to protect beneficiaries. Commenters noted the proposal reflects operational realities while preserving program integrity; assists small and mid-size brokerages regarding storage and cybersecurity; represents a balanced regulatory approach that appropriately reduces administrative and financial burdens; will foster greater competition with the industry, ultimately improving the cost effectiveness and quality of products offered by MA organizations and Part D sponsors; and addresses the issue of compliance costs not proportionality improving oversight outcomes. Commenters stated that a 6-year retention requirement is still sufficient for oversight and monitoring and preserves accountability for enrollment related interactions. Commenters also mentioned that it is unlikely to need call recordings for review beyond certain timeframes ranging from 1 to 6 years. Other commenters supported the proposal with no specific reasons for the support.

Response: We appreciate commenters' support. CMS agrees that the shorter timeframe will still provide CMS, MA and Part D plans, TPMOs, and agents and brokers with the necessary tools for oversight and monitoring. The Agency also appreciates the commenters addressing how the proposal will be beneficial for the industry in areas including storage costs, compliance costs, and operational realities while still protecting beneficiaries.

Comment: Several commenters opposed the proposal and urged CMS to maintain the 10-year record retention requirement. These commenters emphasized that the record retention requirement serves as an important beneficiary protection, supports a Medicare enrollee's marketing violation complaint with Medicare that can lead to a timely resolution (for example, retroactive or prospective enrollment via a SEP), and that the calls constitute an integral source of accountability for TPMOs and MA organizations. A commenter stated that call recordings were needed when plan changes and

billing timelines are pushed into the following year or beyond as claims work through various systems. The commenter stated that CMS's requirements should remain aligned with similar requirements associated with Medicaid and Medicare dually eligible individuals. In addition, this commenter also stated that 10 years may be excessive.

Response: We acknowledge the commenters' concerns. However, we have determined that a shorter record retention period will not compromise beneficiary protections, result in an untimely resolution of a beneficiary, or jeopardize appropriate accountability for TPMOs and MA organizations. Commenters noted that most beneficiary issues and complaints arise within the first few years of a beneficiary's plan enrollment. Reviewing more dated call recordings would provide limited value for oversight, monitoring, or beneficiary assistance, particularly when beneficiaries have transitioned to different plans since the original recording. In some instances, the TPMO, agent, or broker no longer sells MA plans, further limiting the value of a dated call recording. After 6 years, it is also likely that additional training was provided, which resulted in more compliant agent or broker behavior. As for the commenter who stated that call recordings assist in a timely resolution for marketing complaints, CMS agrees that a call recording can assist in a timely resolution for marketing complaints. However, CMS believes that the outcome is often optimized when the issue is addressed within close proximity of a marketing complaint and that keeping call recordings for an additional 4 years would provide no added value in resolving marketing complaints in a timely manner. Regarding the commenter stating that CMS's rules should align with similar Medicaid and Medicare requirements associated with dually eligible individuals, CMS notes that the 6-year requirement would apply to dually eligible individuals who are enrolled into MA or Part D plans, unless a State Medicaid Agency Contract requires a longer retention period. In addition, alignment with State Medicaid programs would be extremely challenging given each state may have different requirements. To protect enrollees, it is longstanding CMS policy that MA and Part D enrollees who believe they may be adversely impacted by an enrollment decision based on an agent or broker misrepresenting plan options may contact 1–800–MEDICARE to request a special enrollment period (SEP) due to the circumstances. CMS reviews the supporting details and documentation for these requests and determines eligibility for an exceptional circumstances SEP on a case-by-case basis.

Comment: A couple of commenters requested that CMS eliminate the call recording requirement entirely without providing any alternatives. These commenters stated that the recordings add unnecessary complexity and cost without demonstratable benefit to clients. The commenters furthered this point in saying the recordings do not solve any issue, and seniors do not like recordings at all.

Response: We appreciate the feedback from the commenters. However, CMS does not support eliminating call recordings in their entirety at this time. Currently, call recordings play an integral role as a beneficiary protection, assist in identifying brokers, agents, and TPMOs that fail to adhere to CMS regulations, and assist in monitoring and oversight of the MA and Part D programs. CMS will continue to gather data on the value of call recordings to further inform future decisions about marketing and sales recording requirements before making any additional changes beyond what was proposed in the Contract Year 2027 proposed rule.

Comment: A commenter stated that CMS should focus monitoring efforts on unscrupulous marketing organizations that have United States call centers that contract with Third Party Marketing Organizations (TPMOs) that use foreign call center representatives. The commenter added that these call centers can spend up to 18 hours a day calling Medicare beneficiaries within the U.S. to get them to enroll or change Medicare Advantage plans. The commenter further stated that these foreign call centers are driven by sales quotas, not beneficiary suitability.

Response: We agree that monitoring call centers, including those contracting with out-of-country entities, is important. Although the commenter's suggestion is out of scope, CMS's review of call recordings assists in identifying unscrupulous marketing organizations, including those that contract with out-of-country entities. In cases where CMS determines marketing violations have occurred, MA and Part D plans are held accountable for the actions of their downstream entities.

Comment: A commenter stated that CMS assumes an audio call meaningfully prevents fraud, citing that beneficiaries sometimes claim the voice is not theirs, resulting in a plan-based enforcement action taken against an agent. The commenter stated that, if a call recording can be dismissed by a beneficiary simply stating, ''that is not my voice,'' recordings are not immune to dispute, do not conclusively prove identity, create massive data security and privacy risks, and expose agents and beneficiaries to long-term breach liability. This same commenter also said that documentation and transcripts are better because they capture intent, document what was discussed, are searchable and auditable, are less costly to store, and reduce exposure to sensitive voice data. This commenter suggested that CMS allow secure transcripts, summaries, or enrollment attestations instead of call recordings.

Response: We thank the commenter but maintain that call recordings are extremely valuable. Call recordings can capture the intent and the tone of the call, providing a clear, realistic view of the interaction between the beneficiary and the agent or broker that transcripts cannot capture. CMS acknowledges that voice recordings can be manipulated but maintains that they are not quite as easy to manipulate as transcripts. Entire sections of a call can be eliminated in a transcript, which could go unnoticed, while removing a portion of an audio recording would likely be more noticeable. CMS also believes a beneficiary's identity is more likely to be authenticated through a call recording over a transcript. Regarding data breaches and security concerns, CMS recognizes these are areas of concern, but requirements are in place for securing sensitive data. Currently, it is the Agency's position that transcript summaries are too limited and do not provide enough detail to capture inaccurate or misleading information between an agent and a beneficiary during a marketing or sales calls. Likewise, enrollment attestations provide even less information than a transcript summary. Summaries and attestations do not provide the information necessary to properly monitor TPMO marketing and sales calls. CMS agrees with the commenter that transcripts are searchable and less costly to store but does not agree that transcripts have more value than call recordings. Because call recordings are a valuable tool, CMS will not be allowing transcripts in lieu of all audio recordings for the entire retention period, however, CMS is modifying its original proposal to allow the use of transcripts in the last 3 years of the retention period.

Comment: About half of the commenters requested that the requirement for call recordings be eliminated, however, they

acknowledged that if CMS determined a full rescinding of the requirement was not feasible, a reduced retention period of 2 years would be more than sufficient for review purposes. The vast majority of these commenters relayed the same concerns, including legal and practical challenges, logistical and financial strain on independent agents with no measurable enhanced beneficiary protection, unwarranted data management burden, and strains on resources that could otherwise be dedicated to serving beneficiaries. Additional concerns included infrastructure, compliance oversight, data storage, privacy, operational complexities, liability risks, the sheer number of recordings to maintain, and an unnecessary barrier to natural communications between the beneficiary and agent. Commenters also stated that a 10-year retention period is excessive, places an undue administrative burden on independent agents and agencies, and far exceeds what is practically necessary for addressing most beneficiary complaints or conducting CMS investigations. According to commenters, a 2-year record retention period would adequately accommodate compliance needs, allowing for thorough review and investigation without creating an unnecessarily extensive and costly data storage requirement for independent agents who are already managing multiple administrative tasks. Commenters also stated that a 2-year retention period would be entirely sufficient to fully accommodate most beneficiary complaints, CMS investigations, and plan or agent reviews, while maintaining adequate oversight without imposing unnecessary burden on independent agents and freeing up resources for more direct beneficiary support.

Response: CMS values these commenters' suggestions and recognizes that record retention requirements impose additional burden and costs, which may affect independent agents and brokers more than other entities. CMS agrees that call recording retention for 10 years is excessive and exceeds what is necessary to review and address beneficiary complaints. CMS appreciates the commenters understanding CMS's need for call recordings and proposing the alternative 2-year record retention requirement. As stated in the Contract Year 2027 proposed rule, the DOJ utilizes call recordings for investigative and legal purposes. DOJ's investigations and legal proceedings often span multiple years, necessitating access to call recordings that extend beyond a 2-year timeframe. Beyond the DOJ requirements, CMS's monitoring activities, including potential audits, may require access to records beyond a 2-year retention period. Insufficient retention or eliminating call recordings could prevent the identification of misleading agent or broker practices and hinder the ability of MA plans and Part D sponsors to take appropriate corrective action.

Comment: Several commenters expressed support of the proposal to reduce the record retention period while recommending alternative timeframes ranging from 2 to 5 years. Commenters' rationales for a 2 to 5 year record retention period varied by specific reasons but the sentiments were similar in nature. These commenters suggested: noting that a much reduced timeframe would be longer than most consumers remain in a particular plan; there would be ample opportunity for post enrollment reviews; requests for recordings beyond 3 years are uncommon; reduced administrative burden and data storage costs would not impair oversight and audit integrity; existence of consumer protection; alignment with the Federal Trade Commission's Telemarketing Record Retention requirement; more efficient storage of call recordings; a more accurate reflection of real-world compliance timeliness while continuing to support complaint resolution, audits, and enforcement actions; significant reduction in data storage volume and associated costs resulting in meaningful financial and administrative efficiencies for MA and Part D plans without compromising program integrity or beneficiary protections; essential accountability and affordability promoting prudent financial guidance and product offering is maintained; reduction of potential cybersecurity risks; and that it is a correct balance of satisfying CMS's interests while reflecting the pragmatic realities of member churn and administrative burden. Commenters expressed similar concerns as previously noted, regarding the 10-year retention requirement, stating that a 10-year requirement is excessive, places an undue financial and logistical burden on independent agents, and has significant storage costs.

Response: CMS values the feedback from commenters recommending a further reduction from 6 years to a range of 2 to 5 years. CMS agrees that a further reduction in call recording retention requirements will further reduce costs, storage volume, and administrative burden. CMS also agrees that a shorter audio recording retention period is a more accurate reflection of CMS's and DOJ's compliance needs without compromising program integrity. However, CMS maintains that a reduction from a 10-year retention period to a 6-year retention period fulfills the Agency's and DOJ's oversight, investigative, and litigation requirements; while a 2 to 5 year retention period is too limited to adequately address those needs.

Comment: A few commenters supported the alternative of permitting transcripts in lieu of call recordings, citing reasons including substantially less storage, transcripts being more easily ingested by AI systems to review, and a reduction of administrative burden.

Response: CMS thanks the commenters for providing feedback on alternatives to current call recording requirements as well as those that were proposed in the Contract Year 2027 proposed rule. CMS agrees that transcripts are substantially less expensive and require less storage. CMS believes transcripts can be a valuable and cost-effective alternative for call retention. However, CMS believes that call recordings provide additional benefits beyond those provided by transcripts. Call recordings provide the tone of both the beneficiary and the agent, including if the beneficiary is pressured into enrolling in a plan. CMS believes the benefits of call recordings outweigh the benefits of transcripts during the time period that most complaints occur. As mentioned by the commenters, most complaints are addressed within the first few years after a beneficiary enrolls in a plan. A decreased retention period will still adequately support CMS's and DOJ's monitoring, oversight, and litigation needs. Following the timeframe in which most complaints are addressed, CMS believes transcripts can provide the pertinent information if additional review is necessary.

Therefore, based on alternative proposals included as part of CMS's request for comments in the Contract Year 2027 proposed rule and CMS's oversight and monitoring requirements, CMS is finalizing its proposal with a modification to allow for marketing and sales call records to be retained using both audio recordings and transcripts. For the first 3 years of the retention period, records must be maintained in audio format. In the last 3 years of retention (of the 6-year retention period), records may be maintained in either audio format or as complete and accurate transcript recordings. A transcription is considered complete and accurate if it documents the full recording, reflecting all statements made

by the participants as it originally occurred. CMS believes this strikes the appropriate balance in maintaining program integrity while reducing burden and costs on MA organizations.

Comment: A few commenters expressed concerns with call centers. These commenters noted that call centers presented more significant concerns than independent agents and recommended that CMS require recordings from call centers but not from independent agents.

Response: CMS appreciates the suggestion but maintains that, at this time, all sales and marketing calls should be recorded, not just those from call centers. Any agent, regardless of whether the agent works for a call center or is independent, may provide inaccurate information or steer a beneficiary into a particular plan. Complaints received by CMS concern both independent agents and agents working for call centers. Call recordings currently allow CMS and other agencies to fully address these complaints.

Comment: A few commenters mentioned that CMS needs to reduce the retention requirements for enrollment calls, citing that many times the sale, marketing, and enrollment calls are combined, making separating them difficult and more burdensome.

Response: CMS thanks commenters for their feedback. However, the Contract Year 2027 proposed rule did not address the call retention timeframe of enrollment calls and therefore this comment is out of scope.

After careful consideration of public comments, CMS is finalizing in §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii) the 6-year marketing and sales call retention policy with a modification to allow for complete and accurate transcripts in the last 3 years of retention. As mentioned above, a transaction is considered complete and accurate if it documents the full recording, reflecting all statements made by the participants as it originally occurred. In summary, all marketing and sales calls, including the audio portion of calls conducted via web-based technology, must be recorded and retained in their entirety for a minimum period of 6 years. For the first 3 years of the retention period, records must be maintained in audio format. For years 4, 5, and 6, records may be maintained in either audio format or as complete and accurate transcript recordings.

H. 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. CMS's NoA requirements are closely aligned with and broadly duplicate OCR's NoA requirements and were adopted by CMS to implement and ensure compliance with Title VI, section 504 of the Rehabilitation Act of 1973, and ACA Section 1557 (incorporating Title VI and section 504 by reference). 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).[56] 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), but recognizes that ''[a]gency heads should make decisions as they deem necessary to fulfill their respective agencies' mission and efficiently provide Government services to the American people'' and notes that ''nothing in [the E.O.] requires or directs any change in the services provided by any agency'' and ''[a]gency heads are not required to amend, remove, or otherwise stop production of documents, products, or other services prepared or offered in languages other than English.'' On January 31, 2025, E.O. 14192 was issued: ''Unleashing Prosperity Through Deregulation'' (hereinafter referred to as E.O. 14192).[57] 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,[58] provides guidance for compliance with E.O. 14224, but indicates that additional guidance will be forthcoming on compliance with Title VI. As CMS stated in the Contract Year 2027 proposed rule, 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 requirements under Title VI and Section 1557 throughout the programs under HHS's purview.[59]

CMS inadvertently omitted references to cost plans from this proposal in the Contract Year 2027 proposed rule and notes that the intent was always for the proposal to rescind the NoA requirement to apply to cost plans pursuant to CMS's authority in section 1876(c)(3)(C) to regulate marketing by section 1876 cost plans and the authority in section 1876(i)(3)(D) to specify new section 1876 contract terms as the Secretary may find necessary and appropriate. It is also established at § 417.428 that most of the marketing and communication regulations in subpart V of part 422, including the NoA requirement, also apply to section 1876 cost plans. Accordingly, the rescission of the NoA requirement applies to cost plans as well as MA organizations and Part D sponsors.

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, Part D sponsors, and cost plans, CMS proposed to eliminate CMS's NoA requirement under §§ 422.2267(e)(31) and 423.2267(e)(33) and to defer to OCR's requirements related to notification of language assistance services and auxiliary aids and services under 45 CFR 92.11. CMS stated that 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 with respect to civil rights and nondiscrimination. On May 18, 2016, OCR published the Nondiscrimination in Health Programs and Activities final rule (81 FR 31376), hereinafter referred to as the ''2016

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

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

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

[59] As discussed later in this section, CMS imposes other language assistance (and auxiliary aid and service) requirements on such entities for programmatic reasons related to the operation of the Medicare program pursuant to its authority under the Social Security Act, and unrelated to nondiscrimination requirements imposed by Title VI or ACA Section 1557.

section 1557 final rule,'' implementing the requirement that all covered entities—any health program or activity, any part of which receives Federal financial assistance (including credits, subsidies, or contracts of insurance), and any program or activity that is administered by an executive agency or any entity established under title I of the ACA (or amendments)—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 five 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 OCR's 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.[60]

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 (Notice of Availability) 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 MA organizations and Part D sponsors to include in the notice that, at a minimum, they provide language assistance services and appropriate auxiliary aids and services free of charge (89 FR 30534). CMS's 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 MA organizations and Part D sponsors to provide CMS's 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 CMS's 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 organizations and Part D sponsors to develop a NoA with more than 15 languages, exceeding OCR's requirements.

In the Contract Year 2027 proposed rule, CMS explained that while currently OCR's and CMS's requirements are mostly aligned, CMS noted 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 explained that its 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 its NoA to be included on all CMS required materials at §§ 422.2267(e) and 423.2267(e), whereas OCR's language regarding where its 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, ACA Section 1557 (42 U.S.C. 18116(a)) 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 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 an Executive Agency; or any program or activity administered by any entity established under Title I of the Act or amendments.

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

[60] 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.

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 CMS's 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 its NoA requirements that also aligned with Medicaid materials requirements, such as updating CMS's NoA to require the 15 most common languages in the State rather than the 15 most common languages nationally (89 FR 30529).

CMS stated in the Contract Year 2027 proposed rule that, while CMS's and OCR's current requirements are now mostly aligned, CMS was 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 CMS's NoA requirement under §§ 422.2267(e)(31) and 423.2267(e)(33). CMS stated that eliminating its 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 under OCR's relevant authorities. CMS notes that dual eligible special needs plans (D–SNPs) 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 in the Contract Year 2027 proposed rule was that eliminating the duplicative nature of OCR's and CMS's regulatory requirements supported the principles set forth in E.O. 14192 by promoting prudent financial management and alleviating unnecessary regulatory burdens.

In summary, removing §§ 422.2267(e)(31) and 423.2267(e)(33) reduces the potential for future confusion and administrative burden on CMS and MA organizations and Part D sponsors by eliminating duplicative requirements. CMS is not scoring this update in the COI section as CMS believes there will be no burden impacts for this update. In addition, this update is not expected to have any economic impact on the Medicare Trust Fund.

CMS reiterates that it is rescinding the CMS-specific NoA requirement promulgated pursuant to Title VI, to avoid duplication and potential misalignment as OCR Title VI policies evolve, but this policy, as finalized, will not reduce Medicare program protections related to language assistance and effective communication, promulgated for programmatic reasons related to the operation of the Medicare program pursuant to its authority under the Social Security Act. Even with the rescission of the CMS-specific NoA requirements at §§ 422.2267(e)(31) and 423.2267(e)(33), MA organizations, Part D sponsors, and cost plans remain subject to multiple Medicare program requirements that ensure meaningful access for individuals with limited English proficiency (LEP) and individuals with disabilities. For example, MA organizations, Part D sponsors, and cost plans must continue to provide interpreter services for non-English speaking and LEP individuals, including requirements related to interpreter availability and wait times for incoming calls, and that such services be available at no cost to the caller consistent with §§ 422.111(h)(1)(iii), 423.128(d)(1)(iii), and 417.427. In addition, CMS's existing translation and accessibility standards for CMS-required materials and content remain in effect. Under §§ 422.2267(a)(2) and 423.2267(a)(2), MA organizations, Part D sponsors, and cost plans must translate required materials into any non-English language that is the primary language of at least 5 percent of individuals in a plan benefit package service area, and under §§ 422.2267(a)(3) and 423.2267(a)(3), upon request or when otherwise learning of an enrollee's primary language, provide non-English materials in any non-English language identified in §§ 422.2267(a)(2), 423.2267(a)(2), 422.2267(a)(4), and 423.2267(a)(4), including the Annual Notice of Change (ANOC), Evidence of Coverage (EOC), Explanation of Benefits (EOB), Summary of Benefits (SB), and provider directories, among others.

CMS solicited comment on the proposed amendments and thanks commenters for their input. In the following section, CMS describes the comments received and CMS's corresponding responses.

Comment: Many commenters supported CMS's plan to rescind CMS's NoA requirement and suggested that this proposal would reduce administrative burden and costs for MA organizations and Part D sponsors while protecting against future misalignment between CMS and OCR's language access requirements. Commenters expressed support for eliminating duplicative requirements and centralizing oversight of language access requirements under OCR, with one commenter noting the importance of this, given forthcoming changes to language access requirements. They also noted that this rescission, while reducing administrative burden, would maintain beneficiary protections around language access. Multiple commenters cited the significant volume of notice requirements, which can be lengthy or confusing to enrollees, as further support for CMS to streamline notice requirements and reduce redundancy. One commenter noted the reduced burden from rescinding this notice could benefit small plans like special needs plans (SNPs).

Response: CMS thanks commenters for their support of this proposal. Because the provisions proposed to be rescinded relate only to the notice of

availability of language access services and auxiliary aids and services, CMS notes that CMS proposed to defer to OCR with respect to such requirements at 45 CFR 92.11, promulgated under Title VI, Section 504, and/or ACA Section 1557, and that it remains responsible for language assistance and auxiliary aids and services requirements promulgated for programmatic reasons related to the operation of the Medicare program pursuant to its authority under the Social Security Act.

Comment: Another commenter, though supportive of the rescission and greater efficiency, noted concern regarding the transition of these requirements to OCR's oversight and requested MA organizations and Part D sponsors receive timely and detailed guidance on future OCR oversight and clarifications on how OCR's requirement will differ from CMS's NoA requirements. The commenter also requested implementation timelines and coordination between CMS and OCR to prevent conflicting directives and clarification of any ongoing notice obligations for D–SNPs.

Response: CMS understands the commenter's concern about changing MA and Part D oversight and will share these concerns with OCR. CMS notes that OCR already has oversight of its NoA requirements, and that oversight will continue despite this final rule. OCR is the HHS component responsible for interpreting, implementing, overseeing and enforcing Title VI/ACA Section 1557 notice requirements related to language assistance.

Comment: The majority of commenters opposed this proposal and requested CMS maintain its NoA requirement, citing the importance of CMS's NoA in informing beneficiaries of their ability to access language assistance services, and auxiliary aids and services, at no cost to the beneficiary. Some commenters stated that beneficiaries with limited English proficiency (LEP) and those with disabilities rely on CMS's NoA as a safeguard for vulnerable populations. A few commenters expressed concern that rescinding CMS's NoA requirement would limit language access and, therefore, effective communication which could lead to worse health outcomes or result in expensive downstream consequences. These commenters were concerned that without the CMS NoA, beneficiaries will face greater barriers to care, with one commenter citing the already substantial barriers to care that beneficiaries with limited English proficiency may face. Another commenter was concerned that without CMS's NoA, enrollees will not be aware of these services for enrollees with LEP or disabilities. Lastly, a commenter noted that CMS's NoA helps reduce burden on community-based organizations with limited resources.

Response: CMS thanks commenters for their thoughts and acknowledges these concerns. However, the Agency wants to emphasize that MA organizations and Part D sponsors will still be required to provide OCR's NoA as required by 45 CFR 92.11 and Medicaid regulations at § 438.10(d)(2), as applicable. As stated earlier, CMS is proposing to rescind CMS's NoA to ensure clarity, minimize administrative burden, and limit confusion for MA organizations and Part D sponsors. Under OCR's requirements, beneficiaries will continue to receive the appropriate notices. Deferring to OCR's oversight, management, and enforcement of Title VI, Section 504, and/or ACA Section 1557 with respect to such notice requirements as required by 45 CFR 92.11, related to language assistance services and auxiliary aids and services, would also mitigate the potential for future misalignment and the need for additional modifications to CMS's Title VI, Section 504, and/or ACA Section 1557 requirements as policy evolves. Moreover, CMS has other language-based requirements, promulgated for programmatic reasons related to the operation of the Medicare program pursuant to its authority under the Social Security Act, that remain in effect that provide a level of protection to non-English speaking beneficiaries. Under §§ 422.2267(a)(2) and 423.2267(a)(2), for example, 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 individuals in a plan benefit package service area, and under §§ 422.2267(a)(3) and 423.2267(a)(3), upon request or when otherwise learning of an enrollee's primary language, provide non-English materials in any non-English language identified in §§ 422.2267(a)(2), 423.2267(a)(2), 422.2267(a)(4), and 423.2267(a)(4).

Comment: A few commenters had specific concerns about deferring oversight to OCR's NoA requirements, with commenters claiming OCR has a limited capacity, due to low staffing, to properly oversee these requirements or that there could be enforcement gaps. Commenters articulated concern that the lack of clear oversight or protection could harm beneficiaries or lead to ineffective oversight and that reducing CMS oversight may mean MA organizations and Part D sponsors are less inclined to provide these notifications. Another commenter noted that, while appreciative of CMS's goal to mitigate future misalignment, they were concerned that this change would create more confusion, without additional benefit for beneficiaries. Furthermore, this commenter recommended CMS communicate changes to OCR guidance through HPMS and continue streamlining requirements. Another commenter requested that CMS not defer oversight and management to OCR until clear, enforceable mechanisms are in place to ensure enforcement.

Response: CMS appreciates commenters' thoughts. However, CMS reiterates that OCR is the HHS component responsible for interpreting, implementing, overseeing, and enforcing Title VI, Section 504, and/or ACA Section 1557 requirements related to notification for language assistance services and auxiliary aids and services at 45 CFR 92.11. Rescinding CMS's NoA requirement will assist MA organizations and Part D sponsors and beneficiaries in removing duplicative requirements that could result in potential confusion for beneficiaries and unnecessary administrative burden, including the need to ensure compliance with both CMS and OCR NoA requirements. Moreover, CMS has other language-based requirements, promulgated for programmatic reasons related to the operation of the Medicare program pursuant to its authority under the Social Security Act, that remain in effect that provide a level of protection to non-English speaking beneficiaries. Under §§ 422.2267(a)(2) and 423.2267(a)(2), for example, 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 individuals in a plan benefit package service area, and under §§ 422.2267(a)(3) and 423.2267(a)(3), upon request or when otherwise learning of an enrollee's primary language, provide non-English materials in any non-English language identified in §§ 422.2267(a)(2), 423.2267(a)(2), 422.2267(a)(4), and 423.2267(a)(4).

Comment: A few commenters expressed concern about limitations to civil rights and that this proposal will harm Americans with disabilities and individuals with LEP. A commenter disagreed with CMS's rationale that CMS and OCR's requirements are duplicative or confusing and instead believes that these requirements work together to promote effective communication. This commenter added that removing CMS's requirement eliminates CMS's monitoring capacity

in its complaint tracking system. An additional commenter disagreed with CMS that CMS's NoA is duplicative with OCR's requirements, arguing that it provides clear directions to MA organizations and Part D sponsors within the Medicare context. Another commenter was concerned administrative burden would shift from MA organizations and Part D sponsors to beneficiaries and providers.

Response: CMS understands commenters' concerns but reiterates that OCR is the HHS component responsible for implementation of Title VI, Section 504, and/or ACA Section 1557 requirements and that CMS is proposing to rescind CMS's NoA due to its duplicative nature and to streamline oversight of notice requirements as required by 45 CFR 92.11 under OCR. Rescinding CMS's NoA does not limit CMS's ability to monitor relevant complaints, and MA organizations and Part D sponsors will still be responsible under their CMS contracts to follow all applicable federal rules and regulations. As previously stated, CMS has other language-based requirements, promulgated for programmatic reasons related to the operation of the Medicare program pursuant to its authority under the Social Security Act, that remain in effect that provide a level of protection to non-English speaking beneficiaries. Under §§ 422.2267(a)(2) and 423.2267(a)(2), for example, 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 individuals in a plan benefit package service area, and under §§ 422.2267(a)(3) and 423.2267(a)(3), upon request or when otherwise learning of an enrollee's primary language, provide non-English materials in any non-English language identified in §§ 422.2267(a)(2), 423.2267(a)(2), 422.2267(a)(4), and 423.2267(a)(4).

Comment: Several commenters expressed concern with deferring to OCR requirements, arguing that those are broader and less specific to Medicare populations. A few commenters noted that MA and Part D requirements are more explicit and supportive of Medicare beneficiaries than OCR's requirements. A commenter noted that the current CMS NoA requirements are clear and prescriptive, requiring CMS's NoA to be included on all CMS required documents, which promotes clarity and consistency for operations and compliance. The commenter explained that while some of the OCR's NoA categories are straightforward, others are subjective and require detailed, document-level interpretation which MA organizations and Part D sponsors would be required to evaluate for all CMS required documents. Another commenter expressed concern that certain CMS-required materials, such as the Mid-Year Change Notifications, Star Ratings Document, and Federal Contracting Statement, would not include the NoA under OCR's requirements. Another commenter requested CMS collaborate with OCR to limit the number of required communications OCR's NoA must be included in, arguing costly printing and a poor enrollee experience and recommended that CMS require the inclusion of the NoA in the Annual Notice of Change (ANOC), Evidence of Coverage (EOC), Explanation of Benefits (EOB), and Summary of Benefits documents.

Response: CMS understands commenters' concerns regarding the minor differences in OCR and CMS's current NoA requirements. However, CMS notes that language access notification requirements have historically been updated based on OCR's language access requirements. Most recently, in the April 2024 final rule, CMS updated its notice requirements from the MLI to the NoA to align with proposed changes to OCR's language access notifications. Furthermore, OCR is the HHS component responsible for implementing and enforcing the HHS civil rights regulations at Section 1557 and 45 CFR 92.11 and their requirements currently include many pertinent and important materials. CMS disagrees with commenters that OCR's requirements are less specific to Medicare beneficiaries or less detailed than CMS's requirements. Some examples, as listed in OCR requirements at 45 CFR 92.11(c)(5), include that the NoA is required to be included on application and intake forms, and communications related to an individual's rights, eligibility, benefits, or services that require or request a response from a participant, beneficiary, enrollee, or applicant. OCR also requires the NoA to be provided annually to participants, beneficiaries, enrollees (including late and special enrollees), and applicants of a covered entity's health program or activity, per 45 CFR 92.11(c)(1), and upon request, per 45 CFR 92.11(c)(2). To streamline regulatory processes and limit duplicative guidance and enforcement, deferring to OCR with respect to Title VI, Section 504, and/or ACA Section 1557 requirements related to notification for language assistance services and auxiliary aids and services, as required by 45 CFR 92.11, will ensure MA organizations and Part D sponsors have clear guidance on civil rights requirements. CMS notes that, although the OCR requirements do not specifically define the applicable CMS materials, OCR's NoA requirements provide clear instructions on which materials should include OCR's NoA,

Comment: Many commenters shared concerns that OCR's NoA requirement does not include the CMS requirement at §§ 422.2267(e)(31)(ii)(B) and 423.2267(e)(33)(ii)(B) that CMS's NoA be provided in additional languages if there are additional languages in a particular service area that meet the five percent service area threshold beyond the languages described in §§ 422.2267(e)(31)(i) or 423.2267(e)(33)(i), and that CMS's NoA must also be translated into those languages. One commenter was concerned about the impact on local populations with LEP that may no longer receive notices in their primary language, leading to barriers to coverage.

Response: CMS understands commenters' concern regarding the five percent service area threshold. CMS notes that while the OCR requirement does not include this additional five percent service area threshold requirement, OCR's current requirement at 45 CFR 92.11(b) requires ''at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States in which a covered entity operates.'' MA organizations and Part D sponsors are permitted to include additional languages in OCR's NoA beyond this requirement. Furthermore, under CMS requirements at §§ 422.2267(a)(2) and 423.2267(a)(2), for all required materials and content under §§ 422.2267 and 423.2267, MA organizations and Part D sponsors must, ''[f]or 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,'' and under §§ 422.2267(a)(3) and 423.2267(a)(3), upon request or when otherwise learning of an enrollee's primary language, provide non-English materials in any non-English language identified in §§ 422.2267(a)(2), 423.2267(a)(2), 422.2267(a)(4), and 423.2267(a)(4). These requirements are also applicable to cost plans pursuant to § 417.428.

Comment: A few commenters who opposed this proposal had concerns

about how this rescission would impact MA organizations and Part D sponsors. A commenter expressed concern the proposal would result in MA organizations and Part D sponsors needing to hire more translators, increased call center volume and a re-allocation of resources to address these changes, which would disproportionally impact smaller MA organizations and Part D sponsors. Another commenter, while appreciative of the effort to streamline communication requirements, was concerned the proposal would inadvertently create increased complexity and introduce additional compliance risks for MA organizations and Part D sponsors. Another commenter recommended CMS revert to CMS' MLI requirement, arguing that the language requirement to include the top 15 non-English languages nationally was less burdensome to MA organizations and Part D sponsors, less costly and better for beneficiaries.

Response: CMS maintains the position that the duplicative nature of these requirements may result in potential confusion and burden for MA organizations and Part D sponsors and beneficiaries as well as resulting in additional regulatory updates, and corresponding burdens as policy evolves. While CMS understands concerns regarding adapting to the requirements, CMS notes that OCR currently oversees its Title VI, Section 504, and/or ACA Section 1557 NoA requirements. Under this proposal, CMS is solely removing a duplicative requirement and deferring to OCR, the agency responsible for implementing these civil rights requirements at 45 CFR 92.11. Additionally, CMS believes that MA organizations and Part D sponsors will benefit from more centralized and streamlined civil rights guidance, especially those organizations whose operations include more insurance products than Medicare Advantage and Medicare prescription drug plans.

Comment: A few commenters highlighted the impact on SNPs and their enrollees, citing the potential for regulatory inconsistency. One commenter noted that, for D–SNPs, coordination with state Medicaid requirements is still applicable and that rescinding the NoA could create problems with enrollment in D–SNPs, who would still be subject to notice requirements in the State Medicaid Agency Contract (SMAC) or State statute. Another commenter noted while CMS's NoA requirement will exist for D–SNPs, for non-D–SNPs, beneficiaries could be harmed in their ability to fully understand and comprehend complex information.

Response: CMS acknowledges that D–SNPs would still be required to follow the Medicaid requirement under § 438.10(d)(2), as described above. By removing the NoA requirements under §§ 422.2267(e)(31) and 423.2267(e)(33), D–SNPs will only need to consider applicable Medicaid and OCR language access notification requirements, which CMS believes will reduce the administrative burden on D–SNPs of complying with MA and Part D, Medicaid and OCR notification requirements concerning language access services and auxiliary aids and services.

Comment: A couple of commenters praised the current CMS NoA requirement burden reduction, by allowing MA organizations and Part D sponsors at §§ 422.2267(e)(31)(ii)(F) and 423.2267(e)(33)(ii)(F), to only provide one notice when mailing multiple required materials together. One commenter noted OCR does not have this requirement, which may result in a higher volume of mail and redundancy for MA organizations, Part D sponsors, and enrollees.

Response: CMS appreciates commenters' insight on the benefits of mailing one notice with multiple required materials. In alignment with CMS's rationale to reduce duplication, CMS's goal with this proposal is to further streamline requirements for MA organizations and Part D sponsors and to prevent beneficiaries being inundated with duplicative notices. OCR's regulations implementing section 1557 of the Affordable Care Act separately require recipients of Federal financial assistance, such as MA organizations and Part D sponsors, to provide an NoA in certain circumstances as set forth in 45 CFR 92.11, including in specified electronic and written communications listed under § 92.11(c)(5). CMS notes that while OCR's requirements do not explicitly permit MA organizations and Part D sponsors to provide one notice when mailing multiple required materials as in §§ 422.2267(e)(31)(ii)(F) and 423.2267(e)(33)(ii)(F), doing so is not explicitly prohibited by OCR's requirements at 45 CFR 92.11.

Comment: One commenter argued that CMS did not provide a sufficient rationale for why previously cited concerns about language barriers for beneficiaries are outweighed by potentially confusing regulations for MA organizations and Part D sponsors. Another commenter disagreed with CMS that OCR's requirement was duplicative, citing CMS's rationale in the April 2024 final rule that OCR's requirements were insufficient to protect beneficiaries and stated that CMS has not provided a rationale to reverse these statements.

Response: As noted in the Contract Year 2027 proposed rule, eliminating CMS's NoA requirement under §§ 422.2267(e)(31) and 423.2267(e)(33) will ensure consistency and clarity for covered entities as any Title VI language access services and Section 504 auxiliary aids and services notification requirements required by 45 CFR 92.11 will be addressed by OCR, which is responsible for enforcing civil rights laws with respect to HHS programs. OCR is the HHS component that implements and enforces civil rights requirements, and CMS will defer to OCR's oversight, management, and enforcement of any Title VI, Section 504, and/or ACA Section 1557 requirements related to notification for language assistance services and auxiliary aids and services at 45 CFR 92.11. Regarding CMS's previous rationale, in the April 2024 final rule, CMS referenced the discussion from the May 2022 final rule that ''relying on the requirements delineated in the 2020 section 1557 final rule for covered entities to convey the availability of interpreter services is insufficient.'' [61] In OCR's 2020 section 1557 final rule, they rescinded their language access notification requirements, known as ''taglines.'' Since that time, in May 2024, OCR finalized new rules implementing their NoA requirements,[62] after proposing these changes in their 2022 section 1557 proposed rule.[63] CMS had already updated its NoA requirements in the April 2024 final rule to align its requirements with OCR's based on OCR's 2022 section 1557 proposed rule. While these requirements are now aligned, CMS is concerned about the redundancy of these requirements and is taking the prudent step to defer to OCR for oversight of Title VI and/or ACA Section 1557 language access requirements at 45 CFR 92.11. CMS reiterates that it has other language-based requirements, promulgated for programmatic reasons related to the operation of the Medicare program pursuant to its authority under the Social Security Act, that remain in effect that provide a level of protection to non-English speaking beneficiaries. Under §§ 422.2267(a)(2) and 423.2267(a)(2), for example, 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 individuals in a plan

[61] 89 FR 30529

[62] 89 FR 37522

[63] 87 FR 47824

benefit package service area, and under §§ 422.2267(a)(3) and 423.2267(a)(3), upon request or when otherwise learning of an enrollee's primary language, provide non-English materials in any non-English language identified in §§ 422.2267(a)(2), 423.2267(a)(2), 422.2267(a)(4), and 423.2267(a)(4).

Comment: One commenter described the legal foundation for the requirement for covered entities to notify individuals of the availability of language assistance services, citing Title VI of the Civil Rights Act of 1964, Section 1557 of the Affordable Care Act, and the implementing regulations at 45 CFR 92.11. The commenter stated that these statutory requirements cannot be overridden by executive orders, and that they cannot nullify civil rights protections established by statute. The commenter noted that the July 2025 Attorney General memorandum cited by CMS does not eliminate Section 1557 requirements and argued that these legal requirements exist because meaningful access to healthcare services requires that individuals first know that language assistance is available to them.

Response: CMS clarifies that rescinding the CMS required NoA should not be construed as the Agency taking a position on the laws and regulations cited by the commenter. Rather, CMS's decision to rescind CMS's NoA requirements under §§ 422.2267(e)(31) and 423.2267(e)(33) is due to concerns previously expressed in this preamble, including the duplicative nature of CMS and OCR's requirements and the corresponding burden placed on MA organizations and Part D sponsors to ensure compliance with NoA requirements from CMS and OCR. OCR is also the HHS component responsible for implementing and enforcing Title VI, Section 504, and/or ACA Section 1557 notice requirements as required by 45 CFR 92.11. CMS has other language-based requirements, promulgated for programmatic reasons related to the operation of the Medicare program pursuant to its authority under the Social Security Act, that remain in effect that provide a level of protection to non-English speaking beneficiaries. Under §§ 422.2267(a)(2) and 423.2267(a)(2), for example, 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 individuals in a plan benefit package service area, and under §§ 422.2267(a)(3) and 423.2267(a)(3), upon request or when otherwise learning of an enrollee's primary language, provide non-English materials in any non-English language identified in §§ 422.2267(a)(2), 423.2267(a)(2), 422.2267(a)(4), and 423.2267(a)(4).

After considering the comments received and for the reasons outlined in the Contract Year 2027 proposed rule and in responses to public comments, CMS is finalizing the rescission of CMS's NoA requirements at §§ 422.2267(e)(31) and 423.2267(e)(33) as proposed.

I. 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 proposed to establish a three level appeals process for Part D program integrity PDE record review audits (90 FR 54962). Specifically, we proposed 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 proposed 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 final rule, we are codifying 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 proposed 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. In alignment with the proposed changes to the scope of subpart Z, we proposed to remove from these regulations any mention of the RACs specifically, as the proposed appeals process would include any Part D program integrity audits that review PDE records for appropriateness (90 FR 54962).

Furthermore, the proposed modifications would serve to 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. As explained in the proposed rule, for these reasons, we believe it is necessary to provide timeframes for decisions to be made at each appeal level (90 FR 54962). 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.

Comment: Several commenters supported the addition of an appeals process for the Part D program integrity PDE record review audits. A commenter requested CMS consider establishing a standard timeframe by which PDE record review audits must be completed, so that plans receive findings or recommendations and delete improper PDE records accordingly.

Response: We proposed specific timeframes for completion of each step of the appeals process (90 FR 54962). CMS thanks the commenter for this feedback. While audit completion timelines are outside the scope of this provision, we will consider this feedback separately.

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. In alignment with our proposal to broaden the scope of subpart Z to include CMS [Part D program integrity PDE record review audits], we also proposed to 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 (90 FR 54962). As such, we proposed to modify the existing regulatory language at § 423.2600 to state Medicare Part D plan sponsors may appeal program integrity prescription drug even record review audit determinations. We proposed 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 proposed 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 deleted, whether the error resulted from actions made by CMS.

We proposed to further amend § 423.2600 by adding a new paragraph (b), which would identify issues ineligible for appeal (90 FR 54962). 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 proposed to require that plan sponsors provide documentation in accordance with the proposed provisions the proposed rule that proposed 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.

Comment: A commenter expressed support for CMS's proposal to introduce a structured appeals process for PDE record review audits, stating the proposal represents a step toward ensuring fairness, transparency, and due process for Part D sponsors. Furthermore, the three-tiered appeal structure and defined timelines will improve predictability and compliance planning. This commenter also believes that the process as proposed has some limitations, including the scope, burden/timelines, adequate evidence standards, technology enablement, and compliance risks.

Response: We appreciate the commenter's support for this provision but disagree with the commenter regarding the limitations of the appeals process. For the three levels of appeals, CMS will not allow additional documentation to be considered during an appeal. It is essential for plans to provide all documentation needed to support coverage under the Medicare Part D benefit at the time of submission. As CMS has previously explained, the issues that are appealable under this process include CMS's application of Part D policy(ies) and factual or data errors because there would be documentation to review to ensure that the payment was proper under the Medicare Part D benefit. CMS has been granting, and will continue to grant, plan sponsors extensions to submit initial documentation when requested. Requests are often made due to plan sponsors' involvement in other concurrent CMS audits or large universe sample size. In addition, the audit methodology is not subject to appeal under our proposed policy.

Regarding the commenter's concerns about the lack of technology enablement or digital submission capabilities and a standardized tracking platform, CMS reminds commenters that a standard system is in place, and CMS utilizes a secure online portal for all steps of aforementioned Part D PDE Record Review Audits.

Comment: A commenter supported efforts to improve audit consistency but was concerned that some of the proposed requirements could create onerous obligations and risk PDE record deletion. Other commenters believed

that the proposals in section IV.D. of the proposed rule to ''Strengthen Documentation Standards for Part D Plan Sponsors'' would involve collecting information not typically available to plans. An example was the identity of the person who submitted the request at the provider's office, which is not information currently collected or easy to retroactively collect if that information is not submitted to the plan, particularly if it comes from a larger provider office or group. Another commenter expressed concern that if this information is not available and documented, then upon audit the PDE record would be marked improper, and the PDE record determination would also be unable to be appealed by the plan sponsor.

Response: We appreciate this concern and assure the commenters that, under this approach, we will review the case file in its entirety and will not require PDE deletions simply because a specific piece of information that does not impact the determination is missing. CMS has clarified that the documentation requirements included in this rule will account for scenarios in which certain information, such as the identity of the requestor, may not be available or not retrievable. CMS also clarifies that if the plan sponsor believes that the information in the case file documentation is sufficient to ensure payment under the Medicare Part D benefit is appropriate, this scenario would be appealable on the basis of ''factual or data errors.'' In addition, CMS reminds the commenter that supporting documentation is not appealable in the instance where a plan sponsor fails to submit a full case file within the audit timeframe specified. This is to ensure that plan sponsors provide CMS complete and accurate case files to avoid unnecessary delays in the audit.

b. Reconsiderations (§ 423.2605)

In existing paragraph (a), we proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed to replace ''45 days'' with ''30 calendar days.'' Furthermore, in existing paragraph (e), we proposed 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.

Comment: A commenter appreciated that the appeals process for PDE record review audits does not create extra burden or require changes to the current process for plan sponsors. The commenter welcomed guidance on the steps and timelines required for each level of appeal. Several other commenters supported the establishment of an appeals process, stating it would enhance transparency and promote greater fairness in the audit process.

Response: We thank commenters for their support of the proposal. Additional information regarding each level of appeal will be provided through program instruction or otherwise.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to those comments, we are finalizing our proposal to update the existing appeals process at 42 CFR part 423 subpart Z to include any CMS Part D program integrity PDE record review audits, without modification.

J. 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, which requires a Part D sponsor to submit an initial PDE record for a selected drug (as described at section 1192(c) of the Act) within 7 calendar days from the date the Part D sponsor receives the claim.

In this rule, we proposed 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 proposed 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 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 listing an excluded prescriber without an applicable waiver.

As reflected in the scenarios described in this Background, it may not be appropriate to resolve every 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, due to operational constraints, 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. CMS's DDPS does not allow Part D sponsors to submit PDE deletion records associated with rejected PDE records.

2. Requirements

As explained earlier, CMS does not have insight into all of the reasons why a Part D sponsor might not submit a revised PDE record to resolve 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 proposed 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 proposed 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

[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/httpseditcmsgovresearch-statistics-data-andsystemscomputer-data-and-systemshpmshpmsmemos-archive/hpms-memo-qtr1-4.*

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.

In the proposed rule, we welcomed feedback on these proposed changes.

Comment: A few commenters expressed their support for CMS's proposal to revise the general PDE submission timeliness requirements specified in § 423.325(a)(3).

Response: We thank the commenters for their support of our proposal.

Comment: Some commenters believed that CMS's proposal was burdensome. One commenter was concerned about potential downstream impacts on contracted pharmacy audit partners and pharmacies, as the proposed requirements would necessitate changes to current research processes related to rejected PDE records.

Response: As stated in our proposed rule and this final rule, since 2011, the vast majority of the PDE records that are rejected are resolved by sponsors within the current 90-calendar-day timeframe. In recent years, nearly all PDE rejections are resolved within this period. The current regulation already requires sponsors to submit a revised PDE record to resolve a rejected PDE within 90 calendar days of the rejection. To the extent rejected PDE records result in claims adjustments to address and resolve these PDE rejections, sponsors are already collaborating with their pharmacy partners, and therefore, we do not believe that our provision will necessitate changes to the current research processes related to PDE records. Therefore, we disagree with the commenters that our proposed rule is burdensome.

Comment: A few commenters stated that the proposal would not provide CMS with additional insight into the underlying status of the rejected PDE records and believed that it would be beneficial for CMS to have a definitive claim status. Commenters recommended alternatives to gain visibility into the status of a claim associated with a rejected PDE record. Some commenters encouraged CMS to consider adopting mechanisms to promote information sharing about the status of a claim associated with a rejected PDE record within the existing PDE record review process, under which CMS flags PDE records and requests additional information from sponsors. Other commenters recommended that CMS create new functionality in the PDE to allow the submitter to inform CMS that the previously rejected PDE is for a claim that has been reversed or has been deemed invalid by the sponsor. One commenter recommended the creation of a new deletion code value (or another field or new value for a field) for the sponsor to specifically inform CMS the claim has been reversed or has been deemed invalid. A commenter noted that such a mechanism could have benefits beyond the intent of the proposal.

Response: We appreciate the recommendations for alternative approaches and acknowledge that these suggestions may provide CMS with more definitive information regarding the status of the claim associated with a rejected PDE record. However, our proposal achieves our goals. As we stated in both the proposed rule and in this final rule, we recognize that submission of a revised PDE record in accordance with the current rule is not always appropriate, and a sponsor may not be able to comply under various scenarios. The new requirements we proposed account for these scenarios, increase transparency, and address circumstances where resubmission of PDE records is not appropriate.

We considered the recommendations from commenters regarding alternatives to promote visibility into the status of a claim associated with a rejected PDE record that they believe would provide a clearer understanding of the status of the claim associated with the rejected PDE record. After careful thought, we concluded that the proposed alternatives—such as additional analysis, outreach to sponsors, and responses from sponsors, or modifications to the PDE file layout or the creation of new functionality in the PDE—would impose a greater burden on CMS and Part D sponsors compared to our proposal.

While we acknowledge that an alternative approach might yield more comprehensive information with benefits extending beyond the intent of this proposal, such considerations are beyond the scope of our proposed rule.

Comment: A few commenters noted that certain PDE rejections cannot be resolved by sponsors because they do not have the ability to resolve the reject. These commenters pointed to plan-to-plan (P2P) PDE rejection edits, for example PDE Edit 706.[67] Commenters also stated that certain beneficiary enrollment and eligibility PDE rejection edits cannot be resolved by the sponsor and that the sponsor may be waiting for a response from CMS on a pending eligibility case prior to resolution of a PDE rejection.

The commenters suggested that when a PDE rejects due to edits that the sponsor cannot resolve, CMS should assume no further action is needed by the sponsor. The sponsor should not be required to continue resubmissions of these PDE records and should be exempt from any compliance action. Additionally, commenters recommended that when PDE rejections occur due to enrollment or eligibility issues, CMS should assume no further action is needed by the sponsor, as there is no way to resolve the error. The sponsor should not be required to continue resubmissions of these PDE records unless enrollment or eligibility changes such that the sponsor would expect the resubmitted PDE record to be accepted by CMS.

Response: We acknowledge that in some cases, our proposed rule will result in a sponsor repeatedly submitting PDE records that will not be accepted by CMS. Based on comments, we explored potential exclusions and exceptions of certain PDE rejection edits from our rule. In doing so, we considered our goal of transparency into claims status and the volume of PDE records impacted. Given that nearly all PDE rejections are resolved within 90 calendar days, our proposed rule will result in only a small percentage of PDE records being repeatedly submitted without resolution until DDPS closes[68]

[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] PDE Edit 706—PDE rejects when the Submitting Contract differs from Contract of Record and does not fall within a valid P2P period (Beneficiary is not enrolled in the Submitting Contract for the given DOS. PDE falls outside of the P2P period facilitated by CMS (greater of enrollment effective date with new Contract of Record + 30 days, or CMS process date + 30 days)). See DDPS Edit Spreadsheet, at *https://www.csscoperations.com/internet/csscw3.nsf/DIDC/FGSMOX8LWK~Prescription%20Drug%20Program%20(Part%20D)~References.*

[68] CMS systems remain open to PDE data (adjustments, deletions, and new submissions) until the end of the 6-year overpayment look-back period. Defined in 42 CFR 423.360(f), the overpayment look-back period encompasses the 6 most recently completed payment years. This period is tied to the ''applicable reconciliation,'' which marks the annual deadline for submitting data for a Part D payment reconciliation, according to 42 CFR 423.360(a). Upon reaching the deadline for a Part D payment reconciliation (*i.e.,* around June 30), the year being reconciled is included in the look-back period, and the earliest year leaves the look-back period. Consequently, from July 1 onward, sponsors are no longer able to submit PDE data for the year that has exited the look-back period. See, for example, the HPMS memorandum titled ''Closing

for the contract year of the PDE at issue. In addition, it is possible that a claim associated with a PDE record that continues to be rejected by CMS is later reversed by the pharmacy. Under that scenario, and consistent with the proposed rule, a sponsor would cease submission of the PDE records, indicating to CMS that the claim was reversed or deleted, or the PDE record that was rejected was otherwise found to have been submitted in error by the sponsor. As proposed, our rule gives us transparency into the status of claims associated with rejected PDE records and allows us to know whether sponsors are compliant with our PDE submission requirements. Therefore, we decline to exempt or exclude certain PDE rejection edits from our requirements.

*Comme*nt: A few commenters noted that CMS's proposal does not address situations where additional CMS guidance or clarifications are needed or when there is a known issue with PDE processing. In these cases, sponsors cannot resolve the errors until CMS takes action to resolve the issue. Commenters recommended that in such scenarios, CMS should allow sponsors to temporarily stop resubmitting the related PDE records until CMS issues additional guidance or corrections are made to DDPS. Furthermore, commenters suggested that CMS should provide a grace period, giving sponsors enough time to implement any necessary changes related to CMS guidance, clarifications, or DDPS changes. One commenter recommended a minimum grace period of 180 days. During this grace period, commenters suggested that the related PDE records should be exempt from any timeliness requirements.

Response: PDE processing and editing can be complicated, and at times, CMS must correct system issues or release new or clarifying guidance for a valid PDE record to be accepted. Under these circumstances, it is still important for us to know if the rejected PDE record is associated with a paid claim or if the claim is reversed or deleted or the PDE that was rejected by CMS is otherwise found to have been submitted in error. In addition, compliance with our proposed rule allows us to understand the scope of the issue.

We acknowledge that there would be various considerations given the nature and scope of an issue preventing acceptance of a valid PDE record. The resolution may or may not reasonably require a ''grace period'' for PDE submissions as suggested by the commenters. Each situation requiring us to take action to resolve a PDE editing issue will be individually assessed based on its unique circumstances. When necessary, we will provide guidance to clarify the requirements for the sponsors.

Comment: Some commenters requested guidance related to the proposed rule. A commenter sought guidance from CMS on when resubmission to correct a rejected PDE record is required. Another commenter requested that CMS clarify its expectations related to rejected PDE records that are actively under research or rework. A commenter also requested technical support and system testing for PACE organizations to ensure that the requirements could be met without disrupting participant care or operations.

Response: As stated in this final rule, there are no exceptions or exemptions to our proposed rule. It is applicable to all rejected PDE records, including those that are actively under research or rework.

We do not believe that CMS system testing is necessary for PACE organizations to comply with the requirements. Under the current regulations at § 423.325(a)(3), sponsors must submit a revised PDE record to resolve a CMS rejected record within 90 calendar days of the rejection. The proposed amendment to that rule will not result in disruptions to participant care or the operations of the PACE organization.

Comment: A few commenters noted that the proposed rule did not address rejected PDE records sent to the Medicare Transaction Facilitator (MTF), which CMS uses to facilitate manufacturer effectuation of negotiated maximum fair prices (MFPs) under Part E of Title XI of the Act (sections 1191 through 1198 of the Act) through the exchange of data and, if applicable, the pass through of MFP refund payments between manufacturers and dispensing entities. One commenter highlighted that it would be beneficial for the MTF to receive information indicating a claim associated with a PDE record that was previously rejected is reversed, so that if an MFP refund has been paid to a pharmacy, it can be recouped by the manufacturer. Commenters encouraged CMS to provide information about such rejected PDE records to the MTF.

Response: We appreciate the feedback on our proposal and how it relates to the operations of the MTF for the purposes of the Medicare Drug Price Negotiation Program. While we value these insights, the operations of the MTF under the Medicare Drug Price Negotiation Program are beyond the scope of this regulation.

Comment: A commenter referenced CMS's memorandum dated July 3, 2013, PDE Guidance for Post Point-of-Sale Claim Adjustments.[69] The commenter stated that the proposal does not appear to clearly align with this guidance.

Response: Our July 3, 2013, PDE guidance for Post Point-of-Sale Claim Adjustments provided sponsors with information on determining the appropriate course of action for post point-of-sale (POS) adjustments to rectify errors under specific scenarios. The guidance explains how to adjust or delete PDE records that were previously accepted. Our proposal amends § 423.325(a)(3) related to rejected PDE records. The proposal does not amend the PDE submission timeliness requirements for adjustments or deletions of accepted PDE records addressed in § 423.325(a)(2). Although we believe that our proposed regulation text is clear, we have slightly modified the proposed regulation text to make clear that the amendment to § 423.325(a)(3) is limited to rejected PDE records for paid claim transactions. The revised § 423.325(a)(3) requires a sponsor to submit a PDE record for a paid claim transaction associated with a PDE record that was previously rejected by CMS 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 that was rejected is otherwise found to have been submitted in error.

After consideration of the public comments we received, we are finalizing the proposal to modify § 423.325(a)(3) with slight modifications to make clear that the requirements are related only to rejected PDE records.

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

The Balanced Budget Act (BBA) of 2018 (Pub. L. 115–123) provided new authorities concerning supplemental benefits that may be offered to chronically ill enrollees in Medicare Advantage (MA) plans. CMS addressed these new supplemental benefits, now known as Special Supplemental Benefits for the Chronically Ill (SSBCI), extensively in the Medicare Program; Contract Year 2021 Policy and

the Drug Data Processing System (DDPS) for benefit year 2018'', dated April 11, 2025 (available at *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-2-april-7-11*).

[69] HPMS memorandum, PDE Guidance for Post Point-of-Sale Claim Adjustments, July 3, 2013.

Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program (hereinafter referred to as the June 2020 final rule) (85 FR 33800 through 33805).

Supplemental benefits, including SSBCI, are generally funded using MA plan rebate dollars. MA rebate dollars may be used for mandatory, but not optional, supplemental benefits offered by the plan (§ 422.266(b)(1)).[70] When submitting an annual bid to participate in the MA program, an MA organization includes in its bid a Plan Benefit Package (PBP) and Bid Pricing Tool (BPT) for each of its plans, where the MA organization provides information to CMS on the premiums, cost sharing, and supplemental benefits (including SSBCI) it proposes to offer. Since the statutory amendment authorizing SSBCI and subsequent guidance in a Health Plan Management System (HPMS) memorandum dated April 24, 2019,[71] the number of MA plans that offer SSBCI—and the number and scope of SSBCI offered—has significantly increased.

Section 422.102(f)(4)(i) and (ii) requires that the MA plans have written policies for making SSBCI enrollment determinations, document that each enrollee eligible for SSBCI is a chronically ill enrollee, and provide this documentation to CMS upon request. As CMS described in Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE) (hereinafter referred to as the April 2024 final rule) (89 FR 30551), to offer an item or service as an SSBCI to an enrollee, an MA plan must make at least two separate determinations, with respect to that enrollee, in order to satisfy the statutory and regulatory requirements for these benefits.

First, the MA plan must determine that an enrollee is eligible for SSBCI by meeting the statutory definition of ''chronically ill enrollee.'' Section 1852(a)(3)(D)(iii) of the Act defines ''chronically ill enrollee'' as an individual enrolled in the MA plan who meets all of the following: (I) has one or more comorbid and medically complex chronic conditions that is life-threatening or significantly limits the overall health or function of the enrollee; (II) has a high risk of hospitalization or other adverse health outcomes; and (III) requires intensive care coordination. Per § 422.102(f)(1)(i)(B), CMS may publish a non-exhaustive list of conditions that are medically complex chronic conditions that are life-threatening or significantly limit the overall health or function of an individual. This list of chronic conditions is the same as the list for which MA organizations may offer chronic condition special needs plans (C–SNPs), which can be found in the definition of ''severe or disabling chronic condition'' within § 422.2. CMS does not further define ''high risk of hospitalization'' or ''intensive care coordination.'' As noted in the June 2020 Final Rule, plans have flexibility in determining what these phrases mean in a way that will best serve their enrollees. However, CMS noted some examples of methods through which plans may assess hospitalization risk or need for care coordination, such as conducting a health risk assessment, performing a retrospective claims review for an enrollee, or by other means the plan deems necessary. Second, the MA plan must determine that the SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the enrollee. Section 422.102(f)(4)(iii)(A) requires that MA plans have and apply written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI. Section 422.102(f)(4)(v) further requires that MA plans maintain without modification, as it relates to an SSBCI, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, or the specific objective criteria used by a plan as part of SSBCI eligibility determinations for the full coverage year.

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

Currently, as permitted by § 422.504(f)(2), CMS may review SSBCI eligibility criteria by requesting it from plans. This is done on a case-by-case basis. Since there is no public posting of a plan's criteria for determining how enrollees qualify for SSBCI, this lack of transparency limits potential enrollees' ability to review and determine what SSBCI are available to them. CMS received numerous comments in response to the Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications proposed rule (herein after referred to as the ''November 2023 proposed rule'') requesting that plans post their objective eligibility criteria for SSBCI on a public-facing website to increase transparency for potential enrollees. In response to these comments, CMS noted that CMS would consider taking this action in future rulemaking (89 FR 30558).[72] CMS believes having MA plan SSBCI eligibility criteria publicly available will improve transparency, promote good governance of the Medicare Trust Fund, and allow enrollees' participation in their care and awareness of their eligibility for benefits.

Therefore, in 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 proposed rule (hereinafter referred to as the Contract Year 2026 proposed rule) (89 FR 99340), CMS proposed that plans must publish the objective eligibility criteria on their public-facing website. Specifically, CMS proposed that MA plans must post on their public-facing website their objective criteria for determining that an enrollee is a chronically ill enrollee within the statutory and regulatory definition and is eligible to receive SSBCI offered by the plan. CMS reminded MA plans of their digital accessibility obligations as recipients of Federal assistance under section 504 of the Rehabilitation Act. CMS proposed to

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

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

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

codify this requirement in the regulation text at § 422.102(f)(4)(iii)(C).

Next, in the Contract Year 2026 proposed rule, CMS proposed several technical changes that align with the statute to clarify SSBCI eligibility requirements and ensure that plans and providers have a clear understanding about which enrollees qualify for SSBCI. When reviewing SSBCI eligibility criteria, CMS discovered that several plans offering SSBCI benefits do not determine eligibility in an objective manner, as required at § 422.102(f)(4)(iii)(A).[73] For example, allowing an enrollee to self-attest that they are eligible for SSBCI without additional criteria or any verification from the plan of this eligibility status would not meet CMS requirements. Additionally, CMS has observed that some plans determine what SSBCI to cover and pay for without consultation with a doctor or other medical professional to determine the clinical appropriateness of the items and services offered under the SSBCI benefit. CMS has also identified instances where plans, when determining eligibility, are not properly evaluating enrollees using all three components of the definition for ''chronically ill enrollee'' as defined in section 1852(a)(3)(D)(iii) of the Act. CMS has identified that the current regulation text (§ 422.102(f)(1)(i)(A)) may need further clarification for plans. It was never the Agency's intention to imply that the presence of a chronic illness or chronic condition alone is sufficient to satisfy all three of the statutory criteria to qualify as a chronically ill enrollee. Therefore, CMS proposed to clarify that having a medically complex chronic condition or comorbidity by itself is insufficient to satisfy the requirements in § 422.102(f)(1)(i)(A)(1), (f)(1)(i)(A)(2), and (f)(1)(i)(A)(3) with a technical edit. Specifically, CMS proposed to amend § 422.102(f)(1)(i)(A) and (f)(1)(i)(A)(1) through (3) to specify that ''a chronically ill enrollee is an individual enrolled in the MA plan who meets all of the following:

- Has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee.
- Has a high risk of hospitalization or other adverse health outcomes.
- Requires intensive care coordination.

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

Next, CMS proposed that plans must demonstrate that an enrollee has met all three of the criteria set forth in § 422.102(f)(1)(i)(A) through the use of an objective process (for example, either a health risk assessment, a claims review, or other similar means). This proposed requirement would help to ensure that the MA plan responsibilities at § 422.102(f)(4)(1)(i)(A) are fully realized while retaining the flexibility plans have in choosing between methods that determine whether enrollees have met all three criteria. For example, a plan could establish that to be eligible for certain SSBCI, an enrollee must have a confirmed diagnosis of diabetes by their primary care physician, and must also have been admitted to the hospital in the last 90 days. Under this example, the diagnosis of a chronic illness is sufficient to satisfy the first criterion (as proposed), that the enrollee, ''has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee[74].'' However, the plan must also determine that the enrollee has met the second and third criteria: (2) has a high risk of hospitalization or other adverse health outcomes; and (3) requires intensive care coordination. The plan may determine that an enrollee meets the second requirement by being hospitalized in the last 90 days. The plan may reason that enrollees who have been hospitalized in the last 90 days are at high risk of readmission and so meet the second statutory requirement of having a high risk of hospitalization. The plan may further decide that the enrollee would require intensive care coordination to prevent further hospitalization and thus would satisfy the third regulatory requirement. In this hypothetical scenario, the plan has determined through an objective process that the chronically ill enrollee meets all three requirements at § 422.102(f)(1)(i)(A).

As described previously, it has become evident through CMS's routine monitoring that MA plans have not consistently applied the statutory requirements to determine eligibility for SSBCI. To address this, CMS also proposed to add regulation text to § 422.102(f)(1)(i)(C). This additional regulation text reiterates that: (1) having one or more comorbidities and medically complex chronic conditions alone is not sufficient to demonstrate that an enrollee meets all three criteria set forth in paragraph (f)(1)(i)(A) and (2) MA plans must (through health risk assessments, review of claims data, or other similar means) demonstrate that enrollees meet all three criteria set forth in paragraph (f)(1)(i)(A). This technical correction would codify existing policy regarding SSBCI eligibility and would not impose any new collection of information requirements.

Finally, CMS proposed to restructure paragraph (f)(4)(iii) to clarify the requirements by adding, ''Have objective criteria for SSBCI. Specifically, the plan must'' and then listing the requirements in paragraphs (f)(4)(iii)(A) through (C).

CMS believes these updates, will provide greater transparency and consistency to the eligibility determination process for potential enrollees and will enhance enrollees' ability to understand what benefits would likely be available to them and thus their ability to make informed decisions about their enrollment. CMS reminds MA organizations that § 422.102(f)(4)(v) requires MA plans to maintain their evidentiary standards or objective criteria for enrollee eligibility for the entire coverage year.

CMS received the following comments on this proposal and responses follow.

Comment: Several commenters were supportive of the proposal to require reporting of SSBCI eligibility criteria on a plan's public-facing website.

Response: CMS thanks commenters for their support of this proposal.

Comment: Several commenters mentioned concerns that CMS proposed to restrict a member's ability to self-attest to eligibility for SSBCI.

Response: CMS did not propose a new prohibition on the ability of members to self-attest to SSBCI eligibility; rather, as

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

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

stated in the Contract Year 2026 proposed rule, enrollees never had such ability and the use of self-attestation is out of compliance with current requirements. CMS has pursued compliance actions against plans that used self-attestation as a method to confirm SSBCI eligibility. Section 422.102(f)(4)(iii)(A) states that plans must have objective criteria for making SSBCI eligibility determinations, and self-attestation is not objective.

Comment: Several commenters were concerned that claims review or other verification of eligibility may delay coverage of certain SSBCI. Some of the commenters also requested a grace or deeming period wherein plans may provide SSBCI coverage while the plan verifies eligibility.

Response: CMS thanks commenters for this feedback and understands the concerns about the potential for delays in coverage. However, as outlined in the preamble, it is, and has always been, the MA plan's responsibility to verify that an enrollee meets the eligibility criteria for SSBCI prior to administering the benefit. Moreover, CMS believes the inherent risk of waste and potential for abuse in administering benefits to ineligible enrollees when providing benefits before determining eligibility outweighs the possibility of delayed coverage. If plans are already performing the intensive care coordination that is required for the enrollee to be eligible for SSBCI, any delay due to verification of eligibility should be minimal.

Finally, CMS does not consider a grace or deeming period to be appropriate because in the event an ineligible enrollee is permitted to access SSBCI during the grace period, this would create a situation where MA plans are out of compliance with their statutory obligation and increase the chance of plans inadvertently providing payment for non-covered items.

Comment: A commenter requested that CMS clarify that MA plans have the flexibility to determine that enrollees have met the three-part ''chronically ill'' definition for SSBCI if they have an approved chronic condition code and a documented food/nutrition, housing/living environment, and/or transportation need. Additionally, several commenters conflated the two determinations MA plans are required to make when evaluating SSBCI eligibility.

Response: CMS appreciates these comments. As outlined in the preamble, CMS reiterates that MA plans are required to make two determinations when evaluating SSBCI eligibility. The first determination is that an enrollee is chronically ill-as per the statutory definition in section 1852(a)(3)(D)(iii) of the Act. To make this determination plans must verify that enrollees have met the three-pronged definition for a chronically ill enrollee.

The second determination, per section 1852(a)(3)(D)(ii)(I), is that each particular SSBCI ''have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.'' Food/nutrition, housing, and transportation needs are all considerations that should be taken into account in this second determination when a plan decides which specific benefits may maintain or improve the overall health or function of the enrollee. Once a plan has confirmed that an enrollee is chronically ill per the statute, the plan may then refer to their objective eligibility criteria for each specific SSBCI.

The following example outlines how a plan may make this determination: The enrollee is diabetic and has been hospitalized in the past 90 days. The plan determines that the enrollee is at high risk of readmission and requires intensive care coordination to prevent further hospitalization, and therefore meets the statutory definition of ''chronically ill.'' The enrollee is then observed during an in-home health risk assessment (HRA) using a walker to get around their two-story home. The plan's criteria for ''structural home modification'' is that the enrollee requires assistance navigating the home (for example, a cane, walker, etc.) and that the home has stairs. In this case, the plan may reasonably recommend a ''structural home modification'' benefit to install a chair lift to assist that enrollee in navigating the home more easily. This example shows how the plan uses objective criteria (that the enrollee requires assistance to walk and live in a home with stairs). The plan may also conclude that the chair lift has a reasonable expectation of improving or maintaining the health or overall function of the enrollee as the use of the chair lift may prevent the enrollee from falls, or from injuries that may cause health complications. This example demonstrates how a plan can meet CMS's requirements of making two separate determinations in order to adequately comply with 42 CFR 422.102(f)(4)(i) and 422.102(f)(4)(iii)(A).

CMS has already made allowances for plans to consider social determinants of health (SDOH) when identifying enrollees whose health or condition could be improved or maintained with SSBCI. This is set forth in the regulations at 42 CFR 422.102(f)(2)(iii). CMS notes however that plans may not use SDOH as the sole basis for determining SSBCI eligibility.

Finally, CMS clarifies that the proposed requirement is such that MA plans must publicly post their objective criteria for both steps of the SSBCI process. Specifically, MA plans must publicly post their criteria for determining that someone has met the definition of a chronically ill enrollee and their specific SSBCI benefit eligibility criteria. To clarify this, CMS is finalizing the proposal with a modification to refer to 42 CFR 422.102(f)(4)(iii)(A).

Comment: A commenter requested that certain chronic conditions such as end-stage renal disease (ESRD), diabetes and chronic obstructive pulmonary disease (COPD) should automatically qualify enrollees for SSBCI due to their high hospitalization risks.

Response: While CMS agrees that many ESRD, diabetes and COPD patients would likely meet the three-pronged definition of a chronically ill enrollee and potentially be eligible for several SSBCI items and services, CMS is not finalizing any automatic eligibility based on chronic condition diagnosis at this time. CMS notes that some patients with these conditions, or others on the chronic condition list set forth at § 422.2, may be able to manage their conditions well, and not be at high risk of hospitalization or other adverse health outcomes or require intensive care coordination. Such enrollees would not meet the chronically ill enrollee definition. It would therefore not be prudent to automatically confirm chronically ill status or SSBCI eligibility based on a singular chronic condition.

CMS acknowledges that many patients with the noted chronic conditions may meet the eligibility standards based on an HRA, which SNPs are required to complete within 90 days, before or after enrollment in a plan. Since many enrollees with these conditions are enrolled in C–SNPs, CMS notes that plans may use these HRAs to determine: (1) chronically ill enrollee status and (2) particular SSBCI items and services that would meet the reasonable expectation standard. However, CMS reiterates its commitment to allowing plans to have the flexibility to determine the form and manner of confirming ''chronically ill'' status and SSBCI eligibility criteria. CMS noted in the Contract Year 2026 proposed rule that HRAs and claims reviews were merely two examples by which a plan may confirm these.

Comment: A commenter requested that CMS exempt C–SNPs from SSBCI eligibility criteria publication.

Response: CMS appreciates this suggestion, however CMS is not finalizing any exemptions to the public posting requirement at this time. It is the Agency's intention to increase the transparency of SSBCI benefits for enrollees. By exempting C–SNPs from the proposed requirement, CMS would exclude a vulnerable population from receiving this important information regarding SSBCI benefits. While many potential C–SNP enrollees may meet the chronically ill statutory definition, the lack of transparency on the eligibility requirements could be a deterrent to them during the enrollment period. For example, a C–SNP enrollee could choose a different plan with benefits less suited to them. The result of such a choice could have negative outcomes for all parties.

Comment: Some commenters noted concerns with being required to post proprietary SSBCI eligibility criteria on the plan's website.

Response: CMS understands that plans may have concerns about competitive advantage with new requirements to publish this information on a public-facing website. CMS notes however that listing eligibility criteria may provide for additional open competition in the marketplace, further incentivizing MA plans to offer supplemental benefits that are valued by enrollees in a clear and consistent manner. CMS has therefore determined that the potential benefit to enrollees far outweigh concerns about posting SSBCI eligibility information.

Comment: A commenter requested that CMS rely on the subset of chronic diseases identified by the Agency itself that allow for the current provision of SSBCI and enrollment in C–SNPs to determine eligibility. They urged CMS not to finalize limitations on SSBCI eligibility by requiring plans to impose an ''objective process'' to ensure beneficiaries meet three criteria to receive SSBCI.

Response: CMS appreciates this comment and attempts to clarify here. The requirement for plans to have and apply objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI is already a regulatory requirement and has been since the inception of SSBCI in the MA program (85 FR 9013).

The commenter suggests that enrollees with chronic conditions identified by CMS meet the chronically ill enrollee definition and qualify for SSBCI solely on the basis of having one of those conditions. As CMS noted in a previous response, this is not the case and plans are required to have further criteria to make such determinations. CMS reminds commenters that this proposal was a technical update to emphasize the existing statutory and regulatory requirements, and CMS has held this standard since the inception of SSBCI.

Comment: Some commenters recommended that CMS consider providing detailed directions on what information must be included on the plan's public-facing website to ensure consistency between plans and help beneficiaries more easily compare their choices.

Response: CMS appreciates this concern and may consider providing additional guidance if, in practice, there is evidence that inconsistency among MA plan websites cause beneficiary confusion.

Comment: A commenter requested that CMS provide a comprehensive list of acceptable methodologies that would meet the definition of ''objective process'' for purposes of determining SSBCI eligibility. This commenter urged CMS to include the review and identification factors that influence disease progression. They suggested that these factors include, but not be limited to, race, ethnicity, socioeconomic status, comorbidities, and recent acute care utilization.

Similarly, another commenter asked that plans be allowed to use low-income status (LIS) and dual-eligibility as part of the objective criteria to support that a member is at risk for hospitalizations or adverse health outcomes and thereby requires care management.

Response: CMS appreciates this recommendation. Per section 1852(a)(3)(D)(iii)(III) of the Act, for purposes of SSBCI, a chronically ill enrollee must ''require[ ] intensive care coordination.'' CMS reiterates that in the June 2020 Final Rule, CMS did not define ''intensive care coordination'' to allow plans flexibility in determining what the phrase meant to best serve their specific enrollee population. However, CMS noted some examples of methods through which plans may determine an enrollee required intensive care coordination, such as conducting an HRA, performing a retrospective claims review for an enrollee, or by other means the plan deems necessary. CMS reaffirms its position stated in the June 2020 final rule, that objective criteria which utilize the above mechanisms for meeting the three-pronged definition are present in the medical community and may be readily accessible to the plan.

CMS reminds commenters that an enrollee's high risk of hospitalization, does not necessarily affirmatively establish that the enrollee will also require intensive care coordination, as these are separate factors to evaluate in determining whether an enrollee meets the statutory definition of ''chronically ill'' for purposes of SSBCI.

CMS notes that the commenters listed several factors that may be useful in meeting CMS' requirements. It is at the plans' discretion to determine their objective criteria for determining whether an enrollee meets the definition of ''chronically ill'' for purposes of SSBCI, based on their specific enrollee population and any other relevant considerations that may be unique to the plan. CMS does not wish to limit the flexibility of MA organizations to determine which objective criteria are best for a particular plan, or their enrollees.

Comment: Another commenter believed that CMS' proposed provision regarding posting criteria for determining chronically ill enrollee status on a public-facing website would increase administrative burden on plans and provide little to no value to enrollees.

Response: CMS acknowledges that this requirement will place administrative burden on plans to implement and discusses the burden in the Collection of Information section of this final rule. CMS proposed to make SSBCI criteria publicly available in response to numerous comments received during previous rulemaking. Commenters expressed the need for such transparency in order for potential enrollees to make informed choices when choosing an MA plan to join and to have a better understanding of their current care options while enrolled. Such transparency will have an overall positive impact on enrollee experience and choice as it fosters enrollee empowerment and competition in the MA market.

Comment: Some commenters requested that CMS not require hospitalization in the past 90 days to meet the second and third criteria that chronically ill enrollees have a ''high risk of hospitalization or other adverse health outcomes'' and ''require intensive care coordination'' respectively. Specifically, a commenter mentioned that I–SNP enrollees are inherently at high risk due to their clinical and care needs and recommended that CMS consider adjusting the eligibility criteria for this population to better reflect the goals of preventative care in long-term care settings.

Response: CMS appreciates this feedback. CMS clarifies that the discussion pertaining to hospitalization in the past 90 days in the Contract Year

2026 proposed rule and in this section of the final rule is meant to serve only as an example of objective criteria an MA plan might apply in determining chronically ill enrollee status. CMS did not propose and will not be finalizing a requirement that MA enrollees must have been hospitalized in the past 90 days in order to be eligible to receive SSBCI.

CMS also appreciates the commenter drawing attention to I–SNP enrollees specifically. CMS agrees that many I–SNP enrollees would likely meet the chronically ill enrollee definition. CMS therefore notes, if plans were to use a qualifying chronic condition diagnosis in conjunction with enrollee utilizing institutional level of care (LOC) to satisfy the 3-pronged criteria for chronically ill enrollee, this would meet CMS requirements and expectations, as the need for an institutional LOC could indicate a high risk of hospitalization or other adverse health outcomes and a need for intensive care coordination.

Comment: A commenter recommended that if finalized, the implementation of the public posting of chronically ill enrollee criteria be delayed at least one year to allow adequate time to inform beneficiaries while minimizing any potential disruptions to care.

Response: CMS appreciates these concerns regarding the timing of these requirements. CMS notes that MA organizations will have until January 2027 to implement these requirements. Additionally, MA plans should already be utilizing objective criteria for both determining that an enrollee meets the definition of a chronically ill enrollee and that a specific SSBCI has a reasonable expectation of improving or maintaining the enrollee's overall health or function. Therefore, requiring MA organizations to post this information on their plan's website should present minimal challenges regarding timeliness and should not require a full year to finalize.

Comment: Another commenter requested that CMS allow plans to proactively approve members for SSBCI benefits prior to their effective date with a plan. This approach would help ensure vulnerable members have access to the support they need as soon as possible, which is essential for improving their health outcomes. They also recommended that plans be allowed to use multiple chronic conditions (MCC) files as a method of SSBCI eligibility verification.

Response: CMS appreciates this commenter's feedback and notes that this proactive approval process would be allowable. For example, many plans choose to complete HRAs before the beginning of the coverage year. The information obtained from the HRA can then be used to help confirm the chronically ill status of an enrollee prior to the plan's effective date. CMS agrees that plans should utilize data streams that provide the most utility in accordance with the resources available to them.

Comment: Another commenter requested additional clarification of the requirements for objective criteria given that some HRAs are self-attested.

Response: CMS appreciates this comment and the opportunity to clarify. Self-attested HRAs include questions about an enrollee's habits, environment, or other pertinent information. The enrollee is answering questions which are specific in nature, and do not rely on the enrollee's judgement to self-diagnose or make SSBCI eligibility determinations about themselves. An MA organization may use an enrollee's HRA responses in determining, based on objective criteria, the enrollee's eligibility for SSBCI. If, by contrast, an enrollee was to certify their own eligibility for SSBCI by checking a box, for example, without first receiving an independent determination by the MA organization that objective criteria for eligibility are met, this would not be compliant with CMS' rules. It is the responsibility of the MA organization (not enrollees) to understand and abide by CMS requirements.

An MA organization cannot delegate its responsibility to make objective eligibility determinations to the enrollee, given that the enrollee may have a strong financial incentive to certify themselves eligible for SSBCI and may not fully understand the applicable criteria. Consider an example where the plan provides money for gas as ''transportation for non-medical benefits'' SSBCI which is administered through a debit card or ''flex card'' and the enrollee is asked to check a box if they are ''eligible to receive a gas card.'' Allowing an enrollee to self-attest or self-certify to SSBCI eligibility in this scenario is inconsistent with the MA organizations' responsibility for ensuring objective SSBCI eligibility determinations. This scenario is distinguishable from self-attested responses to questions on an HRA, which can then be used by the MA organization to determine, based on objective criteria, whether the enrollee is eligible for SSBCI. As a result, self-attestation of eligibility for SSBCI is not permissible, but MA organizations may use self-attested HRA responses in determining eligibility for SSBCI.

Comment: A commenter recommended that CMS not finalize its proposed requirement for plans to publicly post their SSBCI eligibility criteria as they believed it would be duplicative of information provided in the Evidence of Coverage (EOC) and is also required in any marketing of the SSBCI benefits as finalized in the April 2024 final rule.

Response: CMS appreciates this comment and agrees that best practices in providing EOC materials and other plan documents would include this information. CMS stated in the June 2020 final rule that it is expected that plans communicate to enrollees information in a clear manner about the scope of SSBCI that the MA plan covers and who is eligible for those benefits (*85 FR 33803*). The EOC requirements in § 422.111(b)(2) require the inclusion of information about the benefits offered under a plan, including applicable conditions and limitations. In the April 2024 final rule, CMS modified the disclaimer requirements at § 422.2267(e)(34) to require plans to include clear information about SSBCI eligibility criteria in marketing and communications materials that mention SSBCI, including by listing the chronic conditions an enrollee must have in order to be eligible for the SSBCI. However, this regulation does not explicitly state that plans must list their SSBCI eligibility criteria apart from specific chronic conditions that might qualify for SSBCI. Some MA organizations have neglected to include such additional eligibility criteria in their plan's EOC and other documents. For plans that already list the information elsewhere, there will be a lower associated burden. Plans that do not provide this information anywhere in enrollee-facing documentation will be providing an additional level of transparency into their operations that may improve patient experience.

CMS is finalizing the proposal with the following modifications: First, for the reasons discussed in this section, § 422.102(f)(4)(iii)(C) will be finalized as follows, ''For each SSBCI, list all the written policies and objective criteria on which the policies are based, as noted in paragraph (f)(4)(i) and (f)(4)(iii)(A) of this section, on their public-facing website.'' Second, CMS is finalizing non-substantive technical changes at 42 CFR 422.102(f)(4)(iii)(A)–(C) for structure and clarity.

Finally, CMS notes that while this provision was originally proposed in the Contract Year 2026 proposed rule, it is being finalized in the Contract Year 2027 final rule. Therefore, this provision will be applicable January 1, 2027.

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

The following provisions were proposed in 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 proposed rule (hereinafter referred to as the Contract Year 2026 proposed rule) (89 FR 99340). This section discusses what was proposed and the modifications being made in this final rule.

1. Background

Section 1852(a)(3)(A) of the Act gives Medicare Advantage (MA) organizations the ability to offer supplemental benefits to plan enrollees, subject to the Secretary's approval. CMS has adopted rules—primarily in §§ 422.100(c)(2) and 422.102—to regulate how those supplemental benefits, such as vision, dental, gym membership, and others, must be offered. For example, in the Medicare Program, Establishment of the Medicare Advantage Program Final Rule,[75] which appeared in the **Federal Register** on January 28, 2005, CMS established at § 422.102(a)(4) that an MA organization could offer as a mandatory supplemental benefit a reduction in cost sharing below the actuarial value specified in section 1854(e)(4)(B) of the Act (70 FR 4617). Later, in the Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Final Rule [76] (January 19, 2021; 86 FR 5913) (hereinafter referred to as the January 2021 final rule), CMS further clarified the scope of supplemental benefits that reduce cost sharing by adding rules at § 422.102(a)(5) and (a)(6)(i) and (ii) to clarify the different circumstances under which an MA plan may reduce cost sharing for covered items and services as a mandatory supplemental benefit and the mechanisms by which an MA plan may make such reductions in cost sharing available to enrollees. Mandatory supplemental benefits are benefits that are included in the plan and are generally available to all enrollees with no additional premiums. As described in § 422.102(b), optional supplemental benefits are purchased at the discretion of the enrollee and are available to all plan enrollees who choose to pay an additional premium in order to receive those benefits.

In the January 2021 final rule, CMS explained that MA plans may choose to structure mandatory supplemental benefits in a few ways (86 FR 5913). For example, an MA plan may offer, as a mandatory supplemental benefit, the use of a debit card to administer reduced cost sharing for plan-covered services or to provide coverage of 100 percent of the cost of plan-covered items or services. This may include reduced cost sharing for dental and vision services (when offered as a mandatory supplemental benefit—not as an optional benefit) where a claim for additional payment is submitted to the plan, and/or coverage by the plan (through use of the card) of all or part of the cost of OTC items, fitness-related benefits, food and produce, transportation, and utilities support. With respect to a mandatory supplemental benefit in the form of reduced cost sharing, a beneficiary may receive a debit card to use to pay for any applicable cost sharing when receiving a basic benefit or mandatory supplemental benefit, including Special Supplemental Benefits for the Chronically Ill (SSBCI). For example, if the plan provides a transportation service as a covered benefit and provides a debit card to be used to reduce cost sharing for those defined transportation services, the beneficiary could use the debit card to pay for those services. However, MA organizations that choose to use a debit card to administer mandatory supplemental benefits must do so in a manner that ensures the debit card can only be used towards plan-covered items and services. To the extent these items and services are mandatory supplemental benefits, they must also meet all the regulatory supplemental benefit standards at §§ 422.100(c)(2) and 422.102(a) through (f). CMS reminds readers that reduced cost sharing is not permitted as an optional supplemental benefit (that is a supplemental benefit that a beneficiary would select in exchange for additional premiums) (see 86 FR 5913). Thus, this mechanism of using debit cards is not permitted to administer optional supplemental benefits (that is, an optional dental or vision service package).

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

Since the January 2021 final rule, many MA organizations have disclosed the use of debit cards to administer a benefit in their annual bid notes. In reviewing annual bids, CMS has observed that MA organizations appear to regularly use debit cards to administer several mandatory supplemental benefits, including reductions in cost sharing for dental and vision services and/or payment for OTC items, fitness-related benefits, food and produce, transportation, and utilities support. In recent years, based on questions from stakeholders, including beneficiaries, CMS has also become aware that there is some confusion around the use of debit cards. For example, many stakeholders have submitted questions requesting CMS clarify what these cards are and how they can be used. CMS has also received complaints from enrollees who tell us that they are confused when trying to use their debit card. Often these individuals do not receive guidance on

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

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

which plan covered supplemental benefits can be purchased with their debit card or where and how they can use them. Additionally, stakeholders have raised concerns that there are not enough guardrails on how these cards are used and how purchases are tracked, especially at large box stores that carry non-covered items and services (for example, Costco or Walmart) that would be inappropriate for the MA plan to cover as supplemental benefits. For example, there are concerns that the enrollee may use the plan debit card to purchase items and services that are not covered or that do not meet the requirements for MA supplemental benefits.

To provide further clarity to both MA organizations and beneficiaries on the parameters around the appropriate use of plan debit cards, in the Contract Year 2026 proposed rule, CMS proposed requirements on the proper administration of supplemental benefits. Based on CMS's authority under section 1856(b)(1) of the Act to establish standards for MA organizations, along with the authority in section 1857(e)(1) of the Act to adopt additional terms and conditions for MA contracts that are not inconsistent with the Part C statute and that are necessary and appropriate for the MA program, CMS proposed to codify in regulation text the requirements and limitations discussed in the preamble of the January 2021 final rule and later in the May 6, 2024 HPMS memo titled, ''Final Contract Year (CY) 2025 Standards for Part C Benefits, Bid Review and Evaluation'' regarding the administration of supplemental benefits, including the use of debit cards. CMS believes codifying these standards will also ensure that MA requirements regarding supplemental benefits are applied uniformly across the MA industry and for all supplemental benefits: both standard (that is, primarily health-related) supplemental benefits and non-primarily health-related SSBCI. CMS also proposed to expand on these requirements by adopting additional disclosure and access guardrails to increase transparency, protect access to plan-covered services for MA enrollees, and ensure that MA plans cover (that is, provide, furnish, and/or pay for) only those items and services that are permissible MA benefits.

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

2. The Administration of Supplemental Benefits

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

CMS proposed in the Contract Year 2026 proposed rule that MA organizations must have processes for delivering all MA plan-covered supplemental benefits to enrollees that ensure compliance with §§ 422.100(c)(2) and 422.102(a) through (f) and appropriate access to suppliers and providers in accordance with § 422.112(a) as applicable. Per § 422.112(a), MA coordinated care plans may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. The MA organization may therefore contract with providers or vendors to furnish covered services, including supplemental benefits administered via a debit card or otherwise. For example, a plan may contract with a particular vendor to provide their food and produce benefit. In this scenario, that specific vendor is the network provider for furnishing the food and produce benefit. CMS noted that section 1854(a)(6)(B)(iii) of the Act, commonly known as the ''non-interference clause,'' prohibits CMS from requiring any MA organization to contract with a particular provider to furnish covered items and services. Therefore, CMS does not specify which vendors MA organizations contract with to furnish covered items and services. (Note, however, that § 422.204(b)(3) requires that providers that furnish covered Part A and B benefits must meet the applicable requirements of Title XVIII of the Act and that certain types of institutional providers must have participation agreements with Medicare.)

CMS also noted that all coordinated care plans are required to cover benefits, including supplemental benefits, at in-network cost sharing when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs in accordance with the standards set forth in rules and regulations.[77] This is required for all benefits, regardless of how they are administered.

If an in-network provider is unavailable or inadequate to administer covered plan benefits, whether Parts A and B or supplemental benefits, the MA organization should have a plan or process in place to ensure that the requirements under § 422.112(a)(1)(iii) are met. However, given inconsistencies in how supplemental benefits are provided, CMS believes it is necessary to clarify this requirement in regulatory text. Therefore, in the Contract Year 2026 proposed rule, CMS proposed and sought comment on new § 422.102(g)(1) that would require MA organizations to have processes for delivering all MA organization covered supplemental benefits to enrollees that ensure compliance with §§ 422.100(c)(2) and 422.102(a) through (f) and appropriate access to all covered services in accordance with § 422.112(a).

3. New Guardrails for Plan Debit Cards

In the Contract Year 2026 proposed rule, CMS proposed to include a clarification in § 422.102(g)(1) requiring

[77] § 422.112 (a)(1)(iii); Chapter 4, section 30.2 of the Medicare Managed Care Manual; 88 FR 22200.

that MA organizations have processes for delivering all MA organization covered supplemental benefits to enrollees that ensure compliance with §§ 422.100(c)(2) and 422.102(a) through (f) and appropriate access to all covered services per § 422.112(a). Thus, CMS believes it is necessary to specify that this requirement would apply to all plan-covered supplemental benefits, including supplemental benefits administered through debit cards. Under this proposal, plans must have a process in place to maintain enrollee access to these benefits. When plans offer debit cards to assist with the cost sharing for covered benefits or otherwise administer supplemental benefits, the MA organization must ensure that the access requirements at § 422.112(a) are met. This means regardless of the mode of delivery (for example, debit card or other means), MA organizations must ensure that all covered services, including supplemental benefits, and SSBCI for eligible enrollees, contracted for by (or on behalf of) enrollees, are available and accessible under the plan.

In addition, CMS requires that plan-covered benefits be disclosed in the plan's evidence of coverage (EOC). Section 422.111 requires that MA organizations disclose all benefits offered under an MA plan, including applicable conditions and limitations, and any other conditions associated with receipt or use of benefits. These requirements are applicable to all benefits, including those administered via debit card. CMS also noted that MA organizations are required to send an Explanation of Benefits (EOB) to an enrollee that captures all claims activity that occurs during a reporting period (monthly or quarterly cycle). The EOB must include claims information for all Part C claims processed during the reporting period, including all claims for Part A and Part B covered items and services, mandatory supplemental benefits, optional supplemental benefits, and SSBCI.[78] The EOB must disclose for each claim a descriptor, billing code and amount billed, total cost approved for reimbursement, share of the total cost paid by the plan, and share of the total cost for which the enrollee is liable. Additionally, the EOB must include certain year-to-date information such as the amount an enrollee has incurred toward the Maximum Out-of-Pocket (MOOP) limit.[79] These EOB requirements include supplemental benefits that MA plans elect to cover through a debit card.

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

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

Next, CMS proposed at § 422.102(g)(2)(ii) to require MA organizations that use debit cards to administer a supplemental benefit to provide instructions for debit card use and customer service support to enrollees to answer questions or help with issues related to the administration of the card. For example, if an MA organization provides a food and produce benefit that may be accessed via a debit card, the plan must provide eligible enrollees with instructions on how to use the debit card and provide customer support service to beneficiaries who have questions about how to use the debit card. This support service must include instructions to beneficiaries on the process to access these benefits if not accessible by debit card, in accordance with § 422.112(a). CMS believes this is necessary to ensure that enrollees are fully aware of their benefits and how to properly access those benefits, particularly those living in rural areas with limited access to broadband/internet for communication. Finally, all benefits must be limited to the specific plan year. Therefore, the Contract Year 2026 proposed rule proposed to state at § 422.102(g)(2)(iv) that MA organizations must ensure the use of a debit card to administer a covered benefit is limited to the specific plan year.

In the January 2021 final rule, CMS amended § 422.102(a)(6) to state that an MA organization may offer reduced cost sharing as a mandatory supplemental benefit through the use of reimbursement, through a debit card or other means. In order to further support the proposed requirements at § 422.102(g)(1), in the Contract Year 2026 proposed rule, CMS also proposed to revise § 422.102(a)(6) by removing ''or

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

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

other means'' and adding ''manual'' before reimbursement to ensure that reductions in cost sharing as a supplemental benefit are clearly limited to either manual reimbursement or to a debit card governed by the proposed rules under § 422.102(g) for covered items and services. CMS explained that ''other means'' could be interpreted to allow an unrestricted card or other vague mechanisms, which would conflict with CMS requirements that a debit card be exclusively linked to covered benefits and limited to the plan year or the requirements being proposed at § 422.102(g)(1)(i).

While CMS proposed to remove ''or other means,'' CMS also solicited comment on what other means, outside of manual reimbursement or a debit card, would be unintentionally removed as options to plans should this proposed revision be finalized. CMS solicited comment on how these other means or mechanisms may still guarantee compliance with existing requirements at § 422.102(a)(6) and the requirements proposed at §§ 422.102(g) and 422.111(b)(6) (discussed in section III.H.2 of the Contract Year 2026 proposed rule). For example, it was not CMS's intent that the proposed changes at § 422.102(a)(6) would prohibit an organization from using a stored value card,[80] provided the use of these cards by MA plans complies with the requirements at § 422.102(g). Therefore, CMS solicited comment on whether the use of stored value cards meets the requirements at § 422.102(g). Specifically, CMS solicited comment on whether the mechanisms available and used with stored valued cards are sufficient so that the purchases made through such cards can be electronically linked to plan covered items through a real-time identification mechanism that verifies the eligibility of plan covered benefits at the point of sale, and can restrict the time period allowed for the use of the stored value card to the plan year only. CMS also solicited comment on whether stored value cards should be explicitly added to § 422.102(a)(6) and § 422.102(g) as an acceptable means of administering reductions in cost sharing and the coverage of supplemental benefits.

4. Access

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

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

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

CMS also noted that MA plans that are PPOs are required to provide reimbursement for all covered services, regardless of whether the items are provided within the network of providers under § 422.4(a)(1)(v). Regarding reimbursement, § 422.4(a)(1)(v)(B) requires PPOs to provide for ''reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers.'' This applies to all supplemental benefits, including those administered through a debit card (it was noted that in this scenario, an enrollee may be subject to increased cost sharing). For example, an MA organization may contract with a particular grocery store to furnish their food and produce benefit. However, in a PPO, enrollees may purchase eligible food and produce at another non-contracted grocer (out-of-network provider) and be reimbursed for those covered items. CMS expects MA PPOs to have processes to verify out-of-network reimbursement is only made

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

for plan-covered services and to indicate to enrollees the process by which reimbursement can be made. As noted above, that process should be mindful of enrollees in rural or remote areas with limited access to providers and internet-based communication methods.

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

5. Additional Disclosure Guardrails

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

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

CMS has also reviewed items that have been determined not to be permissible MA supplemental benefits because they do not meet the requirement that the item or service be primarily health-related. Such OTC items that cannot be covered as MA supplemental benefits include air conditioners, baby items, bad breath remedies (gum and breath mints), bagging fees, body scrubs, cleaning products (Clorox and Lysol), clocks, dehumidifiers, deodorant, grooming/shaving supplies, hair care (shampoo, conditioner, dye, bleach, hair removal and hair growth products), humidifiers, jar openers, paper products (tissue, toilet paper and paper towels), perfume, pest control, skin moisturizers used for anti-aging, teeth whiteners, water bottles, and personal coolers. It was noted that items such as air conditioners, cleaning products, dehumidifiers, humidifiers, grooming supplies to assist with hygiene, paper

products (tissue, toilet paper and paper towels), and pest control may be permissible as a non-primarily health-related SSBCI provided the item has a reasonable expectation of improving or maintaining the health or overall function of the enrollee and meets the standards at § 422.102(f). For example, research indicates that air conditioners may improve the breathing of patients with COPD and asthma.[81] CMS solicited comment on these listed items.

CMS reiterated that the list of permissible primarily health-related OTC items set forth in the Contract Year 2026 proposed rule was non-exhaustive. CMS also included a non-exhaustive list of items that are not primarily health-related but could be offered as a non-primarily health-related SSBCI, provided the requirements under § 422.102(f) are met. CMS reviews bids each year to ensure that proposed supplemental benefits meet the applicable regulatory and statutory standards.[82] For example, MA organizations may propose to offer OTC items not on this list and CMS may come across items in the future, not listed here, that CMS believes do not meet the definition of a supplemental benefit per § 422.100(c)(2) or are not primarily health-related per § 422.100(c)(2)(ii). However, the Agency believes including these lists in this preamble discussion will help MA organizations consistently apply the requirements at §§ 422.100(c)(2) and 422.100(c)(2)(ii) and assist MA organizations when planning and preparing their annual bid packages.

6. Marketing Supplemental Benefits

Another consideration related to debit cards is MA organizations' marketing tactics. CMS has become aware of certain advertisements that solely mention debit cards, or marketing terms such as ''Medicare flex cards,'' with an alluring value attached to them, potentially giving false impressions that the card itself is the benefit.

In the Contract Year 2026 proposed rule, CMS raised concerns with these advertisements, articulating that there could be a risk that a beneficiary might view this type of advertisement and make an enrollment decision based on the belief that, by enrolling in the plan, they will automatically receive a card with ''free'' money to spend wherever they choose. CMS proposed new parameters for MA organizations' marketing of supplemental benefits. Specifically, CMS proposed to add new paragraph (b)(11) to § 422.2263, prohibiting MA organizations from marketing the dollar value of a supplemental benefit or the method by which a supplemental benefit is administered, such as use of a debit card by the enrollee to provide the plan's payment to the provider for the covered services. CMS solicited comment on all aspects of this proposal.

CMS thanks commenters for their input on CMS's proposed changes to requirements for the administration of supplemental benefits coverage through debit cards. CMS received the following comments and provided responses as follows.

Comment: While several commenters supported the proposed rule, a number of commenters raised concerns about potential member confusion related to various aspects of debit card use. One commenter expressed concern that the ''combined benefit option'' may be confusing, as beneficiaries might not understand they are using their allowance on food at the expense of other benefits like vision and dental. Some commenters also raised concerns that enrollees may unwittingly use cards for uncovered services and be found liable later. Given these concerns about confusion and potential liability, many commenters also expressed support for the proposed additional disclosure requirements around supplemental benefits and how to access them via debit cards. Several commenters also supported the requirements for customer service and support around using debit cards.

Response: CMS thanks commenters for sharing their concerns and support of this rule. CMS has heard from various stakeholders that enrollees are often confused when using plan debit cards. The clarifications being finalized at 42 CFR 422.111(b)(6) and the disclosure and customer service requirements under new subsection 422.102(g) address these concerns. As stated in the Contract Year 2026 proposed rule, plans are currently required to disclose all covered benefits. Given the rapid growth of MA plans' use of debit cards to furnish covered benefits, CMS is requiring that this disclosure must include eligible OTC items and, where supplemental benefits are administered through a debit card, specify which benefits may be accessed using the debit card. Requiring plans to provide debit card usage instructions and customer service support will significantly improve the enrollee experience. While many plans already have customer service processes in place, CMS is requiring that these processes include assistance with debit card access to benefits when necessary. These requirements are expected to enhance the enrollee experience, and CMS will continue to monitor outcomes.

CMS also thanks commenters for noting confusion around the ''combined benefit option,'' also referred to as a maximum plan allowance for a package of supplemental benefits under § 422.102(a)(6)(ii). MA plans have long been able to structure benefits that allow enrollees to choose from a group of covered, eligible supplemental benefit options. However, CMS acknowledges that when plans use this structure in combination with debit cards, it can create confusion as enrollees may not realize that using the card for one benefit means foregoing another. To address this, CMS emphasizes throughout this rule that plans are required to disclose all benefits and accompanying limitations to their enrollees. Specifically, CMS proposed and is finalizing an amendment to § 422.111(b)(6) to require disclosure of the applicable conditions and limitations associated with the receipt or use of supplemental benefits. When offering a ''combined benefit option,'' plans must clearly communicate any associated limitations to enrollees, including that selecting one benefit means foregoing another benefit under this benefit structure.

Comment: Multiple commenters raised concerns about the feasibility and administrative burden of the real-time verification requirement. Some commenters argued that requiring real-time verification with SKU codes for all items would limit access and use of cards, and that plans are at different operational levels regarding their ability to perform point-of-sale verification. Some commenters also asserted that various types of debit cards exist, each with distinct functionalities and operational characteristics that may have varying levels of compatibility with these requirements. Several commenters asserted that even for plans already taking verification steps through third-party fintech card administrators, operational changes could add significant burden given the variety of retailer hierarchies of product identification. A commenter expressed concern that the point-of-sale verification may have the unintended consequence of detracting from the beneficiary experience, with beneficiaries potentially facing

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

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

additional steps with added confusion at the point of sale. A commenter noted that dental benefit and eligibility verification through current HIPAA-mandated standards are insufficient to support the real-time identification mechanism of covered services as described. Another commenter stated that real-time verification technology may be incompatible with certain benefits. Some commenters requested that CMS provide examples of permissible methods of meeting the real-time identification requirements. Other stakeholders supported the real-time verification requirements, emphasizing that these processes are necessary to ensure beneficiaries receive the correct benefits and to enhance the enrollee experience. Another commenter, while supportive of real-time verification, requested that CMS permit either electronic or manual verification of plan-covered benefits at point-of-sale.

Response: CMS thanks commenters for feedback. CMS also reminds commenters that there is longstanding precedent requiring plan debit cards to be explicitly linked to covered items. CMS guidance (Medicare MCM Chapter 40.3) states that debit cards must be electronically linked to eligible, covered items. In the January 2021 Final Rule (86 FR 5913), CMS explained that MA organizations must properly restrict debit cards to appropriate providers and covered benefits to ensure compliance with §§ 422.100(c)(2) and 422.102(a). CMS stated directly that if a plan cannot implement such restrictions—for example, through merchant codes, inventory approval system codes, or other mechanisms—then debit cards may not be an appropriate mechanism for that plan to use (86 FR 5913). It has been and continues to be CMS's expectation that if a plan cannot appropriately restrict debit cards to actual covered benefits, this mechanism should not be used. The codifications in this rule formalize and expand upon these existing expectations for greater clarity given the growth of debit card usage.

Regarding real-time verification specifically, this capability is necessary to ensure ease of access, transparency, proper payment, and fraud prevention, aligning with the Administration's commitment to combating fraud, waste, and abuse in federal programs. Real-time verification helps eliminate fraud by preventing unauthorized purchases, ensuring that benefits are used only for their intended purpose, and reduces the chances of plans inadvertently providing payment for non-covered items, thus ensuring compliance with CMS requirements. Additionally, real-time verification removes uncertainty at the point of sale for plan enrollees and provides assurance that the purchase is aligned with plan rules, which is particularly important for a population that may be dealing with reduced functionality.

CMS's primary concern is that benefits are furnished appropriately to beneficiaries. While debit cards offer one method to administer benefits, they are not the only option available to plans, nor mandatory. Plans may administer supplemental benefits through other methods, including but not limited to, manual claims processing and online claims submission forms. In fact, plans may find these processes more operationally appropriate for certain benefits. CMS originally allowed debit cards as a flexibility to give plans additional options for benefit administration. However, if it is impractical, unfeasible, or difficult to effectuate a particular supplemental benefit through a debit card, CMS does not expect a debit card to be used. Plans should choose the method—whether debit cards, receipt-based reimbursement, electronic catalogs, home delivery, or other approaches—that best enable them to furnish benefits in compliance with program requirements.

In response to the request for examples of permissible methods of meeting the real-time identification requirements, CMS refers commenters to the January 2021 Final Rule, which noted that plans could use merchant codes, inventory approval system codes, or other similar mechanisms (86 FR 5914). CMS recognizes that health plans have successfully utilized debit cards to deliver healthcare benefits for many years and that the industry has developed substantial expertise in this area. CMS anticipates continued technological advancement and therefore refrains from prescribing specific technological solutions or providing exhaustive examples. It is not CMS's intent to dictate the technology employed, but rather to establish clear expectations for outcomes: enrollees should experience seamless front-end user experiences that preserve both ease of access and transparency. Finally, regarding the request to permit either electronic or manual verification of plan-covered benefits at point-of-sale: CMS does not consider manual verification to be real-time verification. Electronic verification requires automated, system-to-system data exchange and validation processes that occur without manual intervention. However, plans may certainly use manual verification as a troubleshooting alternative when experiencing technological issues with their electronic verification systems. This approach can serve as a temporary workaround to ensure continuity of operations while technical problems are being resolved.

Comment: Similarly, some commenters stated that difficulties could arise at small or independently-owned retail stores that do not have the same technological infrastructure or capacity as larger national chain stores. Another commenter explained that in many cases, plans do not have a contractual relationship with retail stores where debit cards are commonly used, as there is often a financial technology company in the middle. They explained that these plans select products that should be covered, then the third-party administrator and the retail store match products to SKUs.

Response: CMS thanks commenters for sharing their concerns and providing additional insight into how plans operationalize the furnishing of covered supplemental benefits through debit cards. It is important to reiterate that MA operates under a particular structure governed by statutory and regulatory rules. MA plans that offer coordinated care plans may specify the networks of providers from whom enrollees may obtain services, including supplemental benefits. Furthermore, MA organizations have the discretion to choose with whom they contract to furnish services. Section 1854(a)(6)(B)(iii) of the Act, commonly known as the ''non-interference clause,'' prohibits CMS from requiring an MA plan to contract with a particular health care provider, including vendors, to furnish a benefit. This applies to supplemental benefits as well. CMS recognizes that the technological landscape has evolved and many plans no longer contract directly with retailers. Instead, they partner with financial technology companies to oversee card usage, which impacts which vendors can participate. These arrangements are acceptable, provided that plans comply with CMS requirements, especially disclosure requirements which describe the applicable conditions and limitations associated with the use of supplemental benefits. Finally, CMS reiterates that debit cards are not unrestricted cash cards. Section 1851(h)(4)(A) of the Act prohibits plans from providing cash to enrollees. Instead, debit cards serve as one mechanism that plans may use to furnish covered benefits. Consistent with the MA program structure—in which plans furnish services through a

network of providers or vendors—debit cards are not intended to be usable everywhere.

Comment: Several commenters expressed support for having alternative reimbursement processes available to protect enrollee access to benefits. Some plans acknowledged that they already have processes in place for alternative reimbursement and one plan requested that CMS recognize these existing practices while clearly stating any intended changes to standard industry practices. Another commenter supported the proposal but recommended that for geographic areas where vendor capacity for alternative processes does not currently exist, CMS should allow adequate timeframe for vendors to build out this function.

However, other commenters raised concerns about the administrative burden that may be associated with manual receipt reimbursement processes as an alternative to debit cards. Some plans stated that supplemental benefits like OTC and food allowances rely on CMS-approved product listings comprising thousands of items, and that the automated nature of debit cards ensures real-time validation at the point of sale. Several commenters indicated that mandating a manual reimbursement process would require extensive administrative effort, including additional full-time staff to individually review each item. Some plans stated that current card vendors lack infrastructure to manage receipt reimbursements, meaning the burden would fall entirely on plans. Another commenter expressed concern that requiring an alternative reimbursement process could lead to member confusion, as the debit card enables members to know at the point of service whether a product is eligible, whereas after-the-fact filing could result in situations where purchases made in good faith are not actually reimbursable. Some commenters requested examples from CMS of permissible alternate payment methods that would comply with requirements, as well as examples of issues that would warrant using an alternate process. Several commenters expressed concern that allowing alternative processes would set a precedent with members that they could obtain other plan services through non-contracted locations or providers.

Response: CMS thanks commenters for their feedback. As described in the Contract Year 2026 proposed rule, longstanding guidance at Section 40.3.1 of Chapter 4 of the Medicare MCM requires plans to allow manual reimbursement for OTC purchases via submitted receipts in certain situations. To maintain enrollee access for all benefits administered through a debit card, CMS proposed to codify at § 422.102(g)(2)(iii) that plans must have an alternative reimbursement process for eligible expenses. This would include technical issues such as difficulty using the debit card, provider system failures, erroneous transaction declines, or other situations where debit card use is unfeasible. However, based on feedback from commenters, CMS agrees that the requirement as proposed could inadvertently cause confusion among enrollees regarding how to access in-network benefits. Therefore, CMS will amend § 422.102(g)(2)(iii) to more specifically state that plans must have an alternative process that allows for reimbursement of eligible expenses for plan covered benefits in circumstances where the debit card is unusable at the point of sale, including but not limited to debit card malfunction.

As noted throughout this rule, plans must ensure that beneficiaries maintain access to covered supplemental benefits regardless of the payment mechanism used to administer those benefits. Whether a plan provides access through a debit card or another payment method, the underlying benefit must remain available to eligible enrollees. The manual reimbursement requirement serves as a safeguard to ensure access to eligible services in situations where the debit card becomes unusable due to malfunction, damage, or other technical failures. This requirement protects beneficiaries from losing access to their covered benefits simply because the payment mechanism is temporarily unavailable.

Comment: One commenter requested that CMS reconsider its proposal to allow PPO supplemental benefits to be used at any retailer, noting that expanding benefits to any retailer would require plans to manage approvals and validations manually, significantly increasing administrative complexity. Another commenter asked CMS not to finalize the out-of-network reimbursement requirement. Some commenters expressed concern that CMS's requirement for plans to provide all benefits at in-network cost-sharing rates when no in-network provider is available could expose the program and plans to potential bad actors, as many supplemental benefit providers are not Medicare-enrolled medical providers and are vetted through contractual agreements.

Response: Regarding PPO out-of-network reimbursement, CMS notes that current regulations at § 422.4(a)(1)(v) require MA plans that are PPOs to provide reimbursement for all covered services, regardless of whether the services are furnished within the plan's contracted network. As CMS stated in the 2005 final rule (70 FR 4598) establishing this requirement, CMS intended that local and regional PPOs reimburse enrollees for all covered benefits, regardless of whether those benefits are provided within the network of providers. This longstanding requirement applies regardless of the mechanism through which a benefit is furnished.

Additionally, while plans may maintain established systems for administering supplemental benefits—such as limiting debit card functionality to contracted vendors—supplemental benefits remain covered benefits, and PPOs must still provide reimbursement for covered services obtained out-of-network. CMS has long articulated a similar expectation in sub-regulatory guidance. For example, section 40.3.1 of Chapter 4 of the Medicare MCM states that MA plans, regardless of the payment method used to furnish OTC benefits, must provide a mechanism for manual reimbursement under described circumstances (such as when a debit card network is not functioning). This guidance reflects CMS's longstanding expectation that the method used to administer a benefit does not alter a plan's obligation to ensure access to and reimbursement for covered supplemental benefits in certain situations.

To provide additional clarity, CMS will further amend § 422.102(g)(2)(iii) to specify that plans must establish an alternative process that permits reimbursement of eligible expenses in circumstances where the debit card is unusable at the point of sale, as described earlier in this section, as well as when a beneficiary is entitled to obtain covered benefits out-of-network. As a best practice, plans retain the discretion to implement appropriate verification procedures and safeguards to ensure reimbursement is provided only for actual covered items. CMS recommends that plans consider these requirements when deciding whether a debit card is the most appropriate mechanism for furnishing certain covered benefits.

For Health Maintenance Organization (HMO) plans specifically, it is important to note that ''eligible expenses'' under the manual reimbursement requirement refer exclusively to covered services obtained in accordance with the plan's network requirements. In an HMO, manual reimbursement does not extend to purchases made from out-of-network providers or vendors or suppliers, as

such services would not constitute eligible covered benefits under an HMO plan structure. The intent of this provision is to protect beneficiary access to covered benefits when the debit card payment mechanism fails, not to expand coverage to out-of-network services that fall outside the plan's benefit design. CMS reminds readers, however, that even if an MA plan chooses to administer supplemental benefits through a debit card, the plan must still arrange for and cover any medically necessary covered benefit outside of the plan provider network, at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs under 42 CFR 422.112(a)(1)(iii).

Finally, in response to the request that CMS not finalize the requirement that MA plans provide all benefits at in-network cost-sharing rates when no in-network provider is available, CMS again notes that this is an existing requirement at 42 CFR 422.112(a)(1)(iii) and is applicable to all covered benefits, including supplemental benefits, regardless of delivery method. This requirement applies only when a plan lacks an adequate contracted provider or vendor to furnish a covered benefit—a situation expected to be rare. It does not require plans to always cover benefits outside the provider network at in-network cost sharing.

Comment: A commenter requested that CMS not finalize the removal of the proposed language ''or other means'' at proposed § 422.102(a)(6)(i), stating that it would unnecessarily restrict plans from using alternatives such as stored value cards or future technological developments like mobile applications.

Response: CMS thanks the commenter for this feedback. The Contract Year 2026 proposed rule proposed to remove ''or other means'' from the regulation and solicited comments on which alternative delivery methods beyond manual reimbursement or debit cards might be unintentionally eliminated, and whether stored value cards can meet the requirements at § 422.102(g), specifically regarding real-time point-of-sale verification and plan-year-only restrictions.

CMS clarifies that, as explained in the January 2021 rule, the cost-sharing reduction flexibilities authorized at § 422.102(a)(6)(i) and (ii) do not exclude stored value cards, provided they can be programmed to permit their use only for the purchase of specific, covered items and services. The changes proposed at § 422.102(a)(6) were not intended to prohibit stored value cards, provided they comply with the requirements at § 422.102(g). CMS solicited comment on whether to remove the phrase ''or other means'' from § 422.102(a)(6)(i) and instead specify the types of cards or mechanisms that would satisfy the proposed requirements under § 422.102(g).

CMS received no direct comments on these questions but appreciates the commenter noting the possible unintended consequences of removing ''or other means.'' Therefore, CMS will not finalize the removal of ''or other means'' in § 422.102(a)(6)(i). Stored value cards will continue to be permitted as a mechanism to administer reduced cost sharing and covered benefits, provided such cards comply with the requirements under § 422.102(g). CMS anticipates continued innovation in this technological space and welcomes opportunities to engage with stakeholders on emerging advancements.

Comment: Multiple commenters requested clarification on various technical aspects of the proposal, including: examples of how plans can meet disclosure requirements and model documents; whether plans may use the same physical card year to year with only the amount expiring; whether a plan can disclose categories of OTC items as opposed to each individual OTC item; and more detailed specifications for customer service requirements. Several commenters stated that MA organizations already have processes in place for delivering plan-covered supplemental benefits and providing education to enrollees, and that the objective of the new proposed requirements is unclear.

Response: CMS appreciates the comments received and acknowledges that many plans are likely to have processes in place to meet several of the proposed requirements in this rule. As stated throughout this rule, many of these requirements primarily codify and further clarify existing expectations. In response to requests for clarification on whether plans may use the same physical card year to year with only the benefit amount expiring, CMS proposed and is finalizing at § 422.102(g)(2)(iv) that supplemental benefits administered through debit cards must be limited to the plan year. Plans may allow enrollees to use the same physical debit card in subsequent plan years; however, the dollar amounts or benefit allocations associated with the card cannot carry over from one plan year to the next. This ensures that each plan year's benefits are utilized within the designated plan year period.

Regarding whether a plan can disclose categories of OTC benefits as opposed to listing each individual benefit, the listing of categories of covered OTC benefits is permissible provided the plan discloses any limitations and is able to provide more specific details to the enrollee if necessary. CMS declines to provide more prescriptive guidance, as the purpose of these requirements (*e.g.,* adequate transparency and enrollee support) is clear, and CMS does not wish to be overly restrictive to plans that may already have adequate processes in place. CMS will continue to engage in dialogue with plans and may provide additional guidance at a later date as necessary.

Comment: A commenter expressed concern that cards function as inducements and that beneficiaries may make enrollment decisions based on having a ''card'' rather than the overall benefit package.

Response: As noted in the Contract Year 2026 proposed rule, CMS shares concerns that beneficiaries may base enrollment decisions on perceived debit card access rather than the comprehensive benefits package. CMS encourages all enrollees and potential enrollees to consider the full benefits package when selecting a plan. The increased disclosure requirements in this rule are designed to improve transparency and support informed enrollment decisions, and CMS will continue to monitor developments in this area and welcomes ongoing stakeholder feedback.

Comment: Some commenters expressed concern about lack of transparency surrounding delivery and use of benefits. While supporting the proposal, another commenter noted concerns that it would not allow other agencies or entities to monitor whether plan-provided debit cards are being used only for items that meet criteria. Another commenter suggested that CMS should work to ensure MA plans share information with providers on supplemental benefits available to patients in real time, at the point of care, and in a standardized manner. A commenter, while supporting the proposal, expressed concern that the proposed guardrails do not prevent someone other than the beneficiary from using the card.

Response: CMS thanks commenters for sharing their concerns. It is noted that existing requirements mandate MA plans to disclose all supplemental benefits. The new requirements clarify that such disclosures must include all applicable conditions and limitations associated with the receipt or use of supplemental benefits, and that this disclosure applies to all benefits, including those administered through a

debit card. The existing requirements, along with the proposed disclosure clarifications regarding applicable conditions and limitations and benefits furnished through debit cards, are sufficient to ensure transparency. Additionally, per § 422.2267(e)(34), plans offering CMS-approved SSBCI are required to include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI. In the SSBCI disclaimer, plans must list the chronic condition(s) the enrollee must have in order to be eligible for the SSBCI (in accordance with CMS requirements). Plans must also convey in the SSBCI disclaimer that even if the enrollee has a listed chronic condition, the enrollee will not necessarily receive the benefit because other eligibility and coverage criteria also apply. Additionally, in section IV.L. of this rule, CMS is finalizing a requirement that MA organizations post their SSBCI eligibility criteria on their plan websites. CMS believes this requirement, together with existing transparency requirements, will enhance overall transparency regarding SSBCI benefits.

Regarding comments about provider transparency, CMS expects MA plans to ensure that contracted providers are informed about covered benefits and plan policies relevant to the furnishing and coordination of care. Such information-sharing supports appropriate benefit administration and care coordination between the plan and its network providers. Lastly, CMS thanks the commenter for raising concerns that the proposed guardrails do not prevent non-enrollees from using the debit card. CMS shares these concerns about potential abuse and will further evaluate this issue for possible additional guardrails in future rulemaking.

Comment: A commenter opposed CMS requiring debit card transactions to be included in the Explanation of Benefits (EOB).

Response: Thank you for the comment. As explained in the Contract Year 2026 proposed rule, MA organizations must send enrollees an Explanation of Benefits (EOB) monthly or quarterly that includes all Part C claims activity—covering basic benefits, mandatory and optional supplemental benefits, and SSBCI. Each claim must show a descriptor, billing code, amount billed, approved reimbursement, plan payment, and enrollee liability. EOBs must also include year-to-date information such as amounts toward the Maximum Out-of-Pocket (MOOP) limit. These existing requirements apply to all benefits, including those accessed via a plan debit card, regardless of delivery method. Plans experiencing operational challenges in meeting these requirements when using debit cards may wish to evaluate whether an alternative mechanism would be more suitable for furnishing covered benefits.

Comment: Some commenters requested additional items be added to the allowable OTC list and expressed concerns that non-allowable examples—such as grooming supplies, shampoo, lotion, and hygiene-related items—are overly restrictive. These commenters argued that requiring these items to be available only to members with certain chronic conditions would limit access to many members and increase benefit complexity, making it more difficult to use. They asserted that requiring some OTC items to be offered to all enrollees as primarily health-related supplemental benefits, while allowing others to be limited to chronically ill enrollees as SSBCI, could lead plans to reduce the overall scope of their OTC offerings. Another commenter requested that if CMS proceeds with codifying these changes, the Agency should provide an exhaustive list of allowed and prohibited OTC products to ensure all plans operate under consistent expectations. Additionally, a commenter suggested that only oral health products bearing the ADA Seal of Acceptance should be included as eligible OTC items for purchase with debit cards.

Response: CMS thanks commenters for their suggestions. As explained in the Contract Year 2026 proposed rule, plans have indicated that a non-exhaustive list would provide further clarity for MA organizations and would assist in their bid preparations. Such lists were common in previous sub-regulatory guidance, making this an appropriate opportunity to provide an updated list of items CMS has previously approved. CMS declines to add more items to this list because an item's absence does not prohibit a plan from proposing to offer it. CMS also declines to provide an exhaustive list, as this would inhibit plans' ability to further innovate in this area. Regarding the comment that plans only provide oral health products bearing the ADA Seal of Acceptance, plans may propose to offer any OTC provided they meet CMS requirements, particularly those at § 422.100(c)(2) and under § 422.102. Further delineations, such as products endorsed by specific independent advisory groups, are at the discretion of the plan. With respect to grooming supplies, shampoo, lotion, and similar hygiene-related items, a supplemental benefit is not primarily health-related if the item or service is used solely or primarily for cosmetic, comfort, general use, or social determinant purposes (86 FR 5971). CMS considers such items to be general use items that do not qualify as primarily health-related benefits. Alternatively, plans may propose to offer these items as SSBCI benefits, provided all requirements under § 422.102(f) are met.

Comment: Some commenters requested that CMS allow food, housing, and transport as primarily health-related, and another commenter requested a non-exhaustive list of allowable special supplemental benefits for the chronically ill. Some commenters raised concerns about cards counting towards resources in federal programs and suggested CMS should issue a rule clarifying that these benefits are not income for purposes of Medicaid and other federally funded programs. A commenter recommended CMS regularly analyze and report plan-level data on supplemental benefits to assess their impact on health expenditures and outcomes. Another commenter suggested that CMS expand supplemental benefit data reporting. Others expressed concerns regarding the potential consequences of VBID sunsetting, particularly the inability of plans to transition certain VBID benefits in MA. Some FQHCs requested CMS update Medicare Claims Processing Manual guidance concerning supplemental payments.

Response: CMS appreciates these comments. However, they are out of scope of this regulation.

Comment: Regarding comments on CMS's proposal to prohibit MA organizations from marketing the dollar value of a supplemental benefit or the method by which a supplemental benefit is administered, most comments were not supportive. The majority of commenters argued that prohibiting marketing of supplemental benefit dollar values would reduce transparency and harm informed decision-making. They stated beneficiaries have a right to know benefit values before enrolling, that supplemental benefits were often the most important reference point, and that the restrictions would create ''secret benefits.''

Response: CMS thanks commenters for their feedback. In consideration of the comments received, at this time, CMS has decided not to finalize the proposed amendment to § 422.2263, regarding MA organizations' marketing of supplemental benefits.

Comment: Commenters also questioned how beneficiaries would obtain this information beyond dense

Evidence of Coverage documents and noted that failing to disclose benefit values was itself potentially misleading. Commenters noted that without benefit value information, beneficiaries could not differentiate between similar plans or compare value across MA organizations. which could create distrust and cause beneficiaries to decline plans they might otherwise prefer. In addition, some commenters were concerned that the proposal would burden seniors by requiring them to call multiple plans for critical information, potentially leading to more complaints, unwitting enrollment, and benefit misuse.

Response: CMS appreciates these additional concerns raised by commenters. As noted previously, CMS is not finalizing the proposed supplemental benefits marketing provision.

Comment: Some commenters suggested that low-income seniors and dual-eligible beneficiaries would be particularly affected if the proposal to restrict debit card marketing were finalized. For example, commenters noted that in Puerto Rico, where over 45 percent of MA enrollees were dual eligible, debit card availability and benefit dollar values were most relevant to low-income seniors. Commenters stated that supplemental benefits filled gaps in federal benefits, helped cover Part B premiums, reduced pharmacy costs, and provided food and nutrition services, and furthermore, beneficiaries with specific health needs relied on supplemental benefits existing only in MA plans. In addition, a few commenters believed CMS's proposed debit card marketing restrictions would disincentivize plan innovation and stated it was not within CMS legal authority to impose judgment on which benefits were most significant to beneficiaries.

Response: CMS again thanks commenters for this valuable input. In light of concerns raised by the commenters and as previously discussed, CMS is not finalizing the marketing proposal at this time.

Comment: Other commenters urged CMS to focus on bad actors rather than broadly restricting all plans. They recommended revising guidance to provide clear examples of prohibited misleading marketing, working with plans to develop clearer communication standards, requiring disclaimers when marketing benefit values, and establishing limits on card amounts and approved services.

Response: CMS thanks commenters for these ideas and may take them under consideration for future policymaking regarding supplemental benefit marketing issues.

Comment: Several commenters supported prohibiting marketing of administration methods but opposed prohibiting marketing of dollar values, arguing this deprived beneficiaries of critical decision-making information. They understood CMS concerns about consumer confusion but believed these should be addressed with more information and transparency, not less. They also noted that not providing information on benefit access could result in beneficiary confusion contrary to CMS transparency efforts and could negatively impact Star Ratings measures based on the Complaints Tracking Module.

Response: CMS appreciates this feedback. While CMS is opting not to finalize this aspect of the proposal at this time, the Agency may take this feedback into consideration for future rulemaking.

Comment: Some commenters supported CMS efforts to prevent misleading advertising that interfered with beneficiaries' plan selection, particularly ads suggesting ''free money'' without restrictions. They endorsed prohibiting marketing of benefit administration methods. Commenters reported instances where flex card advertising induced individuals to disenroll from PACE or switch plans, resulting in loss of care. A few commenters recommended additional safeguards requiring ads to identify coverage limits, covered items, and eligibility restrictions in the same font or volume as the main content. Other commenters recommended limiting television, billboard, and radio marketing mentioning debit card amounts while allowing such information in plan materials with appropriate disclaimers.

Response: CMS again thanks commenters for their comments and recommendations on these various issues. CMS is not finalizing the marketing proposal at this time but will consider the comments received for future policymaking.

Summary of Regulatory Changes

After considering the comments received and for the reasons outlined in the Contract Year 2026 proposed rule and in responses to comments, CMS is taking the following actions in this final rule:

1. Finalizing § 422.111(b)(6) as proposed, which requires MA plans to disclose all supplemental benefits, including applicable conditions and limitations, eligible over-the-counter items, and benefits accessible through debit cards.

2. Finalizing the new subparagraph § 422.102(g) with modifications, specifically amending § 422.102(g)(2)(iii) to state that plans must have an alternative process that allows for reimbursement of eligible expenses for plan covered benefits in circumstances where the debit card is unusable at the point of sale, including but not limited to debit card malfunction or when a beneficiary is entitled to obtain covered benefits out-of-network.

3. Not finalizing the proposed amendment to § 422.102(a)(6)(i), which would have eliminated ''or other means'' as an acceptable way to administer cost-sharing reductions.

4. Not finalizing the proposed amendment to § 422.2263, which would have prohibited MA organizations from marketing the dollar value of a supplemental benefit or the method by which a supplemental benefit is administered, such as use of a debit card by the enrollee to provide the plan's payment to the provider for the covered services.

V. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (Star Ratings) (§§ 422.162, 422.164, 422.166, 423.182, 423.184, and 423.186)

A. Introduction

CMS develops and publicly posts a 5-star rating system for Part C,[83] 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 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

[83] We generally use ''Part C'' to refer to the quality measures and ratings system that apply to MA plans and cost plans.

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 [84] evolves over time to increase the health and wellbeing of enrollees. In this final rule, we are finalizing most of the changes proposed to simplify and refocus the areas included in the Star Ratings, including changes to the measure set, with the exception of the proposal to remove the Diabetes Care—Eye Exam measure from the Star Ratings. We also are finalizing our proposal 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 are finalizing adding 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 solicited comments in the Contract Year 2027 proposed rule 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. In this rule we are also finalizing a technical clarification proposed in 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 proposed rule, which appeared in the **Federal Register** on December 10, 2024, to provide details about how the enrollment-weighted measure score is calculated when a consumed or surviving contract is missing data for a measure. We also solicited additional feedback related to Star Ratings in the Request for Information on Future Directions in Medicare Advantage in section 6 of the Contract Year 2027 proposed rule.

B. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184)

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) (''Contract Year 2019 final rule''), we stated we are committed to continuing to improve the Part C and 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 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.

The regulations at §§ 422.164 and 423.184 specify the criteria and procedures for adding, updating, and removing measures for the Part C and D Star Ratings program. 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 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 proposed 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 also proposed 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.

We received several comments on our proposal to clarify existing policies and procedures on measure removal. A discussion of these comments follows, along with our responses and final decision.

Comment: All commenters expressed support for the proposed language to clarify the process of measure removal.

Response: We appreciate the support received for the proposed clarification and thank the commenters for their feedback.

Comment: A few commenters emphasized the importance of transparency and the value of stakeholder engagement as part of the comment process for measure removal, particularly for high-impact clinical measures, including those affecting common chronic conditions.

Response: We agree with these commenters and highlight here that removals for the reasons stated in §§ 422.164(e)(1) and 423.184(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 (that is, the annual Advance Notice and Rate Announcement) or proposed and finalized through rulemaking. We intend to use whichever process allows for the most expedient notification to MA organizations and Part D sponsors. We appreciate the value of robust stakeholder engagement and note that stakeholders will continue to have an opportunity to provide input regarding measure removals.

Comment: Another commenter urged CMS to ensure that MA enrollees are not harmed by any measure removal and that the needs of enrollees and their providers take priority in decision-making concerning MA and Part D.

Response: CMS monitors the Part C and D Star Ratings and display page

[84] *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

measures for quality improvement, relevance, and necessity. CMS publishes display measures on *www.cms.gov* each year, including measures that have been transitioned from the Star Ratings, new measures that are tested before inclusion in the Star Ratings, or measures displayed for informational purposes only. This listing of measures is separate and distinct from CMS's Part C and D Star Ratings. If CMS identifies the need to remove a measure from the Part C and D Star Ratings program for any of the reasons stated in §§ 422.164(e)(1) and 423.184(e)(1), measure removal will be announced in a timely manner either 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. CMS will consider public input on measure removals, including any impact on enrollees and providers.

After consideration of the comments received and for the reasons outlined in the Contract Year 2027 proposed rule and our response to comments, we are finalizing the proposal at §§ 422.164(e)(2), 422.164(e)(3), 423.184(e)(2), and 423.184(e)(3) without modification. Since this codification is consistent with current practice and policy, it will apply immediately on the effective date of the final rule and to the 2027 Star Ratings.

1. Removing Measures

As the Part C and D Star Rating program continues to evolve and align with the measures included in the Universal Foundation,[85] a strategy to align measures across the agency's quality and value-based care goals, we proposed 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[86] and other interested parties that CMS consider having fewer measures in the Part C and 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''),[87] as well as from the Star Ratings Technical Expert Panel (TEP) in October 2024.[88]

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,[89] we proposed 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 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 D Star Ratings program, 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 D Star Ratings program, and MA organization and Part D sponsor performance rates are consistently fairly high.

We also proposed 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

[85] *https://www.cms.gov/medicare/quality/cms-national-quality-strategy/aligning-quality-measures-across-cms-universal-foundation.*

[86] Replacing the Medicare Advantage quality bonus program—MedPAC.

[87] *https://www.cms.gov/files/document/2026-advance-notice.pdf.*

[88] *https://www.rand.org/pubs/conf_proceedings/CFA3973-1.html.*

[89] See pages 107–110 at *https://www.cms.gov/files/document/2026-announcement.pdf* for a summary of comments.

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 proposed to remove the 12 measures in Table 3 beginning with the Star Ratings year shown in the table for each measure. As stated in the Contract Year 2027 proposed rule, 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 final rule, would generally increase ratings. We provide the estimated combined impact of the final Star Ratings policies in section XI.C.6. of this final 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 3: 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

We solicited feedback on all of the potential measure removals discussed in the Contract Year 2027 proposed rule, including feedback on the timing of measure removals and received many comments. A discussion of general measure removal comments, along with our responses follows. Comments about specific measures and our responses are summarized below each specific measure discussion.

Comment: Some commenters supported streamlining and refocusing the Star Ratings measure set. These commenters supported a focus on clinical care, outcomes, and patient experience.

Response: We thank these commenters for their support.

Comment: Some commenters were concerned that removing measures will reduce oversight and transparency of plan performance. Several commenters recommended that the measures continue to be reported on the display page. Some commenters were also concerned about the potential loss of quality gains if the measures are removed.

Response: CMS agrees that continued transparency and oversight are important when measures are removed from Star Ratings. Thus, CMS will continue to publicly report removed measures on the display page, which are displayed separately on cms.gov and not on Medicare Plan Finder, and will continue to monitor plan performance through its existing oversight and compliance activities. Where CMS identifies that an MA organization has failed to comply with the terms of its contract, we will continue to take appropriate compliance actions per 42 CFR 422.504(m)(3) and publicly post warning letters and corrective action plan requests (CAPs). If an organization receives too many compliance actions, CMS may deny applications for new contracts or service area expansions under 42 CFR 422.502(b)(1) for failure to perform in accordance with CMS contractual requirements. This approach preserves oversight of plans and transparency for beneficiaries and other interested parties while allowing the Star Ratings program to focus on measures that more meaningfully differentiate performance across contracts.

Comment: Some commenters expressed concern about removing administrative measures and noted that it may distort competition in MA by disproportionately harming smaller or regional plans and SNPs, and increase revenue volatility. They cautioned that outcomes-based measures alone are often harder for plans to control, and that administrative measures provide a stabilizing counterbalance within the Star Ratings system.

Response: CMS appreciates commenters' perspectives regarding the potential programmatic impacts of removing administrative measures from the Star Ratings program. CMS recognizes that outcomes-based measures can be more challenging for plans and that administrative measure scores have historically remained stable within the Star Ratings system given the high performance across all contracts. However, measures included in Star Ratings should meaningfully differentiate performance across contracts. Measures with little variation across contracts do not provide meaningful comparative information for potential enrollees when choosing a plan. CMS will continue to evaluate the mix of measures included in the Star Ratings program and its impact on plans of varying sizes. With regard to smaller plans or SNPs, in simulations of the impact of the proposed changes, we did not find that there were disproportionate impacts to these types of plans (see the Impact of Proposed and Finalized Changes section for more details).

Comment: Some commenters supported simplification of the Star Ratings, but cautioned against wholesale removal of measures without replacement. They recommended that if measures are removed from Star Ratings, CMS should consider beneficiary impacts and maintain robust, transparent compliance monitoring, enhanced CAHPS

questions, or public reporting to preserve accountability. Many of these commenters emphasized that the removed measures should still be publicly reported, even if CMS restructures how they are measured or incentivized.

Response: CMS appreciates commenters' support for simplifying the Star Ratings program while maintaining accountability. CMS agrees that continued transparency and oversight are important when measures are removed from Star Ratings. Thus, CMS will publicly report removed measures on the display page and will continue to monitor plan performance through its existing oversight and compliance activities. This approach preserves transparency for beneficiaries and other interested parties while allowing the Star Ratings program to focus on measures that more meaningfully differentiate performance across contracts.

Comment: A commenter stated that as CMS makes changes to the Star Ratings including proposing to eliminate the HEI reward, and adding and removing measures, CMS should ensure that changes are communicated to beneficiaries in an accessible way, including with State Health Insurance Assistance Programs (SHIPs) assistance. The commenter also stated that educational and training materials should be provided to SHIP counselors to help them understand and interpret the changes.

Response: We agree it is important for beneficiaries to understand the Star Ratings and we are considering how to best present the Star Ratings to make it easier for beneficiaries to understand. For example, we are reviewing how the ratings are presented on the Medicare Plan Finder website.

Comment: Some commenters raised concerns about Star Ratings volatility, destabilizing the Star Ratings system, and downstream impacts to QBPs if CMS removes multiple administrative measures at the same time. These commenters also raised concerns about making the remaining measure set smaller and more sensitive to single-measure changes. Some commenters were concerned about removing too many measures too fast and recommended a phased approach for removal of measures. Commenters also raised concerns about program disruption, which they believe will undermine the predictability and stability of the program and impact beneficiary experience.

Response: CMS does not agree that removal of measures destabilizes the Star Ratings program. The measures we proposed for removal have topped out (*i.e.,* have very high performance across all contracts such that cut points for the measure are very close together and do not reflect meaningful differences in performance), are duplicative, or no longer provide meaningful differentiation across plans. Retaining such measures reduces the impact of measures that better distinguish differences in plan quality and performance. Removing these measures in a timely manner strengthens the Star Ratings program and supports informed beneficiary choice.

Comment: A couple of commenters recommended changing measure specifications or redesigning measures rather than removing measures. Other commenters proposed alternative approaches to deal with a ''topped-out'' measure apart from removing it from Star Ratings, including increasing the cut points, penalizing contracts if performance is not maintained, creating a composite measure of operational performance, and reassessing whether or how high-scoring measures should impact payment.

Response: As discussed in the Contract Year 2027 proposed rule, the Part C and D Star Ratings program continues to evolve and align with the measures included in the Universal Foundation. As such, we proposed simplifying and refocusing the measure set to focus on measures of clinical care, outcomes, and patient experience 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 MAHA initiative. Our proposal aimed to strike a balance between streamlining the measure set and maintaining enough measures to assess performance across the range of health care quality.

Comment: A commenter expressed concern that the removal of measures will create a substantial shift in how the measures are weighted, stating that 44 percent of the weighting would shift to member survey results for CAHPS and HOS. The commenter stated that these surveys are often unduly influenced by factors such as timing of the survey, memory recall bias, and survey fatigue. The commenter also stated that there is randomness, unpredictability, and volatility inherent in survey measures and how they are scored does not correlate to actual plan performance.

Response: We appreciate the commenter's concern regarding the potential impact of removing certain measures on the weighting of remaining measures, including the increased contribution of CAHPS and HOS survey measures. We disagree that these survey measures are unduly volatile or fail to reflect actual plan performance.

CAHPS and HOS are standardized, validated instruments designed to capture beneficiary experience and health outcomes. CMS employs multiple methodological safeguards, including standardized survey administration, large sample sizes, and case-mix adjustment to ensure reliable information that is comparable across contracts.

CAHPS and HOS measures provide information that complements clinical and administrative measures. Incorporating beneficiary-reported measures also aligns with CMS's commitment to evaluating beneficiaries' experiences of care and ensures that quality measurement reflects aspects of care that are best assessed by beneficiaries themselves. Accordingly, we find that the weighting of CAHPS and HOS measures remains appropriate.

Comment: A commenter stated that administrative measures were within plan control rather than health care provider control and should be retained. Another commenter recommended that CMS evaluate measures based on the degree of plan-level control and overlap with existing incentives in order to help prioritize measures where Star Ratings are most likely to produce improvements.

Response: CMS does not agree that non-administrative measures are not within plan control. The measures included in the Star Ratings are evaluated at the contract level and reflect the collective performance of the organization, including the organization's provider network. For each of its contracts, MA organizations are responsible for establishing provider networks, designing benefits, furnishing care management and care coordination services, and implementing quality improvement strategies to support measure performance.

Comment: A commenter supported the idea of simplifying the measure set in concept but did not support the proposal because of the associated increase in Medicare spending. The commenter stated that if CMS streamlines the measure set in future rulemaking, it should do so in a way that does not add cost.

Response: As we stated in the Contract Year 2027 proposed rule, 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 not implementing the HEI reward, along with keeping the

historical reward factor, would generally increase ratings. While the combination of these two proposals results in net costs, the measure removal proposal on its own would result in savings.

Comment: A couple of commenters raised concerns about the ability of I–SNPs to have data for enough measures to receive an overall Star Rating. A commenter also stated that the measures proposed for removal are in areas where these plans typically perform well, noting that their removal would magnify the impact of the remaining measures which the commenter believes are not well-suited for long-term care populations.

Response: We appreciate this commenter's concerns about I–SNPs having data for enough measures to qualify for an overall rating. We will continue to monitor this and will consider what additional measures may be available for I–SNP only contracts. With regard to I–SNPs performing well on the measures proposed for removal, we note that this is also true of plans more broadly because performance on many of the measures is very high.

Comment: A commenter raised concerns that removing too many operational and administrative measures may weaken the program's ability to capture aspects of performance that are most relevant to beneficiaries, and that removing the measures may shift focus away from day-to-day experiences that shape beneficiary satisfaction and trust. Another commenter disagreed that the measures proposed for removal are not meaningful to beneficiaries.

Response: CMS will continue to closely monitor any measure removed from Star Ratings through existing oversight and compliance activities and will publicly report these measures on the display page. This approach preserves transparency for beneficiaries and other interested parties while allowing the Star Ratings program to focus on measures that more meaningfully differentiate performance across contracts.

Comment: A commenter stated that some measures that appear topped out are actually influenced by gaming among plans.

Response: We appreciate the commenter's concern. CMS is not aware of evidence of widespread gaming across Star Ratings measures. However, CMS agrees that measures that are vulnerable to manipulation or no longer meaningfully differentiate plan performance are not appropriate for continued inclusion in the Star Ratings.

Comment: A commenter recommended using statistical tests of variation over time to determine whether a measure should be removed and implementing a cap in the number of measures removed in a year.

Response: CMS appreciates this comment; however, we have evaluated performance on the measures proposed for removal and find that it is appropriate to remove them now in line with our goal of streamlining and refocusing the measure set.

a. Plan Makes Timely Decisions about Appeals (Part C) and Reviewing Appeals Decisions (Part C)

We proposed 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.

We solicited comment on removing the appeals measures from the 2029 Star Ratings. A discussion of Part C appeals measure removal comments, along with our responses follows.

Comment: Many commenters opposed removing appeals-related measures from the Star Ratings, emphasizing that these measures are essential indicators of access to care. They argued that appeals measures capture utilization management problems, including inappropriate denials, delays in post-acute care, and failure to process or forward appeals appropriately. Other commenters stressed that these measures are not merely administrative but directly tied to care continuity, discharge planning, transitions of care, and prevention of avoidable complications, hospitalizations, or functional decline. Several commenters emphasized that Star Ratings are the primary enforcement and accountability mechanism for the appeals measures within MA. They stated that because Star Ratings drive financial bonuses, enrollment growth, and marketing advantages, they significantly influence plan behavior. Some commenters also noted that appeals measures included in Star Ratings create tangible incentives for plans to reduce inappropriate denials, process appeals correctly, and comply with beneficiary protection requirements. Removing these measures would, in their view, erode accountability and shift reliance to oversight mechanisms that may lack sufficient resources or enforcement power.

Some commenters raised concerns about vulnerable populations, including individuals with complex medical needs, dually eligible individuals, and patients requiring specialized or time-sensitive care such as cancer treatment, post-acute services, or chronic disease management. For these populations, delays in appeals decisions can lead to irreversible harm. These commenters argued that maintaining appeals measures is especially important to ensure these groups are not disproportionately disadvantaged.

Response: CMS appreciates the thoughtful comments regarding the removal of appeals-related measures from the Star Ratings. We agree that the appeals process is a critical beneficiary protection and plays an important role in ensuring access to medically necessary care for all enrollees. Appeal rights are a core component of MA requirements, and plans remain fully accountable for appropriately administering the appeals process for all enrollees, regardless of whether specific appeals measures are included in the Star Ratings.

While CMS is removing the appeals-related measures from the Star Ratings, this action does not diminish plans' obligations under existing regulations at 42 CFR part 422, subpart M to comply with appeals requirements, including timely, accurate, and complete processing of appeals. CMS will continue to actively monitor plans' appeals adjudication through multiple oversight mechanisms, including audits, monitoring activities, and compliance actions. Where CMS identifies noncompliance, we will take appropriate compliance actions per 42 CFR 422.504(m)(3), publicly post warning letters and corrective action plan requests (CAPs), and if an organization receives too many compliance actions may deny applications for new contracts or service area expansions under 42 CFR 422.502(b)(1) for failure to perform in accordance with CMS contractual requirements.

CMS recognizes commenters' concerns that appeals measures reflect issues related to utilization management, inappropriate denials, and

care delays, and that failures in appeals processing can affect care continuity, discharge planning, and transitions of care. CMS also acknowledges the particular importance of an effective appeals process for vulnerable populations, including individuals with complex medical needs, dually eligible individuals, and those requiring specialized or time-sensitive care. Plans are expected to appropriately administer the appeals process for all enrollees, including these populations, as part of their fundamental responsibility to provide access to covered benefits.

Although Star Ratings serve as one mechanism to promote accountability, they are not the sole means by which CMS ensures compliance with MA requirements. CMS will continue to use its full range of oversight and compliance authorities to hold plans accountable for appeals-related failures and to protect beneficiaries' access to care. Appeals are not optional administrative functions; they are a core responsibility of MA plans, and CMS expects plans to administer appeals processes appropriately, consistently, and in compliance with all applicable requirements.

Comment: Some commenters supported removal of the appeals measures, citing methodological concerns such as disproportionate impact on smaller plans due to a smaller number of appeals and the lack of a volume adjustment. Other commenters supported removing the measures because they are operational, topped out, or poorly differentiated across contracts. These commenters argued the measures no longer meaningfully reflect quality, can be excessively burdensome, and are better suited for compliance monitoring than Star Ratings. These commenters supported shifting the Star Ratings program's focus toward clinical outcomes and value-based measures, with appeals oversight handled through audits, CAHPS surveys, or internal CMS monitoring instead of financial incentives.

Response: We appreciate commenters' support for the removal of the appeals-related measures from the Star Ratings program. CMS agrees that these measures no longer meaningfully differentiate performance across contracts due to consistently high performance levels and limited variation, and can be burdensome in that small changes in performance can have an impact on ratings given the measures are topped out. Consistent with commenters' feedback, CMS agrees that these appeals measures are better suited for compliance and program oversight rather than inclusion in Star Ratings as quality measures tied to financial incentives. Appeals processes remain an important safeguard for beneficiaries; however, CMS will conduct oversight of these activities through other monitoring efforts. By removing these measures from Star Ratings, CMS intends to refocus the program on measures that more effectively assess clinical care and beneficiary experience, while continuing to ensure robust oversight of appeals processes through other established channels.

Comment: Some commenters suggested that removing appeals measures from Star Ratings could disadvantage smaller, regional, or single-state plans that often excel in member experience, while benefiting large national plans. Other commenters argued that the appeals measures create uneven operational burden and do not reliably differentiate plan performance, particularly for plans near minimum thresholds.

Response: CMS has found that the appeals measures generally have high performance across all types of contracts which limits their ability to meaningfully distinguish differences in plan performance across contracts, regardless of plan size. For a measure to be useful for a beneficiary choosing a contract, it needs to have variation across contracts to be able to highlight differences in performance. Nevertheless, it will be critical to still calculate, monitor, and publicly report these measures since appeals processing is critical for the success of the MA program. As a reminder, CMS calculates the scores for the appeals measures from data contained in the Independent Review Entity (IRE) data system; thus, there is no burden to plans in these calculations.

Comment: Some commenters stated that high performance on appeals measures may be misleading rather than proof that the measures are no longer needed. Commenters described plan practices that artificially inflate performance, such as overturning denials early to avoid independent review, mislabeling valid beneficiary appeals as provider disputes, or improperly asserting that certain denials are not appealable. These tactics can block access to the IRE and obscure inappropriate denials from CMS oversight.

Response: We appreciate commenters'concerns that high performance on the appeals measures may not accurately reflect beneficiary protections and that tying these measures to Star Ratings may create incentives for plans to focus on appeals measure performance rather than meaningful access to the appeals process. CMS strongly objects to inappropriate practices by plans, such as overturning denials to avoid independent review or misclassifying appeals that can obscure access issues and limit visibility into inappropriate denials. Due to concerns regarding gaming, CMS implemented scaled reductions for the appeals measures to try to ensure all requisite appeals are sent to the IRE. By moving the appeals measures to the display page, CMS intends to reduce incentives to game measure performance while maintaining transparency into plans' appeals performance for beneficiaries and other interested parties. CMS will continue to monitor appeals and address inappropriate denials outside of the Star Ratings and QBP programs and hold plans accountable through compliance strategies as described in the section about general comments regarding measure removals.

Comment: Some commenters expressed concern that plans may deny more services, knowing fewer denials will be challenged or scrutinized. This would increase administrative costs for providers, delay care, and undermine CMS's goals of value-based care and program integrity. A few commenters emphasized that the ''Reviewing Appeals Decisions'' measure is particularly important for ensuring that plans do not shield indefensible denials from independent oversight.

Response: CMS shares commenters' concerns about inappropriate service denials and agrees that it is important to continue close oversight of plan appeals processing. While CMS is removing the appeals measures from the Star Ratings program, CMS will continue to monitor appeals through program audits and other oversight and compliance activities and will publicly report these measures on the display page. Removing these operational measures from the Star Ratings reduces administrative burden for CMS in the calculation of the ratings and allows the Star Ratings program to focus on measures with greater variation across contracts.

Comment: Several commenters argued that improved performance over time should be viewed as evidence that these measures are working, not as justification for elimination. These commenters suggested that sustained increases in appeals timeliness and review scores are attributed to the incentives created by Star Ratings. These commenters suggested that removing the appeals measures risks reversing years of progress and sending a signal that timely, fair appeals are no

longer a priority, even as utilization management and prior authorization remain major sources of access barriers. These commenters emphasized that removing the appeals measures would reduce plans' focus on appeals timeliness and accuracy, likely leading to backsliding, longer delays, and increased inappropriate denials. Several commenters emphasized that when financial and reputational incentives are removed, plans tend to redirect resources away from appeals processing.

Other commenters stressed that the high or ''topped-out'' performance on these measures reflects the success of the Star Ratings program rather than evidence that oversight is no longer needed. Commenters also noted recent declines in performance and persistent outliers at the contract level, arguing these trends show it is premature to remove the measures.

Response: CMS appreciates commenters' views that improved and sustained performance on the appeals measures reflects the effectiveness of the Star Ratings program and the incentives it creates. CMS agrees that timely and accurate appeals processing remains an important beneficiary protection and that continued oversight is necessary. However, the consistently high performance and limited differentiation across contracts indicate that these measures no longer function effectively as Star Ratings quality measures. We have not seen a decline in measure scores over the past year. For the 2026 Star Ratings, Plan Makes Timely Decisions about Appeals had an average score of 98%, and Reviewing Appeals Decisions had an average score of 97%, up from 96% and 95%, respectively, from the prior year.

While CMS is removing the appeals measures from Star Ratings, this does not diminish the importance of appeals timeliness or accuracy nor does it mean that CMS will stop calculating these measures. CMS will continue to closely monitor appeals processing and will publicly report these measures on the display page. Existing MA oversight processes such as program audits and contract monitoring will also continue to apply to the appeals processing measures. This approach maintains accountability and transparency while allowing the Star Ratings program to focus on measures that better differentiate performance.

Comment: A number of commenters urged refinement rather than removal of these measures from Star Ratings to help improve differentiation across contracts. Some commenters focused on methodological and data issues, acknowledging CMS's concerns about small denominators and limited variation. Other commenters recommended standardizing IRE determinations.

Response: CMS appreciates commenters' thoughtful suggestions to refine the appeals measures to improve differentiation across contracts. We will take these comments into consideration if we make future changes to these measures after moving them to the display page. The process of standardizing how the IRE makes decisions is outside the scope of the Star Ratings program.

Comment: Several commenters advocated for expanded public reporting and transparency if CMS proceeds with removal of the appeals measures, including requiring plans to publish annual reports on appeals timeliness, independent review outcomes, and overturned denial rates with stratification by service type. Other commenters suggested that CAHPS surveys and compliance monitoring cannot replace appeals measures in Star Ratings. While CAHPS provides valuable high-level patient experience data, commenters expressed it is lagged and lacks the operational specificity needed to detect real-time access barriers or improper plan practices.

Response: CMS appreciates commenters' recommendations regarding expanded transparency and public reporting following removal of the appeals measures from Star Ratings. CMS agrees that transparency remains important and will continue to publicly report appeals-related measures on the display page, while maintaining oversight and compliance through various monitoring activities. While CMS acknowledges commenters' views regarding limitations of CAHPS surveys for identifying real-time operational issues, CMS will use a combination of public reporting and existing oversight mechanisms to provide appropriate visibility into appeals processing.

After considering the comments we received and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to the comments, we are finalizing the removal of the Plan Makes Timely Decisions about Appeals (Part C) and Reviewing Appeals Decisions (Part C) measures beginning with the 2029 Star Ratings.

b. Special Needs Plan (SNP) Care Management (Part C)

We proposed 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 proposed removing 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.

We solicited comment on removing the SNP Care Management measure from the 2029 Star Ratings. A discussion of SNP Care Management measure removal comments, along with our responses follows.

Comment: Some commenters supported the removal of the SNP Care Management measure, primarily because it is an administrative measure that tracks the percentage of members with a completed a Health Risk Assessment (HRA), as opposed to a more meaningful clinical outcome measure. Several other commenters simply appreciated the simplification of the Star Ratings measures, or recommended monitoring care management through other mechanisms.

Response: We appreciate the support for removing the SNP Care Management measure.

Comment: A number of commenters opposed removal of this measure since they were concerned that removal would reduce plan oversight and they claimed there is already underutilization of HRAs. Several commenters were specifically concerned about how proposed Star Ratings changes would impact SNP contracts, concerned that the removal would have a negative impact on dually eligible individuals as well as I–SNP enrollees, who are typically sicker and have more complex care needs. There were also concerns expressed about specific groups, such as those with kidney disease; commenters emphasized the importance of ensuring access to services for all vulnerable populations.

Response: CMS recognizes that HRAs are an important tool for providers and care teams in determining enrollee needs and ensuring access to appropriate services, particularly for vulnerable populations, including individuals with chronic or complex conditions such as kidney disease. The removal of the SNP Care Management measure from Star Ratings is not intended to reduce the use or importance of HRAs, nor to diminish

the quality of care delivered to SNP enrollees.

The removal of this measure from Star Ratings does not eliminate the requirement for SNPs to conduct HRAs at 42 CFR 422.101(f)(1)(i) and (ii). HRAs remain a required component of SNP model of care requirements and are critical for identifying enrollees' clinical, functional, and cognitive needs, as well as for informing individualized care planning and ongoing care management. Additionally, the SNP Care Management measure will remain available on the display page so performance information will continue to be publicly reported.

Comment: Some commenters suggested ways to modify the current measure. For example, CMS could work with SNPs and other stakeholders to develop a more meaningful measure, including a measure about whether the care identified in the HRA was provided. Other suggestions included expanding the SNP Care Management measure to all MA members and reporting at the geographic level. Another commenter expressed the need for clearer alignment between the NCQA Model of Care accreditation process and any future measures in this area.

Response: We appreciate the suggestions regarding changes to the SNP Care Management measure. We will take these suggestions into consideration for any future updates to this measure after moving it to the display page. We agree that it would be useful to measure whether care was provided since currently the measure just notes whether an HRA was completed and not if the information collected was used to develop and deliver a care plan.

After considering the comments we received and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to the comments, we are finalizing the removal of the SNP Care Management measure beginning with the 2029 Star Ratings.

c. Call Center—Foreign Language Interpreter and TTY Availability (Part C and D)

We proposed removing the Call Center—Foreign Language Interpreter and TTY Availability (Part C and 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 issue compliance actions, and the Star Ratings would continue to capture similar issues related to customer service through the CAHPS survey measures.

We solicited comment on removing the Call Center measures from the 2028 Star Ratings. A discussion of Call Center measure removal comments, along with our responses follows.

Comment: Some commenters supported the removal of the call center measures, noting that their continued inclusion in the Star Ratings system does not meaningfully distinguish plan quality or drive further improvement. Other commenters supported removal since performance is topped out. Some commenters noted the reduction in administrative burden with the removal of these measures and that the current high-performance rates indicate that these measures may no longer be necessary. A few commenters agreed that the focus of Star Ratings should shift to measures that more directly impact clinical outcomes and patient experience. A commenter mentioned that these measures should be removed due to litigation around these measures and volatility in scores due to small denominators.

Response: We appreciate the support for removing the Part C and D Call Center—Foreign Language Interpreter and TTY Availability measures.

Comment: A number of commenters opposed the removal of these measures, stating that they are essential for ensuring meaningful language access and communication for non-native English speakers and those with disabilities. Some of these commenters emphasized the importance of maintaining measures that assess beneficiary experience with plan operations and policy. They stated that removing these measures could reduce oversight and accountability, ultimately harming beneficiary outcomes.

Response: CMS agrees that it is critical to continue to monitor performance on these measures to ensure that enrollees who speak languages other than English and those that are hearing impaired have access to plan call centers. CMS plans to move these measures to the display page so information on performance will still be publicly available. We will also closely monitor performance, issue compliance actions per 42 CFR 422.504(m)(3) and 423.505(n)(3), publicly post warning letters and corrective action plan requests (CAPs), and if an organization receives too many compliance actions may deny applications for new contracts or service area expansions under 42 CFR 422.502(b)(1) and 423.503(b)(1) for failure to perform in accordance with CMS contractual requirements.

Comment: A handful of commenters highlighted the potential negative impact on dually eligible individuals and I–SNP enrollees, who are often sicker and have more complex care needs. They emphasized the importance of maintaining transparency and accountability for measures that ensure access to services for these vulnerable populations.

Response: We agree that it is important to continue to monitor performance on these measures for all contracts, including those that serve vulnerable populations. We will be adding these measures to the display page so we can continue to monitor and make publicly available information about how contracts perform.

Comment: Some commenters requested that CMS provide information on how it will continue to monitor and ensure compliance with language access and TTY requirements if the measures are removed. They urged CMS to maintain robust monitoring and transparency to safeguard beneficiaries' access to these critical services. Some commenters suggested moving these measures to the display page. Some commenters stressed the importance of ensuring equitable access to healthcare services for non-native English speakers and individuals with disabilities.

Response: CMS agrees that monitoring compliance with language access and TTY requirements is critical and is committed to continuing to monitor performance and utilize compliance processes per 42 CFR 422.504(m)(3) and 423.505(n)(3) in this area. We are planning to move these measures to the display page and will continue to carefully review performance and issue compliance actions as needed if we do see poor performance on these measures.

Comment: Some commenters urged CMS to consider alternative approaches to measuring performance that preserve accountability and support meaningful access to language and communication services. A few commenters suggested modifying the call center measures to address concerns about small sample sizes rather than removing them entirely. Other commenters offered specific recommendations for making changes to the call center measures, such as using a multi-year approach for scoring, setting revised minimum denominator rules, or combining Part C

and D measures into a single measure to improve stability and consistency. Other commenters suggested that CMS consider regional language prevalence and contract-level demographic composition when assessing language access. A commenter suggested breaking contracts into groups based on size and demographics to provide a more accurate assessment of a plan's ability to support all of its members. Other commenters suggested calling the current member line versus the prospective member line or calling outside of the annual and open enrollment periods.

Response: We appreciate the suggestions for potential future changes to the Part C and D Call Center—Foreign Language Interpreter and TTY Availability measures, but making changes to measure specifications is out of scope for this final rule. We will take these suggestions into consideration for any future updates to these measures following moving them to the display page.

After considering the comments we received and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to the comments, we are finalizing the removal of the call center measures beginning with the 2028 Star Ratings.

d. Complaints About the Health/Drug Plan (Part C and D)

We proposed removing the Complaints about the Health/Drug Plan (Part C and D) measure. We stated that this measure demonstrated exceptionally high performance with limited variation across contracts. 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 minimal variation in performance 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.

We solicited comment on removing the complaints measure from the 2029 Star Ratings. A discussion of the complaints measure removal comments, along with our responses, follows.

Comment: The majority of commenters opposed the removal of the Complaints about the Health/Drug Plan (''complaints measure'') from the Star Ratings. Many commenters expressed concern that removal would weaken a key accountability mechanism and incentive for plan sponsors to address issues impacting beneficiaries and providers, and stated the measure is a transparent indicator of plan performance and insight into beneficiary experience and access to care. Several commenters believed that the complaints measure was not just an administrative process measure but a beneficiary protection measure, and the complaints process reflects the final recourse for beneficiaries when the plan does not meet their needs.

A couple of commenters stated that oversight and quality incentives are not mutually exclusive, but complement each other, as a reason to retain the measure in the Star Ratings. Some cited CMS's changes to ensure uniform entry of provider complaints into the Complaints Tracking Module (CTM), and marketing and oversight reforms, as more reasons to keep the measure. Some commenters defended the complaints data as important information regarding providers' experience with plans' utilization management tools. Some commenters stated the complaints process fosters cooperation between plans and providers to resolve beneficiary issues or emphasized the complaints measure included direct feedback from beneficiaries and providers.

Other commenters said that uniformly high performance is evidence of success and the measure's effectiveness in incentivizing plans to improve their processes, rather than a justification for elimination. Commenters expressed concern that CMS was removing a measure they do well in, is within the plans' control, or that acted as a deterrent to non-compliant behavior by plans.

A few commenters believed that removing the complaints measure would weaken a key incentive for plans to maintain adequate staffing, systems, and operational capacity to resolve complaints effectively. One commenter stated that plans may be less likely to take proactive actions to address beneficiary and provider issues if the complaints measure is removed from the Star Ratings, which could unintentionally increase burdens on beneficiaries, providers, and CMS.

Response: We appreciate the thoughtful comments regarding the importance of the complaints measure for plan accountability and beneficiary protection. We acknowledge that it has historically served as an important tool for monitoring plan performance and promoting member-centered customer service. However, the high performance across contracts and minimal variation indicate that this measure no longer effectively differentiates plan quality in the Star Ratings system. The Star Ratings program is most effective when it focuses on measures where meaningful performance differences exist that can inform beneficiary choice and drive continued improvement.

Removal of this measure from Star Ratings does not eliminate CMS's oversight of complaints or our commitment to beneficiary protections. It also does not diminish plans' accountability for researching and resolving complaints, which may include coordination with beneficiaries, providers, or others.

CMS developed the CTM in the Health Plan Management System (HPMS) to track complaints received by CMS from beneficiaries, providers, and their representatives regarding specific MA organizations, Cost Plans, and Part D sponsors. Complaints are recorded in the CTM and assigned to the appropriate plan. Data may be populated into the CTM from various sources, such as 1–800–MEDICARE, CMS staff or contractors, Medicare Ombudsman, SHIPs, the Medicare.gov online complaint form for beneficiaries at *https://www.medicare.gov/my/medicare-complaint,* or the provider complaint form (regarding MA organizations) at *https://www.cms.gov/medicare/health-drug-plans/provider-complaints-form.*

As required under the contract provisions established at 42 CFR 422.504(a)(15) and 423.505(b)(22), plans are required to address and resolve the complaints received by CMS against them in the CTM. Plans must adhere to the timelines to resolve complaints in compliance with 42 CFR 422.125 and 423.129. The January 6, 2025 HPMS memorandum, Updated Complaints Tracking Module Standard Operating Procedures, provides information to sponsors on handling, resolving, and documenting complaints. Given the time-sensitive nature of many of the complaints, plans should continuously access, view, respond, and resolve the complaint(s) assigned to their organization in the CTM. CMS expects plans to enter periodic casework notes, including initial and subsequent contacts, developments, or research.

Furthermore, requirements for resolution of complaints received in the CTM do not override requirements related to the handling of appeals and grievances set forth in 42 CFR part 422 subpart M (which apply to cost plans as well as MA organizations per § 417.600) and Part 423 subpart M, for Part D sponsors. Rather, CTM requirements

supplement the appeals and grievance requirements by specifying how organizations must handle complaints received by CMS in the CTM and passed along to the plan. In accordance with the regulations at 42 CFR 422.564 and 423.564, plans must provide meaningful procedures for the timely hearing and resolving of enrollee grievances. As such, beneficiaries are encouraged first to contact their plan directly to file a complaint (*i.e.,* grievance). See the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeal Guidance [90] for information about grievance procedures.

CMS will continue to closely monitor complaint trends, and how complaints were resolved in CTM casework notes, to ensure that plans maintain appropriate grievance and complaint processes regardless of whether this measure is included in Star Ratings, and CMS will continue to review plan practices for compliance. The complaints provide early warning signs of problems through feedback from beneficiaries and providers, and CMS will continue to calculate complaint rates and resolution timeliness to identify plan outliers for corrective action as necessary.

Comment: Several commenters supported the removal of the complaints measure, agreeing that performance has reached high levels with minimal variation among plans and that complaints are better suited for compliance oversight. A commenter stated that the measure is heavily influenced by factors outside of the plan control, and another pointed out that the measure is prone to manipulation. A couple of commenters agreed that the complaints measure is duplicative of CAHPS measurement. A commenter felt that the measure has systemic biases, and that biases due to plan design or geography could inflate performance.

Response: CMS appreciates the support for removal of the complaints measure from the Star Ratings to focus on measures with meaningful variation, which is consistent with recommendations from the Medicare Payment Advisory Commission (MedPAC) [91] and our broader goals of reducing administrative burden while maintaining focus on outcome-oriented quality measures.

Comment: Multiple commenters asserted that CAHPS survey measures capture general satisfaction but not specific or real-time feedback about operational issues like the complaints measure. Commenters stated CAHPS and complaints data are complementary rather than duplicative. A few commenters noted that the CAHPS survey-based measures rely on sampling and member recall, but the complaints measures capture direct beneficiary feedback from all beneficiaries. A commenter pointed out that the breadth and specificity of the CTM complaint categories highlights that the CTM captures issues are not reflected in CAHPS. Another commenter stated that measuring access to care and patient experience through the CAHPS survey measures is not meaningful because survey results are not actionable (like complaints are), as questions are broad and ambiguous. A commenter did not want CMS to solely rely on CAHPS survey measures as an indicator of beneficiary experience.

Response: We acknowledge that CAHPS survey measures and complaint data capture feedback on member experience and access to care in different ways. However, the complaints measure no longer supports the purpose of the Star Ratings program, which is to differentiate plan performance in areas where meaningful variation exists. As noted in the response directly above, CMS will continue to monitor complaint data outside of Star Ratings and use this real-time, actionable information for compliance and oversight purposes. This approach allows us to maintain robust oversight while focusing the Star Ratings program on measures that effectively differentiate plan quality. Several measures will remain in the Star Ratings that capture beneficiary satisfaction, care coordination, and quality of care.

Comment: Several commenters recommended delaying the removal of the complaints measure to allow for further evaluation of its impact on plan behavior and beneficiary protection. Some commenters suggested that CMS should implement enhanced monitoring or alternative accountability mechanisms before removing the measure from Star Ratings.

Response: We have carefully considered the timing of this change and find that implementing the removal beginning with the 2029 Star Ratings (based on 2027 measurement year data) provides adequate notice to plans and stakeholders to prepare for the change.

CMS will continue to monitor complaint data and maintain robust oversight mechanisms outside of the Star Ratings program. We do not find that delaying implementation is necessary given the historically low complaints volume and the continued availability of other accountability tools.

Comment: Some commenters suggested changes to the CTM measure specifications. For example, some commenters recommended CMS exclude certain complaints, such as duplicates or provider complaints from the measure; reflect root cause of beneficiary complaints; remove Tukey outlier deletion when calculating this measure's cut points; calculate complaint rates by geographic area instead of by contract; create a new measure solely based on provider complaints or a measure that places a higher weight on provider complaints; or distinguish complaints about inpatient admissions, denials, and post-acute care delays from general customer service issues.

Response: We appreciate the suggestions and will consider them for future measure development or internal oversight metrics.

Comment: Some commenters urged CMS to make CTM complaint data more publicly accessible, including the substance of complaints and plan responses or total complaints stratified by complaint type, to help showcase true beneficiary experience and assist prospective enrollees in comparing plans.

Response: We appreciate these suggestions and recognize the value of transparency in helping beneficiaries make informed enrollment decisions. We will continue to evaluate opportunities to enhance the transparency and accessibility of complaint data while balancing privacy considerations and administrative feasibility.

However, these transparency efforts are separate from the Star Ratings program and do not affect our decision to remove the complaints measure from Star Ratings because of its limited value as a quality measure in light of the lack of variability across contracts.

When the complaints measure is removed from the Star Ratings, the measure will be moved to the display page and continue to be publicly reported.

Comment: Some commenters requested that more information be shared by CMS about the complaints process itself, so that beneficiaries and providers are able to navigate the system effectively.

Response: Information on how to file a complaint with 1–800–MEDICARE is available in multiple Medicare publications and online references. An online complaints form is available, and CMS recently released a provider

[90] Available at: *https://www.cms.gov/medicare/appeals-grievances/managed-care.*

[91] Replacing the Medicare Advantage quality bonus program—MedPAC available at: *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch3_reporttocongress_sec.pdf.*

complaint form to improve consistent intake of those issues. We will continue to work with stakeholders to improve the visibility of these important avenues for beneficiaries and providers to contact CMS.

After considering the comments we received and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to the comments, we are finalizing the removal of the complaints measure beginning with the 2029 Star Ratings.

e. Medicare Plan Finder (MPF) Price Accuracy (Part D)

We proposed 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.

We solicited comment on removing the MPF Price Accuracy measure from the 2029 Star Ratings. A discussion of the MPF Price Accuracy measure removal comments, along with our responses, follows.

Comment: Many commenters supported the removal of this measure. Most supporters mentioned their agreement with the reasons for removal stated in the Contract Year 2027 proposed rule, such as high average scores and limited variability across contracts, which limits ability to distinguish between plan performance. A few commenters mentioned that removal of this measure would reduce administrative burden, with a couple mentioning resources could be redirected to patient outcomes. Another commenter stated that the measure does not meaningfully reflect quality.

Several commenters supportive of removal also noted that they agreed with CMS's plan to continue to monitor these data outside of Star Ratings. One commenter specifically stated that CMS's announcement of MPF monitoring in the October 31, 2024 HPMS memorandum with the subject ''Medicare Plan Finder Part D Drug Pricing Data Submission Monitoring'' was an important step for drug price monitoring, and recommended CMS continue to improve the methodology of this measure when it is removed from the Star Ratings.

A couple of commenters stated that this measure has methodology issues, with one offering ideas to improve the measure if it is not removed. A commenter also stated there was potential ''gaming'' of this measure through artificial adjustments of pricing files. Another stated that several large national insurance providers ''control'' the measure due to their dominance in the Pharmacy Benefit Manager (PBM) market, so removal of the measure would create a more level playing field.

Response: We thank these commenters for their support.

Comment: Many commenters opposed the removal of this measure. Most of these commenters noted the importance of accurate data on the MPF so that beneficiaries can make informed choices about their drug coverage. Several noted that the measure is important for holding plans accountable for transparent and accurate pricing data. A commenter noted that lower-income beneficiaries would be especially impacted by removal of the measure since they are more sensitive to price changes. A commenter stated that removing the financial incentive that this measure provides for plans to provide accurate pricing data could reverse progress toward beneficiary protection.

Response: We agree that transparent and accurate data on the MPF are critical for all beneficiaries to make informed decisions about coverage. We would like to assure commenters that CMS will continue to monitor the accuracy of plans' MPF pricing data when this measure is removed from the Star Ratings. This measure will be moved to the display page, and CMS will explore potential future improvements to the measure methodology. CMS will follow up with plan sponsors with poor performance on the MPF price accuracy display measure as necessary.

CMS also performs validations when the pricing data are submitted to CMS for the MPF. The May 27, 2025 HPMS memorandum titled ''Contract Year (CY) 2026 Part D Pricing Data Submission Guidance'' states that HPMS uses a multi-tiered approach when validating the in-bound drug pricing file submissions from plan sponsors. These validations are tools used by CMS to identify potential inaccuracies prior to display on MPF and may prompt CMS to contact a sponsor for clarification of the accuracy of its submission.

CMS will suppress the display of a sponsor's information when the sponsor fails to correct its data, confirm the accuracy of its data, or respond to a CMS inquiry. Sponsors may be subject to Part D program compliance actions because of MPF suppressions or inaccurate data submissions.

Validations may be added or updated based on CMS's monitoring of the MPF drug pricing data.

Comment: A few commenters that opposed removal of the measure noted that beneficiary experience with MPF in the 2025 Annual Enrollment Period (AEP) was difficult due to the prices constantly changing from week to week, and that this pricing information needs to remain reliable.

Response: CMS notes that the MPF Price Accuracy measure does not use data from AEP (October–December). CMS has a separate monitoring initiative for price changes between AEP and the contract year (CY), as announced in the HPMS memorandum dated October 31, 2024 with subject ''Medicare Plan Finder Part D Drug Pricing Data Submission Monitoring''.

Comment: A commenter stated that this measure is important for small plans to distinguish their plan performance for prospective enrollees.

Response: This measure has high average scores and limited variability across contracts, limiting its ability to distinguish between plan performance.

After consideration of the comments we received and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to comments, we are finalizing the removal of the MPF Price Accuracy measure for the 2029 Star Ratings.

f. Diabetes Care—Eye Exam (Part C)

We proposed 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 proposed to move this measure to the display page.

We solicited comment on removing the Diabetes Care—Eye Exam measure from the 2029 Star Ratings. A discussion of the Diabetes Care—Eye Exam measure removal comments, along with our responses follows.

Comment: Most commenters opposed the removal of the Diabetes Care—Eye Exam measure from the Star Ratings. Some commenters noted that diabetic retinopathy is a leading cause of preventable blindness and that routine eye exams are essential for early detection of asymptomatic disease and timely intervention preventing severe vision loss. They also emphasized that the eye exam measure captures a clinically distinct and non-duplicative aspect of diabetes care that is not

addressed by other Star Ratings measures related to glycemic control, medication adherence, or kidney health. Other commenters noted that these exams serve as one of the most efficient and non-invasive tools for identifying broader health concerns. A number of commenters argued that preventing vision loss helps avoid expensive late-stage ophthalmic treatment, caregiver and long-term services and supports costs, functional decline and institutionalization.

Response: CMS appreciates the extensive feedback received on the Diabetes Care—Eye Exam measure and agrees with commenters that routine retinal screening is a critical component of comprehensive diabetes care. We agree that retinal examinations can identify broader health concerns and that preventing vision loss may help avoid costly late-stage treatment, functional decline, caregiver burden, and long-term services and supports. CMS also agrees that these considerations are consistent with the goals of the Star Ratings program to promote preventive care, preserve functional independence, and support whole-person care.

After careful consideration of public comments, CMS is retaining the Diabetes Care—Eye Exam measure in the Star Ratings program. Continued inclusion of this measure will help maintain plan accountability, support access to preventive screening, and encourage care coordination and innovation in screening approaches, particularly for high-risk and underserved populations.

Comment: Many commenters stated that removing this measure would create a vision-care gap in the Star Ratings program, as this measure is the only ophthalmic/vision-focused measure. They argued that downgrading the measure to display-only would lead to fewer screenings and more avoidable blindness, as well as other economic and public-health repercussions.

Response: CMS acknowledges commenters' concerns regarding the importance of monitoring vision-related preventive care for beneficiaries with diabetes and agrees that diabetic eye exams are a critical component of comprehensive diabetes management. Regardless of whether the measure is included in the Star Ratings calculation, MA plans and their contracted providers remain responsible for ensuring beneficiaries have access to clinically appropriate preventive services and supporting beneficiaries in obtaining recommended care, including diabetes-related eye exams. After consideration of the comments received, we are retaining this measure in Star Ratings.

Comment: Several commenters argued that Star Ratings measures drive outreach, provider engagement, care-gap closing, benefit design, and investment, whereas display-only measures receive far less operational prioritization. Many commenters stressed that if the measure is no longer included in Star Ratings, plans may redirect resources away from screening programs even if coverage technically remains.

Response: CMS recognizes that inclusion as a Star Ratings measure can influence plan prioritization, operational focus, and investment. At the same time, the Star Ratings program cannot encompass every facet of clinical care, and the absence of a specific measure from the ratings calculation does not diminish the clinical importance of the service. Eye exams are a critical component of high-quality diabetes care regardless of whether the measure is included in Star Ratings. CMS expects plans to support appropriate screening, outreach, and provider engagement to ensure beneficiaries receive recommended diabetes-related eye exams consistent with established standards of care.

Comment: Numerous commenters disputed that the measure is topped out or no longer differentiates plans. They pointed to continued gaps in screening rates and variation across plans, arguing plan performance still has room to improve and the measure still functions as an accountability lever.

Response: CMS agrees with commenters that performance on this measure has not topped out and continues to show variation across plans. As discussed in the Contract Year 2027 proposed rule, CMS proposed to remove this measure as part of a broader effort to streamline the Star Ratings measure set in areas where multiple measures address diabetes care. However, after consideration of public comments, CMS is retaining the Diabetes Care—Eye Exam measure in the Star Ratings program because it captures a clinically distinct and preventive aspect of diabetes care that is not fully addressed by other measures.

Comment: Some commenters expressed concern that removing the measure from the Star Ratings program could reduce MA plans' outreach, care coordination, and investment in screening programs, potentially leading to declines in screening rates. Commenters emphasized that the measure is particularly important for SNP (D–SNP, C–SNP, and I–SNP) populations with complex chronic conditions, as well as beneficiaries in rural communities facing provider shortages, transportation challenges, and other access barriers. Commenters also noted that homebound, low-mobility, and underserved beneficiaries often rely on in-home, mobile, and community-based screening programs, which are frequently structured around closing Star Ratings measure gaps and may be scaled back if the measure is no longer scored.

Response: CMS agrees that ensuring access to recommended diabetes-related preventive services is especially important for beneficiaries with complex needs and those facing access barriers, including SNP enrollees and beneficiaries in rural or institutional settings. Regardless of whether a measure is included in Star Ratings, plans remain responsible for ensuring all beneficiaries have access to appropriate preventive services and supporting timely diabetes-related screenings. CMS will be keeping this measure in Star Ratings since routine retinal screening is a critical component of comprehensive diabetes care and can identify broader health concerns. As we have considered the comments received, we agree this measure focuses on a clinically distinct and preventive aspect of diabetes care that is not fully addressed by other measures.

Comment: Many commenters stated that inclusion of this measure in the Star Ratings program has been a significant driver of innovation in care delivery. Commenters noted that the measure has incentivized MA plans and providers to adopt new screening models such as teleophthalmology, mobile and in-home screening services, point-of-care retinal imaging in primary care settings, and FDA-cleared autonomous artificial intelligence technologies to help expand access to diabetic eye exams. Commenters emphasized that these innovations have helped overcome workforce shortages, transportation barriers, and specialist access challenges, particularly in rural and underserved communities, while improving efficiency and reducing administrative burden. Several commenters expressed concern that removing the measure from the Star Ratings calculation could slow or reverse investment in these innovative approaches.

Response: CMS appreciates commenters' perspectives on the role of this measure in encouraging innovation and expanding screening access. As previously explained, CMS is retaining this measure in the Star Ratings program.

Comment: Several commenters offered alternatives to removal,

including refining or strengthening the measure rather than deleting it (*i.e.,* adjusting weighting, improving reporting alignment), adding follow-up care or care coordination after abnormal results, adopting hybrid or chart review approaches, and revisiting exclusions and/or measurement scope for certain populations (*e.g.,* ESRD patients and members who receive optical care through other benefits or coverage). These commenters suggest delaying removal until a suitable replacement exists. A commenter supported moving the measure to the display page but urged ongoing monitoring and possible reassessment if screening rates decline.

Response: CMS appreciates the recommendations for potential future refinements, including approaches related to follow-up care, exclusions, and measurement methodology. We will take these suggestions into consideration for potential future updates to this measure.

Comment: Some commenters supported removing this measure, stating that diabetes care is already represented in Star Ratings through other measures and that removing this process measure supports streamlining and refocusing on outcome and patient experience measures.

Response: CMS appreciates support for streamlining the Star Ratings measure set and focusing on measures that best reflect outcomes and beneficiary experience related to diabetes care. We agree that several existing diabetes measures capture important aspects of diabetes clinical management and treatment outcomes. Collectively, these measures provide meaningful insight into plan performance in managing diabetes. At the same time, after consideration of public comments, CMS is retaining the Diabetes Care—Eye Exam measure in the Star Ratings program because it captures a clinically distinct and preventive aspect of diabetes care that is not fully addressed by other measures.

Comment: A few commenters raised concerns about persistent data gaps, challenges capturing eye exams completed outside MA plan networks or channels, coding and interoperability limitations between primary care and vision providers, and confusion regarding what services qualify for measure compliance. Commenters stated that these issues may limit the measure's ability to fully reflect true care delivery or plan performance and may contribute to administrative burden.

Response: CMS appreciates the feedback regarding data collection, measurement reliability, operational burden, and clarity of measure specifications. CMS recognizes the challenges associated with capturing services furnished across multiple care settings and providers, including those outside plan-contracted networks, as well as coding and interoperability limitations. CMS will continue to evaluate data sources and measurement approaches and consider opportunities for improvement.

After considering the comments we received and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to the comments, we are not finalizing this proposal to remove the Diabetes Care—Eye Exam measure from the Star Ratings.

g. Statin Therapy for Patients With Cardiovascular Disease (Part C)

We proposed 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. In light of this substantive change, the Statin Therapy for Patients with Cardiovascular Disease measure was already set for removal to the 2028 display page following the process described at § 422.164(d)(2), and any adoption of the updated measure would need to be proposed and finalized through future rulemaking. While § 422.164(d)(2) gives CMS the discretion to continue to use a legacy measure in Star Ratings while a substantively updated version is on the display page, use of the legacy measure was not feasible here due to the nature of the substantive changes. CMS will monitor changes in performance for this measure, as updated and included on the display page, since statin therapy is important in lowering cholesterol and reducing the risk of cardiovascular disease.

We solicited comment on removing the Statin Therapy for Patients with Cardiovascular Disease measure from the 2028 Star Ratings. A discussion of the Statin Therapy for Patients with Cardiovascular Disease measure removal comments, along with our responses follows.

Comment: Many commenters supported removing this measure due to minimal performance variation and the availability of similar measures already in Star Ratings, such as Medication Adherence for Cholesterol (Statins). Commenters highlighted significant clinical limitations with the measure, such as that it captures prescriptions but not adherence, inadequately accounts for statin intolerance, creates administrative burden, and encourages coding behaviors that conflict with clinical judgment. A commenter also emphasized that a single prescription is insufficient for cardioprotective benefits, with some commenters adding that the measure excludes alternative cholesterol-lowering treatments, such as diet, exercise, or alternative medications. Commenters also noted the measure would remain on the 2028 display page as another reason for their support.

Response: We thank these commenters for their support of our proposal.

Comment: Some commenters opposed removing the measure, emphasizing its importance for the health and quality of life of patients with cardiovascular disease. Commenters noted that statin therapy is evidence-based for this population and linked to reduced mortality. Others urged CMS to delay removal until another validated outcome-based measure is introduced.

Response: This measure will be on the display page so it will still be publicly reported and used for monitoring. Given the substantive change for the 2026 measurement year for this measure, the measure has to be moved to the display page for at least two years following the process described at § 422.164(d)(2). The updated measure would need to be proposed through rulemaking. We do not have data for the legacy measure to continue to include in the Star Ratings.

Comment: Some commenters recommended replacing the Statin Therapy for Patients with Cardiovascular Disease process measure with a low-density lipoprotein cholesterol (LDL–C) control or LDL–C response outcome measure. These alternative measures would account for statin intolerance while expanding the denominator to include all patients who could benefit from cholesterol-lowering therapy. Additionally, rather than

removing the measure, a commenter recommended considering a complimentary measure focused on medication access, affordability, and utilization since statins remain underused in peripheral arterial disease. Another commenter recommended that CMS eliminate the exclusion of individuals aged 66 and above to align with the Statin Use in Persons with Diabetes.

Response: We appreciate the suggestions and will take them into consideration as we consider future measure changes. If we were to introduce an alternative measure in the future, it would need to be proposed and finalized through the rulemaking process. It is important that providers and plans provide appropriate care for Medicare beneficiaries with cardiovascular disease whether the Star Ratings includes the Statin Therapy for Patients with Cardiovascular Disease measure or not.

Comment: Some commenters noted that despite an apparent performance ceiling for this measure at the contract level, substantial disparities in statin initiation and adherence persist among older adults, women, and racial/ethnic minorities, populations disproportionately represented in MA organizations.

Response: This measure will be on the display page so performance on this measure will still be publicly available. While Part C and D Star Ratings cannot measure every aspect of care delivery, providers and plans should still deliver clinically appropriate care to all populations.

Comment: Some commenters argued that removal of this measure is premature given NCQA's recent substantive specification changes expanding the eligible population. They urged CMS to evaluate the updated measure's performance before removal. Some commenters urged CMS to reintroduce the measure after the two-year display period, with one commenter arguing that the measure is more robust at identifying high risk patients than the Statin Use in Persons with Diabetes (Part D) measure and more methodologically sound as it includes clinically justified exclusions.

Response: The measure will be on the display page starting with the 2028 Star Ratings due to the substantive change made by NCQA discussed above. CMS is committed to continuing to monitor performance on the updated measure. If CMS were to bring back this measure into Part C Star Ratings, it would have to be proposed through future rulemaking.

After considering the comments we received and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to the comments, we are finalizing the removal of the Statin Therapy for Patients with Cardiovascular Disease beginning with the 2028 Star Ratings.

h. Members Choosing To Leave the Plan (Part C and Part D)

We proposed removing the Members Choosing to Leave the Plan (Part C and 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 proposed removing 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.

We solicited comment on removing the Members Choosing to Leave the Plan measure from the 2029 Star Ratings. A discussion of the Members Choosing to Leave the Plan measure removal comments, along with our responses, follows.

Comment: Some commenters supported removing the measure, emphasizing that disenrollment can be driven by non-quality factors and can be hard for beneficiaries to interpret without context on why members left. Common reasons for supporting removal included cost or price shopping, broker or marketing dynamics, competitors, geographic moves, policy changes, and other external forces.

Response: CMS appreciates these comments and agrees there can be challenges in interpreting why beneficiaries may leave a plan and the extent to which disenrollments may be influenced by factors not solely related to plan quality.

Comment: Some commenters argued that voluntary disenrollment is one of the most straightforward indicators of whether a plan is meeting member needs so should remain in Star Ratings. They stated that disenrollment rates serve as the best proxy for beneficiary dissatisfaction by reflecting members' decisions to leave a plan. Many of these commenters contrasted this measure with the CAHPS survey, noting that CAHPS relies on survey sampling and captures reported perceptions rather than observed enrollment behavior.

Response: CMS appreciates these comments regarding the value of voluntary disenrollment as an objective, behavior-based indicator that may reflect enrollee experience with the plan. Although the Members Choosing to Leave the Plan measure may reflect beneficiary dissatisfaction to an extent, it is difficult to interpret from an overall disenrollment rate why beneficiaries are leaving a contract, so it is less useful as a quality measure. Disenrollments do not necessarily reflect issues with the quality of care provided. We know that beneficiaries disenroll for many reasons, including financial reasons, issues receiving needed care, coverage related to doctors, hospitals, and prescriptions, and issues getting information and help from the plan. The most common reasons for disenrollment are financial reasons and doctors, clinics, and hospitals not belonging to the enrollee's plan network. CMS plans to continue publicly reporting this measure on the display page so overall information about voluntary disenrollment remains transparent and available to beneficiaries and other interested parties.

Comment: Some commenters noted that the Members Choosing to Leave the Plan measure functions as an accountability and oversight mechanism, and that reporting it on the display page does not create the same incentive for plans to fix root causes.

Comment: Several commenters emphasized that the disenrollment measure is especially important for high-need populations (particularly individuals diagnosed with end-stage renal disease (ESRD) and SNP enrollees) because disenrollment can indicate serious mismatches between plan design and member needs. Some of these commenters urged CMS to retain the measure and refine it with these vulnerable groups in mind.

Response: CMS appreciates these comments. CMS will continue public reporting of this measure on the display page and will take into consideration recommendations for future measure updates.

Comment: Some commenters suggested that we retain the measure in Star Ratings but modify the technical specifications to better measure voluntary disenrollments. Several commenters argued that evaluating disenrollment at the contract level can misclassify switching within the same parent organization as negative performance. They encouraged CMS to evaluate disenrollment at the parent

organization level. Other commenters urged CMS to refine exclusions by excluding disenrollments tied to state Medicaid eligibility or policy changes affecting dual status and using reason codes to better capture true voluntary disenrollment.

Response: CMS appreciates these comments. CMS will publicly report this measure on the display page and take into consideration recommendations for future measure updates.

Comment: Some commenters raised concerns that if the Members Choosing to Leave the Plan measure is removed from Star Ratings, plans might face less pressure to avoid practices that frustrate members. A commenter specifically warned that removing this measure could enable plans to adopt policies that drive away members and could distort CAHPS survey participation (since members who leave may not be captured as intended).

Response: CMS disagrees that retiring this measure will meaningfully reduce plan incentives to address disenrollment-related issues, as plans have existing financial and operational incentives separate from Star Ratings to retain enrollees and maintain high-quality performance. Additionally, we will continue to monitor performance on this measure over time.

After considering the comments we received and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to the comments, we are finalizing the removal of the Members Choosing to Leave the Plan measure beginning with the 2029 Star Ratings.

i. Customer Service and Rating of Health Care Quality (Part C)

We proposed 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 solicited comment on removing the Customer Service and Rating of Health Care Quality measures from the 2029 Star Ratings. A discussion of the Customer Service and Rating of Health Care Quality measure removal comments, along with our responses, follows.

Comment: Some commenters supported the removal of the Customer Service and Rating of Health Care Quality measures, noting there is minimal variation in performance across contracts and that cut points have been stable for many years. A couple of commenters noted that these measures often reflect factors outside a health plan's direct control.

Response: We appreciate the support for removing the Part C Customer Service and Rating of Health Care Quality measures. As stated in the Contract Year 2027 proposed rule, we are proposing removal as part of an effort to streamline the Star Ratings. We disagree, however, that these measures are outside of health plans' control. Consumer experiences with customer service and perceptions of health care quality are important aspects of a patient's experience. The MA and PDP CAHPS surveys have been rigorously developed and tested to assess enrollee experiences on domains that enrollees have reported to be important to them in defining high quality care from Medicare health and drug plans.

Comment: Many commenters opposed the removal of the Customer Service and Rating of Health Care Quality measures, noting the importance of measures that reflect member experience. Commenters stated that excluding these measures from Star Ratings calculations diminishes their value and ability to incentivize health plans to invest in high-quality beneficiary experiences. Some commenters stated these measures are important for individuals selecting a health plan to consider, as well as for CMS to measure the overall quality of care provided by plans.

Response: CMS agrees these measures capture important areas of plan performance. The measures will still be collected through the MA and PDP CAHPS Survey and results will be included in the CAHPS health plan reports provided each year to plans to support their quality improvement efforts and reported as display measures on *CMS.gov*. Also, the Rating of Health Plan measure that will remain in the Star Ratings will capture these areas of performance.

Comment: Many commenters expressed concern that removing the Customer Service measure assessing beneficiary experience with MA plan operations will reduce MA plan oversight to ensure enrollees are receiving timely and quality access to their respective benefits and coverage. Commenters recommend that CMS consider opportunities to better measure customer service, rather than removing the measure entirely from the Star Ratings program.

Response: CMS appreciates commenters' emphasis on the importance of customer service and beneficiary experience with MA plan operations. CMS agrees that timely, accurate, and high-quality customer service is essential to ensuring enrollees' access to benefits, regardless of whether such measures are included in the Star Ratings program. Removing the Customer Service measure from Star Ratings does not reduce CMS's expectations that MA plans will provide high-quality customer service to their enrollees. CMS will continue to report this measure on the display page and continue to monitor performance. CMS also remains committed to evaluating opportunities to better measure beneficiary experience and customer service.

After considering the comments we received and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to the comments, we are finalizing the removal of the Customer Service and Rating of Health Care Quality measures beginning with the 2029 Star Ratings.

2. Adding Measure

a. Depression Screening and Follow-Up (Part C)

We are committed to continuing to improve the Part C and 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 as described at 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 proposed to add the Part C Depression Screening and Follow-Up (DSF) measure to the 2029 Star Ratings (measurement year 2027). CMS began 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 two 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.[92] DSF

[92] See page 162 at *https://www.cms.gov/files/document/2024-announcement-pdf.pdf* for a summary of comments.

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,[93] 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 August 2021 through August 2023.[94] 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.[95]

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.[96] 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 [97] 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.

We solicited comment on adding the Depression Screening and Follow-Up measure to the 2029 Star Ratings. A discussion of the Depression Screening and Follow-Up measure addition comments, along with our responses, follows.

Comment: Many commenters supported adding the DSF measure to the Star Ratings program. Commenters noted that this measure would encourage MA plans to screen for depression and follow up with appropriate care and to expand access to behavioral health services. Some commenters noted that the DSF measure would fill a gap in the Star Ratings program related to behavioral health and is aligned with the Universal Foundation set of measures across quality programs.

Response: We thank the commenters for their support.

Comment: Some commenters were concerned with the administrative burden related to the DSF measure, such as the investment needed to set up the data structures and workflows to track and report depression screening and follow-up data. Other commenters noted challenges implementing the measure due to inconsistent availability of data and issues with the interoperability of electronic data. Specifically, a few commenters had concerns with the measure requiring the use of Logical Observation Identifiers Names and Codes (LOINC) codes, which they claimed are inconsistently used and not always transmitted to plans. Some commenters recommended expanding the measure to include hybrid reporting or use of any digital data source including both claims and clinical data including CPT and HCPCS codes such as 96127, 96160, 96161, and G0444 (Annual Depression Screening). A commenter further suggested that CMS should work with smaller practices and community-based organizations to address technical barriers they face with Electronic Clinical Data Systems (ECDS) reporting and LOINC codes. Another commenter recommended that CMS: (1) publish detailed ECDS specifications, including accepted standardized instruments, LOINC tables, and mapping examples for common EMRs, (2) issue an electronic medical records (EMR)/Health Information Exchange (HIE) readiness checklist and provider toolkit that include clinical workflow, documentation, and data flow, and (3) offer technical assistance with measure testing, data ingestion pilots, and feedback on cases.

Response: We appreciate the feedback on the challenges of implementing this measure. ECDS is a HEDIS reporting method for health plans to collect and submit quality measures. The DSF measure uses the ECDS reporting method, which was developed to allow for better tracking of patient outcomes across systems and to reduce the burden on providers to conduct manual chart reviews by pulling in data across EHRs, HIEs, clinical registries, and claims data. While we understand that this ECDS measure will require upfront investment in setting up the IT and workflow infrastructure, over time the ECDS, rather than traditional or hybrid reporting, will decrease the burden on providers. The ECDS reporting method used in DSF requires the use of electronic data standards and that all data be stored in structured fields in a standard layout. The data sources for ECDS reporting include electronic health records/personal health records, health information exchange/clinical registry, case managements systems, and data from administrative claims. Given the need for structured data, DSF requires the use of LOINC codes. To allow some flexibility, HEDIS does allow mapping to the measure's specified LOINC codes as appropriate. For example, if the questions of a specified instrument are used, but are labeled with the name of a different instrument (*e.g.,* PHQ–2 questions within the PHQ–A), mapping to one of the specified LOINC codes is acceptable.

CMS appreciates the commenters' recommendations regarding additional technical resources to support implementation of this measure. The measure specifications are developed and maintained by NCQA, the measure steward, and include the technical requirements necessary for reporting. Detailed specifications, including

[93] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-depression-suicide-risk-adults.*

[94] *https://www.cdc.gov/nchs/data/databriefs/db527.pdf.*

[95] *https://pmc.ncbi.nlm.nih.gov/articles/PMC7661597/* and *https://www.amjmed.com/article/S0002-9343(22)00524-1/fulltext.*

[96] *https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf.*

[97] 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.

coding and data element guidance, are available through NCQA's established measure maintenance processes. CMS encourages stakeholders to refer to NCQA resources for the most current technical guidance. CMS is not prescribing EMR- or HIE-specific implementation tools, workflow guidance, or mapping examples through regulation, given the significant variation in health IT systems, data sources, and clinical workflows across MA organizations and provider settings. MA organizations remain responsible for working with their providers and vendors to operationalize measure reporting within their existing infrastructure.

Comment: Some commenters were concerned about their ability to track whether follow-up care occurred, noting limitations such as state-specific legal barriers to accessing behavioral health data and limited visibility into care delivered outside their network. A couple of commenters further suggested that CMS conduct an impact analysis of how federal and state privacy laws may affect data availability given stricter limits on sharing mental health records in some places.

Response: CMS acknowledges that data availability and access to behavioral health information may vary based on state law, privacy requirements, and whether care is furnished outside of a given organization's network. However, CMS does not agree that these considerations warrant modification of the finalized policy. This measure does not require access to detailed psychotherapy or mental health treatment records. The measure is designed to allow reporting based on information reasonably available to health plans, including documentation of referral, care coordination, or other appropriate follow-up actions consistent with existing legal and operational constraints. CMS notes that similar considerations apply broadly across quality measurement and care coordination activities and are not unique to depression screening or follow-up care.

Comment: A few commenters stated their belief that this measure will disproportionately burden physicians and indicated that the responsibility for strong performance is primarily the responsibility of providers rather than MA plans. These commenters requested that CMS hold MA plans accountable for providing support and increasing access to behavioral health resources. Another commenter suggested that CMS help ensure community mental health and substance use provider organizations are seamlessly able to contract with MA plans.

Response: CMS does not agree that the measure inappropriately places the burden of performance solely on physicians or other individual providers. The DSF measure is reported at the MA contract level and reflects the collective performance of the MA organization's provider network. MA contracts are responsible for establishing provider networks, designing benefits, furnishing care management and care coordination services, and implementing quality improvement strategies to support measure performance. Accordingly, MA organizations retain primary accountability for ensuring that their networks are equipped to conduct depression screening and facilitate appropriate follow-up care.

MA organizations already have multiple mechanisms to support providers and improve access to behavioral health services, including network adequacy requirements, utilization management policies, care coordination programs, supplemental benefits, and quality improvement initiatives. The measure is intended to encourage MA organizations to leverage these existing tools to strengthen screening and follow-up processes, including addressing gaps in access to behavioral health resources, and to collaborate with providers.

Comment: Some commenters request that CMS delay implementation of this measure to give plans and providers more time to get systems and processes in place to meet requirements. A commenter specifically asked for phasing in follow-up requirements over time.

Response: This measure was reported on the 2026 display page. This measure will be on display for three years prior to it being added to the 2029 Star Ratings. This provides sufficient time for MA organizations to prepare for inclusion of this measure in Star Ratings.

Comment: Some commenters were concerned about inadequate behavioral health resources in communities that already face significant behavioral health workforce and capacity shortages, potentially limiting their ability to provide follow-up care for those who screen positive for depression. These commenters requested that CMS monitor behavioral health network adequacy before implementing this measure.

Response: We recognize the health care workforce shortages facing many communities, particularly in the field of behavioral health. Measuring depression screening and follow-up care will increase focus on behavioral health and likely lead to MA plans expanding access to behavioral health care. In addition, the measure specifications allow for telehealth or virtual appointments so that enrollees with limited access to follow-up care in their local vicinity may be able to access services in a virtual setting.

Comment: Some commenters recommended that CMS report the depression screening and follow-up rates separately because averaging the rates may discourage depression screening since plans that screen fewer people may more easily achieve high follow-up rates. A commenter also suggested a higher weight for the follow-up rate.

Response: There is incentive to do well on both rates. For the screening rate, performance will be worse if fewer individuals are screened since the measure focuses on screening among the general population. We will display the rates for screening and follow-up separately on the display page so this information is publicly available. For the Star Ratings program, CMS plans to take an average of the rates to minimize the number of measures displayed on Medicare Plan Finder. We will monitor the rates for both the screening and follow-up measures and may propose changes over time if we see issues with combining the rates.

Comment: Some commenters recommended including telehealth and home-based depression screening and follow-up care in the measure.

Response: We clarify that telehealth visits and home-based visits can count toward this measure if other requirements are met.[98]

Comment: A commenter recommended restricting the measure denominator to the subset of patients with at least one valid encounter during the measurement year to increase the likelihood of screening being performed by a provider with an established relationship with the patient and minimize the need for population-wide outreach by health plans or other providers with no previously established relationship.

Response: We appreciate the commenter's recommendation to restrict the measure denominator to patients with at least one valid encounter during the measurement year. The inclusive denominator is intentionally designed to encourage comprehensive preventive care for all enrolled members, regardless of their recent utilization patterns. This

[98] NCQA HEDIS Measurement Year 2026 Volume 2.

ensures that screening opportunities are not inadvertently limited to only those individuals who have already accessed care during the measurement year.

While we recognize the commenter's concern regarding the administrative burden of outreach to members without established provider relationships, proactive engagement with all enrollees is a fundamental component of effective preventive care delivery. Members who have not had recent encounters may represent a population at higher risk for unmet health needs and would benefit most from targeted outreach and screening initiatives.

Comment: A few commenters requested CMS provide clear guidance about what counts as ''appropriate follow-up care.''

Response: Follow-up care includes outpatient, telephone, e-visits, or virtual check-in follow-up visits; depression case management encounters; behavioral health encounters including assessment, therapy, collaborative care, or medication management; an encounter for exercise counseling; or a dispensed antidepressant medication.[99]

Comment: Out of concern for the impact of this measure on medically complex individuals, a commenter recommended applying a case-mix adjustment that includes geography, LIS/DE status, and other demographic data. Another commenter recommended tracking rates across demographic groups.

Response: Since this is a process measure, there is no case-mix adjustment so as not to set different performance standards for different groups or to mask differences in the quality of care across parts of the country. We encourage contracts to analyze their data and track and address differences in performance across subpopulations in their contract.

Comment: A commenter requested flexibility as to who may administer the screening, especially for rural and underserved areas.

Response: The HEDIS specifications for the depression screening rate are focused on screening using a standardized instrument rather than who administers the screening. The specifications also indicate that depression screening captured in health risk assessments or other types of health assessments are allowed if the questions align with a specific instrument that is validated for depression screening.

Comment: A commenter recommended avoiding duplicative requirements such as rescreening patients already diagnosed with depression.

Response: The HEDIS specifications for the DSF measure already exclude individuals with a history of bipolar disorder or a current diagnosis of depression.[100]

Comment: As an alternative to the proposed measure, a commenter recommended implementing the Follow Up After Hospitalization for Mental Illness (FUH) measure. Another commenter recommended using a measure of Medicare Annual Wellness Visit (AWV) since depression screening often occurs at wellness appointments. Another commenter suggested moving to an outcome performance measure such as improvement in depression as measured by the Patient Health Questionnaire (PHQ–9).

Response: We appreciate the recommendations, but we disagree that these measures are feasible alternatives. The DSF measure was chosen over the FUH measure because of the focus on earlier identification and intervention for depression in an outpatient setting. The DSF measure is also part of the Universal Foundation set of measures across quality programs, which focuses on improving the well-being of beneficiaries. It is also aligned with MAHA priorities by encouraging MA health plans to screen for depression and follow up with appropriate care. Wellness visits are often an encounter where depression screening occurs, yet this alone is an insufficient way to measure depression screening. It also does not address a key component of DSF which is follow-up care for those who screen positive for depression within 30 days. Although DSF is a process measure, health outcomes can be improved by identifying those with depression early and giving them access to treatments for depression.

Comment: A few commenters recommend that CMS exclude patients with Major Neurocognitive Disorder (dementia) from this measure because the PHQ–9 is an invalid tool for this population. Another commenter recommended that CMS incorporate clinically appropriate exclusions for grief and loneliness, which may be prevalent in the Medicare population.

Response: We appreciate the feedback from commenters. Depression is prevalent among older adults, including individuals with Major Neurocognitive Disorder (dementia), and appropriate screening and treatment may improve quality of life, reduce morbidity, and help manage symptoms. While the PHQ–9 is a commonly used and validated screening instrument, it is not the only tool that may be used to meet the depression screening requirement under the DSF measure. Clinicians may use other standardized, validated depression screening instruments that are appropriate for the patient's cognitive status and clinical circumstances, consistent with accepted clinical practice.

We also acknowledge commenters' recommendations regarding grief and loneliness. Grief and loneliness are recognized risk factors for clinical depression and are prevalent in the Medicare population. Their presence does not preclude depression screening; rather, it underscores the importance of screening to identify individuals who may benefit from further assessment, monitoring, or treatment. Accordingly, we do not find that categorical exclusions for dementia, grief, or loneliness are warranted, as the DSF measure is intended to support clinically appropriate, whole-person care and relies on provider judgment to determine the most suitable screening approach for each patient.

Comment: A commenter indicated the measure is misaligned with MAHA principles and suggested using the MAHA Elevate model that emphasizes lifestyle and prevention over medicalized screening.

Response: We thank the commenter for their feedback; however, we disagree that the DSF measure is misaligned with MAHA principles. There is a transparent process for adding measures to the Part C Star Ratings described at § 422.164(c). Any new measure first needs to go through the Pre-Rulemaking Review process and initial input is solicited through the Advance Notice process before being proposed through formal rulemaking. New measures must be on the display page for at least two years prior to inclusion in the Star Ratings. The DSF measure supports MAHA priorities by promoting whole-person care through early identification of depression and timely, appropriate follow-up, which are foundational to prevention and long-term health. Depression screening is a well-established, evidence-based preventive service that enables clinicians to identify individuals who may benefit from a range of interventions, including lifestyle-based, psychosocial, and clinical approaches.

Follow-up care under the DSF measure is not prescriptive or one-size-fits-all. Appropriate follow-up for individuals with a positive depression screen may include outpatient, telephone, e-visits, or virtual check-in

[99] NCQA HEDIS Measurement Year 2026 Volume 2.

[100] NCQA HEDIS Measurement Year 2026 Volume 2.

follow-up visits; depression case management encounters; behavioral health encounters including assessment, therapy, collaborative care, or medication management; an encounter for exercise counseling; or a dispensed antidepressant medication. By supporting early detection and flexible, patient-centered follow-up, the DSF measure advances prevention, wellness, and individualized care consistent with MAHA principles.

Comment: A commenter stated that the measure encourages MA plans to interfere with the patient-physician relationship by incentivizing MA plans to screen for depression and provide appropriate follow-up care.

Response: We thank the commenter for this feedback, yet we disagree. This measure should encourage collaboration between the plan and the provider to ensure the enrollee gets the care they need.

Comment: Several commenters request CMS align the DSF measure with other CMS quality programs, such as the DSF measure used in the Merit-based Incentive Payment System (MIPS), before implementation to avoid conflicting specifications, duplicative reporting, and additional administrative burden on providers.

Response: We agree with the efforts to align measures across CMS quality programs. In the 2024 Pre-rulemaking Measure Review Process (PRMR), the committee recommended that the MIPS program consider replacing their measure with the one used for Medicare health plans to improve alignment across quality programs.[101] There are key factors that make the NCQA-stewarded version of the DSF measure more appropriate for the Star Ratings program, including that the specification is at the health plan level. 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. Regarding clinical exclusions, the MIPS version only excludes individuals with a diagnosis of bipolar disorder, whereas the NCQA-stewarded version excludes individuals with bipolar disorder or a current diagnosis of depression.

Comment: A commenter stated that depending on the denominator definition and exclusions, the DSF measure may disproportionately limit applicability for I–SNP and Institutional Equivalent (IE)-SNPs, which may exacerbate measurement gaps for these plan types.

Response: We thank the commenter for the feedback. As long as an I–SNP only contract meets the denominator requirements for the measure, it will have a score for this measure. If an I–SNP is part of a larger contract that has non I–SNP enrollees, the measure score will include I–SNP and non I–SNP enrollees.

Comment: A few commenters stated that the large number of measures proposed for removal, as discussed in section V.B of this final rule, may negatively impact plans and that CMS should not implement a new measure at the same time.

Response: Removing multiple measures should help reduce burden for plans and help them focus on new areas where there is significant room for improvement in clinical care. Depression screening is a serious and common mental disorder that occurs in people of all ages. The lifelong prevalence of depressive disorders is estimated to range from 10 to 15 percent.[102] 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.[103] The addition of the DSF measure to the Star Ratings program will encourage screening and follow-up care for depression.

Comment: A commenter recommended implementing the DSF measure through coordinated, interdisciplinary workflows that integrate physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP) due to their high frequency touchpoints with patients and to leverage existing data sources to minimize administrative burden. Another commenter recommended alternative screening options such as voice-based and modality-agnostic tools, which may be appropriate for older adults and those with limited English proficiency.

Response: We thank the commenters for their recommendations. The DSF measure is provider and team agnostic, so implementation through coordinated interdisciplinary workflows is accepted and encouraged. For alternative screening options, if there is evidence that alternative screening mechanisms are clinically validated, these options will be considered for inclusion in the future.

After considering the comments we received and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to the comments, we are finalizing the addition of the Depression Screening and Follow-Up measure to the Star Ratings beginning with the 2029 Star Ratings.

3. Summary of Measure Changes for the Part C and Part D Star Ratings

Table 4 summarizes the additional measure addressed in this final 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 final rule, CMS does not codify the specific measures for the Part C and 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.

[101] *https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf.*

[102] Lépine, J.P., M. Briley. 2011. ''The Increasing Burden of Depression.'' *Neuropsychiatric Disease and Treatment* 7(suppl 1): 3–7.

[103] O'Connor, E.A., E.P. Whitlock, T.L. Beil, B.N. Gaynes. 2009. ''Screening for Depression in Adult Patients in Primary Care Settings: A Systematic Evidence Review.'' *Annals of Internal Medicine* 151(11):793–803.

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 solicited 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 also solicited feedback on additional measures that could be removed in future years.

Commenters broadly supported CMS's goal to streamline the Part C and D Star Ratings program and shift towards more outcome-focused and prevention-oriented measures, but many commenters cautioned against rapid, large-scale changes that could destabilize plans, reduce competition, and disproportionately harm plans serving high-need, complex, or vulnerable populations (*e.g.,* SNPs, dually eligible individuals, and ESRD beneficiaries). Commenters urged CMS to phase in changes slowly, preserve stability tools in the methodology (guardrails, hold harmless, predictable cut points), and ensure fair benchmarking through stratification by plan type, population, and geography. Many commenters recommended reducing reliance on process and survey-based measures that have small samples or high volatility, while expanding outcome measures tied to chronic disease management, functional status, behavioral health access, nutrition/food-as-medicine, primary care investment, provider experience, and care transitions. Across commenters, there are comments related to aligning measures across programs, reducing administrative burden, improving transparency, and ensuring that quality incentives reflect plan-driven actions that improve beneficiary health, access, and well-being.

We will take all comments received into consideration as we consider ways to streamline and modify the Star Ratings methodology and continue to review the Star Ratings measure set. Any additional changes to the methodology and measure set would need to go through the rulemaking process.

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) (''Contract Year 2024 final rule''), we finalized the addition of the Health Equity Index (HEI) reward (also called the Excellent Health Outcomes for All (EHO4all) reward) [104] along with the removal of the historical reward factor at the same time. The HEI reward was intended to further incentivize Part C and 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 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 Contract Year 2024 final rule, we have reviewed the HEI reward consistent with the Executive Order 14192, ''Unleashing Prosperity Through Deregulation'' and proposed to remove the HEI reward from the Star Ratings methodology. We proposed 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 policy finalized in section V.B. of this final 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 final 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.

[104] 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.*

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 proposed to keep the methodology consistent for now as we explore ways to simplify the methodology in the future. See section V.C., where we solicited comment 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 HPMS, to reflect the temporary addition of the HEI reward and removal of the historical reward factor. Therefore, we proposed to not 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 proposed 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.''

We invited public comment on this proposal and received several comments. A discussion of these comments, along with our responses follows.

Comment: Many commenters supported not implementing the HEI reward and adding back the historical reward factor in the 2027 Star Ratings. These commenters cited many reasons for support including:

- perceived unfairness of the HEI reward enrollment thresholds and not all contracts being able to qualify for the HEI reward factor,
- perceived disadvantage to smaller, regional, or provider-owned plans in meeting enrollment thresholds compared to larger plans and the potential for anti-competitive dynamics as a result,
- perceived geographic bias against states that have not expanded Medicaid, because of dual eligibility being one of the main social risk factors included in the HEI,
- state policies in some states requiring D–SNP only contracts,
- some states have expanded or more generous Medicaid eligibility, while other states use a more limited definition of low income;
- continued recognition of consistent high performance on the Star Ratings through inclusion of the historical reward factor,
- inadequate understanding of methodology and performance outcomes associated with the HEI,
- request for predictability and stability of the Star Ratings and associated QBPs while CMS considers broader simplifications to the Star Ratings methodology,
- reduced administrative burden and complexity,
- exclusion of some groups with social risk factors such as rural enrollees,
- belief that the Star Ratings already incentivized plans to invest in improving health outcomes for enrollees with social risk factors,
- perceived ability for plans to better maintain supplemental benefits, have more resources for quality improvement initiatives and member services, and avoid increasing premiums and potential loss of coverage for some enrollees,
- perceived ability for plans to invest in prevention and management of chronic disease, and avoid placing additional strain on local healthcare systems,
- focus on overall quality for all members, and
- belief that improvements made among the populations included in the HEI will help overall Star Ratings performance.

Commenters also appreciated CMS's responsiveness to previous stakeholder feedback recommending not implementing the HEI reward and retaining the historical reward factor.

Response: CMS appreciates these commenters' support. We agree that not implementing the HEI reward and continuing the historical reward factor will result in more stability in the Star Ratings as we consider other changes to refocus the measure set and simplify the Star Ratings methodology. Additionally, we agree that any improvements made by contracts among populations included in the HEI reward will only help with performance on the Star Ratings more broadly, and such improvements should be made regardless of the Star Ratings methodology. We also feel it is important to be responsive to concerns raised by commenters as we have received feedback consistent with these comments over the past few years, including in response to 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 proposed rule and 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.

Comment: Some commenters encouraged CMS to continue to look for ways to evaluate health equity and address social risk factors, cultural competency, and complex care needs in the Star Ratings. Commenters expressed that it is important to ensure vulnerable populations do not have barriers to care and to hold MA plans accountable for improving the care of vulnerable populations. A commenter stated that future proposals in this area should be supported by a clear policy rationale, transparent methodology, and robust stakeholder engagement.

Response: CMS appreciates these comments and will take them into consideration as we continue to consider future changes to the Star Ratings methodology. Any changes to the Star Ratings methodology will be proposed through the rulemaking process and would include a policy rationale and impact analysis of the proposed changes and an opportunity for stakeholder feedback.

Comment: Several commenters encouraged CMS to implement a one-year or multiple-year hold harmless policy starting with the 2027 Star Ratings where contracts would earn the better of the HEI reward and the historical reward factor, or a phased transition for removing the HEI reward.

Response: CMS does not agree that such a hold harmless or phased transition is necessary, because any improvements contracts made among the populations included in the HEI are consistent with existing program goals and expectations to provide high quality care to all enrollees, including those that are dually eligible (DE), receive a low-income subsidy (LIS), or are disabled. Improvements made for these populations are not isolated to the HEI reward and will only help contracts in their performance on the Star Ratings more broadly. Contracts can earn five stars for the overall rating without either the HEI reward or the historical reward factor, and adding back the historical reward factor does not penalize contracts because it is an upside only reward. Additionally, implementing the

HEI reward for only one year would be operationally complex and it would be potentially confusing for plans and beneficiaries for the methodology to change for just one year only to then revert back to the prior methodology. Additionally, all of this would happen at the same time that we are considering ways to simplify the methodology in the future.

Comment: A couple of commenters supported removing the HEI reward but did not support adding back the historical reward factor. A few other commenters suggested changes to the historical reward factor methodology. A commenter stated their belief that some measures included in the Star Ratings are flawed or may be influenced by administrative scale, vertical integration, or extensive outreach, and they argued for the historical reward factor to be sunset or narrowed. The commenter also stated that the reward factor favors plans with resources to optimize across a large measure set. A couple commenters believed the historical reward factor should not be based on variance in performance either because they believed this penalizes plans or because the ratings are dynamic in terms of the measure set and cut points. A commenter stated that the historical reward factor creates a cliff problem, because it includes cut offs for mean and variance, and further stated that CMS should develop a continuous reward that incentives excellent performance.

Response: CMS will consider whether the historical reward factor should continue to be part of the Star Ratings in the future. However, performing consistently well across the full set of Star Ratings measures is an indicator of overall plan quality. This is consistent with the Star Ratings methodology as a whole, which emphasizes the importance of performing well across a variety of measures and showing improvements from the prior year. This is also reflected in how we set cut points each year based on industry performance, include the improvement measures, and include a measure set focused on a range of clinical care, outcome, and patient experience measures. Contracts should not focus on performing well on only a few measures.

CMS also appreciates the suggestions for changes to the historical reward factor methodology. We are continuing to implement the historical reward factor under the current methodology at this time while we consider ways to simplify and modify the Star Ratings methodology to further drive quality improvement. Any changes to the historical reward factor methodology would need to be proposed through rulemaking.

Finally, we note that the historical reward factor is intended to reward consistent high performance across the Star Ratings measures. If a contract has high variance in performance, it will not receive a reward under the historical reward factor. Since the intent is to reward contracts with both high mean and high variance, cut offs are required to define high mean and high variance. CMS will take the comments related to a continuous reward factor into consideration; however, it would not be appropriate to assign a reward factor to all contracts regardless of the level and consistency of performance as this is inconsistent with the intent of the reward factor. We also note that no contracts are penalized by the reward factor because it is upside only.

Comment: A number of commenters opposed removing the HEI reward and adding back the historical reward factor. Several commenters raised concerns about the timing of this proposal since it is not in advance of the measurement years for the HEI reward and historical reward factor for the 2027 Star Ratings. Commenters argued plans have made investments in improving care for populations included in the HEI reward. A couple of commenters noted negative financial implications for plans that invested in improving care as a result of the HEI reward. Other commenters raised concerns about removing incentives for plans to invest in care models, improved access, and high quality care for populations with high needs and social risk factors. A few commenters stated that plans are consistently denying patients needed care and the historical reward factor does not address this, and that therefore CMS should allow plans to move forward with efforts to implement the HEI. A commenter stated that it reasonably relied on the finalized HEI provisions in its planning.

Response: CMS expects that plans will invest in improving care for all enrollees regardless of the Star Ratings and QBPs, including among enrollees that may have higher needs, such as the populations included in the HEI reward. This expectation is appropriate and consistent with MA statutory and regulatory requirements under section 1852 of the Social Security Act (the Act) and implementing regulations at 42 CFR part 422. Under section 1852(a)(1)(A) of the Act and § 422.101(a), MA organizations must furnish, with limited exceptions, all Medicare-covered benefits to enrollees. Section 1852(e) of the Act and § 422.152 further require MA organizations to maintain ongoing quality improvement programs designed to improve the quality of care provided to all enrollees, while section 1852(d) of the Act and § 422.112 require that MA organizations offering network-based coordinated care plans ensure that covered services are available and accessible to each enrolled individual with reasonable promptness and continuity of care. Collectively, these provisions establish that MA organizations must ensure equitable access to high-quality care for all enrollees, including dually eligible, low-income, and disabled beneficiaries. While CMS recognizes that plans have made investments to improve care for populations included in the HEI reward, these investments should not be viewed as contingent on the continuation of a specific reward mechanism, as improvements in care delivery, access, and outcomes for these populations are foundational to the MA program and remain important regardless of the Star Ratings structure. Improvements in performance among these populations will still contribute to higher performance on the Star Ratings by increasing measure-level scores even if the HEI reward is not implemented. Furthermore, as previously explained, maintaining the historical reward factor instead of implementing the HEI reward will incentivize improvement efforts on clinical care, outcomes, and patient experience for all enrollees, rather than incentivizing improvement for only certain populations. This consideration outweighs concerns about any potential reliance by plans on a future policy that had not yet been implemented. CMS expects that plans will work to provide high quality care to all enrollees and address instances where lower quality care may be provided to certain groups of enrollees. CMS expects this regardless of the Star Ratings methodology and incentives. Further, any improvements plans made in anticipation of a future HEI reward are for the benefit of enrollees and have the potential to boost the plan's Star Ratings performance, whether the HEI reward is included in the Star Ratings or not. While CMS acknowledges the commenter's statement regarding reliance on the inclusion of the HEI reward, CMS notes that plans remain responsible for meeting existing quality requirements and delivering appropriate care to all enrollees. Removal of the HEI provisions do not negate or undermine investments made to improve care, as such efforts continue to advance quality improvement goals and overall

performance under the Star Ratings program.

Comment: A couple of commenters stated that removing the HEI reward from the 2027 Star Ratings is impermissibly retroactive or a retroactive policy change.

Response: CMS disagrees with the commenters' assertion that removing the HEI reward from the 2027 Star Ratings is retroactive. There are no retroactive effects on past Star Ratings. That is, all Star Ratings that have already been calculated stay exactly the same. This change only affects how Star Ratings will be calculated in the future, starting with the 2027 Star Ratings.

Removing the HEI reward is a methodology change, not a measure specification change. At §§ 422.164(c) through (e) and 423.184(c) through (e), CMS lays out rules for adding, removing and updating measures and what needs to be finalized prior to the measurement year. In this case, we are not changing any measure specifications or the data plans must collect or report to CMS. We are updating how a reward will be calculated using existing data.

Pursuant to our authority under sections 1856(b) and 1860D–12 of the Act to adopt standards to carry out the Part C and D programs, CMS may update and improve the Star Ratings methodology over time. This methodology change is being made through the notice-and-comment rulemaking process, which means plans and other stakeholders were given advance notice, had the chance to submit comments, and are receiving a formal response in this preamble. CMS did take into consideration that some plans may have made investments based on the HEI reward being implemented; however, these investments should still be reflected in the measure scores and benefit contracts that showed significant improvement in the care that they provided to the populations includes in the HEI reward.

Comment: A couple of commenters stated that removing the HEI and continuing the historical reward factor risks allowing plans to improve on average while not improving or potentially worsening disparities in performance among high-need and socially disadvantaged populations. One commenter stated if CMS does not move forward with the HEI it should replace it with stratified reporting or weighting for dual eligible/LIS enrollees so that plans can't improve on average while neglecting high-need populations.

Response: CMS appreciates these suggestions for modifying the Star Ratings methodology to account for dual eligible/LIS enrollees and will take them into consideration as we consider future changes to the Star Ratings methodology. CMS expects that plans will work to provide high quality care to all enrollees and address instances where a lower quality of care may be provided to certain groups of enrollees. CMS expects this regardless of the Star Ratings methodology and incentives. Plans remain responsible for meeting existing quality requirements and delivering appropriate care to all enrollees.

Comment: A few commenters did not support rewarding historical performance through the historical reward factor. A commenter stated that tying incentives to historical performance may result in plans focusing on preserving existing metrics rather than making forward-looking investments in care coordination, preventive services, and community-based supports that are important for socially complex populations. The commenter further stated that without adjusting for social risk, the historical reward factor may dampen incentives for innovation among plans serving more complex populations.

Response: These commenters may have misunderstood what we meant by historical reward factor. This reward factor does not rely on historical data. The use of historical was meant only to clarify that we were referring to the reward factor that has been in the Star Ratings since the 2009 Star Ratings and to distinguish this reward factor from the HEI reward. The historical reward factor uses the same, most recently available data as the rest of the Star Ratings calculations.

Comment: A commenter stated their belief that removing the HEI would perpetuate D–SNPs being penalized by the Star Ratings as a result of the impact of non-medical risk factors on enrollees' health. The commenter supported continuing the HEI or making changes to the Categorial Adjustment Index (CAI) for D–SNPs. The commenter also stated the Star Ratings do not adjust for member mix effectively.

Response: CMS appreciates these comments and will take them into consideration as we continue to consider future changes to the Star Ratings methodology. CAHPS and HOS measures are adjusted for case mix, and the Part D medication adherence measures will be adjusted for case mix beginning with the 2028 Star Ratings. Other measures are included in the CAI, as described at §§ 422.166(f)(2) and 423.186(f)(2), which adjusts for within-contract performance differences associated with the percentages of beneficiaries that receive an LIS or are dual eligible or have disability status.

Comment: Several commenters stated that the historical reward factor embeds disparate quality standards that favor more resourced, healthier populations. A couple of commenters also stated that removing the HEI reward and adding back the historical reward factor would mask gaps in care and remove the focus on fixing such gaps.

Response: CMS appreciates these comments and will take them into consideration as we consider future changes to the Star Ratings methodology. CMS expects that plans will work to provide high quality care to all enrollees and address instances where a lower quality of care may be provided to certain groups of enrollees. CMS expects this regardless of the Star Ratings methodology and incentives. Plans remain responsible for meeting existing quality requirements and delivering appropriate care to all enrollees.

Comment: A commenter stated that without the HEI reward there is an unfair advantage for larger plans compared to smaller regional plans that results in perpetuating disparities and weakening incentives for plans that serve vulnerable populations.

Response: CMS appreciates these comments and will take them into consideration as we consider future changes to the Star Ratings methodology.

Comment: A couple of commenters stated that removing the HEI reward and adding back the reward factor is not consistent with the objective of shifting the Star Ratings toward outcome-based measures and away from operational incentives, because the reward factor is unrelated to improving clinical care, outcomes, or patient experience.

Response: CMS disagrees that the reward factor is unrelated to clinical care, outcomes, and patient experience. The reward factor incentivizes high, consistent performance across all measures included in the Star Ratings, including those focused on clinical care, outcomes, and patient experience. As we consider how to simplify and modify the methodology and refocus the measure set, we will continue to focus on how to incentivize improvements in clinical care, outcomes, and patient experience.

Comment: A commenter did not support adding back the historical reward factor, stating that it benefits a small subset of plans and does not recognize improvement because it is intended to only reward plans that have consistently high Star Ratings across multiple years. Another commenter

stated that the reward factor may distort ratings by making them less responsive to changes in quality.

Response: The reward factor is not based on multiple years of performance; it is based on consistent, high performance across measures in a single Star Ratings year. As such, the historical reward factor was in fact intended to incentivize improvement because plans must have high performance during the measurement year across the measure set in order to qualify.

Comment: A commenter stated that the only rationale provided for removing the HEI reward is that it aligns with our focus on exploring ways to simplify and modify the Star Ratings methodology. A few commenters stated that simplicity should not be the key factor in performance measure selection or come at the expense of meaningful measurement.

Response: Our rationale for removing the HEI reward, as stated in the Contract Year 2027 proposed rule, is to incentivize improvement efforts on clinical care, outcomes, and patient experience in line with our proposed changes to the measure set, rather than incentivizing improvement among certain populations. We also noted that we are exploring ways to simplify and modify the methodology, and we proposed to keep the methodology consistent for now while we conduct this exploration. Finally, as we explained in our responses to comments above, we are also being responsive to stakeholder feedback received over the past several years.

When we consider changes to the methodology and measure set, the key factors we consider are consistent with the guiding principles for making enhancements and updates to the Star Ratings we stated 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 at 83 FR 16521. The MA and Part D Star Ratings are designed to align with CMS's Quality Strategy and to fairly, accurately, and transparently reflect plan quality and beneficiary experience, using reliable data and consensus-based measures that are stable over time and largely within plans' control. The system is intended to support public accountability, informed beneficiary choice, and quality improvement while minimizing unintended consequences and incorporating meaningful stakeholder input.

In addition, the Star Ratings methodology has become more complex over time, prompting us to consider ways to simplify and modify the methodology to maintain statistical rigor while making the methodology easier to understand and implement. Simplifying the methodology may also improve how well the Star Ratings incentivize quality improvement.

Comment: A commenter opposed our proposal to not implement the HEI reward and add back the historical reward factor, stating that policies should support, not penalize, clinicians and plans serving high-risk populations and should encourage investment in primary care, care coordination, and community-based interventions.

Response: CMS appreciates these comments; however, the historical reward factor is an upside-only reward that encourages consistent, high performance across Star Ratings measures and does not penalize plans or clinicians. CMS expects that plans will invest in improving care for all enrollees regardless of the Star Ratings and QBPs, including among enrollees that may have higher needs, such as the populations included in the HEI reward. This expectation is appropriate and consistent with MA statutory and regulatory requirements under section 1852 of the Social Security Act (the Act) and implementing regulations at 42 CFR part 422. Under section 1852(a)(1)(A) of the Act and § 422.101(a), MA organizations must furnish, with limited exceptions all Medicare-covered benefits to enrollees. Section 1852(e) of the Act and § 422.152 further require MA organizations to maintain ongoing quality improvement programs designed to improve the quality of care provided to all enrollees, while section 1852(d) of the Act and § 422.112 require that Medicare organizations offering network-based coordinated care plans ensure that covered services are available and accessible to each enrolled individual with reasonable promptness and continuity of care. Collectively, these provisions establish that MA organizations must ensure equitable access to high-quality care for all enrollees, including dually eligible, low-income, and disabled beneficiaries.

After consideration of the public comments we received and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to comments, we are removing the paragraphs at §§ 422.166(f)(3) and 423.186(f)(3) and modifying §§ 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 proposed 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 Contract Year 2019 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 proposed 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).

We solicited comment on this proposal. In this section, we summarize the comments we received and provide our responses and final decisions.

Comment: A majority of commenters expressed support for CMS's proposal to codify its current practice of providing sample data during the plan preview periods. Some commenters stated that increased transparency will help plans more accurately review, validate, and understand their Star Ratings calculations, ultimately improving the integrity of Star Ratings and leading to improved quality assurance and better outcomes for beneficiaries.

Response: CMS appreciates the support for the proposed codification of

our current practice of providing sample data for one measure of each type during the second plan preview period. CMS agrees this approach aligns with our goals of promoting accountability, improving the integrity of Star Ratings, and leading to better outcomes for beneficiaries.

Comment: Several commenters recommended CMS expand the current practice of providing sample data for one of each measure type by providing sample data for all measures. They stated that without full access to the underlying data for all measures, plans cannot fully validate CMS's methodologies and calculations. Another commenter noted that much of the data already exists and asked that CMS provide a list on the HPMS Star Ratings website of all data sets available to plans and where to obtain them.

Response: As stated in the Contract Year 2027 proposed rule, CMS provides de-identified contract-level sample data for one measure of each type so MA organizations and Part D sponsors can replicate calculation of the measure-level cut points. Because the same cut point programming is used for all measures of the same type, only de-identified contract-level data for the sample measures are needed to validate CMS's cut point methodology. Adding de-identified contract-level data for all measures would be burdensome to implement, and data provided during the plan preview are preliminary. The purpose of the plan preview is for Part C and D sponsors to closely review their own Star Ratings data, including preliminary Star Rating assignments. Contracts are not entitled to review other contracts' preliminary Star Ratings data before they are public. Adding a list of all data sets available to plans and where to obtain them may be easier to implement and CMS will take this suggestion under consideration as a future enhancement.

After consideration of the public comments we received and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to comments, we are finalizing §§ 422.166(h)(2) and 423.186(h)(2) as proposed without modification.

F. Impact of Proposed and Finalized 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 the Contract Year 2027 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 final rule, we are adding and removing certain Star Ratings measures. The new measure entails moving an existing measure from the display page to Star Ratings, which would have no impact on plan burden. The measures being removed are either calculated from administrative data [105] or would still be submitted by plan sponsors and, as such, there would be no decrease in plan burden. The finalized 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 are not making changes under any of the aforementioned control numbers.

We solicited feedback on the impact of these proposed changes.

Comment: A commenter requested that CMS conduct an impact analysis that separates out SNP from non-SNP plans. The commenter also requested an analysis broken out by region and size of enrollment. The commenter stated that these analyses would ensure that the proposed changes do not inadvertently harm vulnerable populations.

Response: In the tables below, we break out the impacts for MA contracts by SNP-only contracts, partial SNP contracts (those with both SNP and non-SNP plans), and non-SNP contracts and by contract enrollment size. These tables show the impacts of the changes finalized in this final rule (*i.e.,* removing 11 measures as finalized in section V.B. of this final rule, removing the HEI reward, and keeping the historical reward factor). We do not provide a breakout of the impacts by region because some contracts have broad service areas.

TABLE 4. CHANGE IN OVERALL RATING AND ELIGIBILITY FOR QBPS FOR SNP-ONLY, PARTIAL SNP, AND NON-SNP CONTRACTS*

Overall Rating	SNP-Only Contracts	Partial SNP Contracts	Non-SNP Contracts
No Change	65%	65%	60%
Increase by half star	4%	15%	15%
Decrease by half star	31%	20%	25%
Gain QBPs	0%	3%	7%
Lose QBPs	4%	4%	3%

*Percentages out of contracts in the category receiving a numeric overall rating.

[105] 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.

TABLE 4. CHANGE IN OVERALL RATING AND ELIGIBILITY FOR QBPS BY CONTRACT ENROLLMENT*

Overall Rating	Less than 10,000 Enrollees	10,000 to less than 125,000 Enrollees	Greater than or Equal to 125,000 Enrollees
No Change	63%	63%	66%
Increase by half star	12%	13%	22%
Decrease by half star	25%	24%	12%
Gain QBPs	4%	4%	7%
Lose QBPs	1%	5%	2%

*Percentages out of contracts in the category receiving a numeric overall rating. Enrollment as of October 2024.

After consideration of the public comments we received, and for the reasons outlined in the Contract Year 2027 proposed rule and our responses to comments, we are finalizing all Star Ratings proposals from the Contract Year 2027 proposed rule, except for the removal of the Diabetes Care—Eye Exam (Part C) measure. The impact of the finalized changes based on the simulations using data from the 2025 Star Ratings and accounting for changes implemented in the 2026 Star Ratings, as explained at the beginning of this section, show most contracts (63 percent) would have no change in their overall rating. The overall rating would increase by a half star for 13 percent of contracts, and would decrease by a half star for 24 percent of contracts. Four percent of contracts would gain QBPs, and three percent of contracts would lose QBPs.

G. Contract Consolidations (§§ 422.162(b)(3) and 423.182(b)(3))

In 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 proposed rule, which appeared in the **Federal Register** on December 10, 2024, we proposed a technical clarification of existing policy at § 422.162(b)(3)(iv)(A)(2) and (B)(2) and § 423.182(b)(3)(ii)(A)(2) and (B)(2) to provide details about how the enrollment-weighted measure score is calculated when a consumed or surviving contract is missing data for a measure. In the first year of the consolidation when a measure score for a consumed or surviving contract is missing as a result of not having enough data to meet the measure technical specification or for a CAHPS measure having reliability less than 0.6, CMS proposed to treat this measure score as missing in the calculation of the enrollment-weighted measure score. Similarly, in the second year of the consolidation for all measures, except HEDIS, HOS, CAHPS, and call center measures, when a measure score for a consumed or surviving contract is missing as a result of not having enough data to meet the measure technical specification, CMS proposed to treat this measure score as missing in the calculation of the enrollment-weighted measure score. For § 423.182(b)(3)(ii)(A)(2) and (B)(2) we also removed reference to § 423.184(g)(1)(ii) since it was reserved in the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE) final rule (pages 30639–30642).

We solicited comment on this proposal.

Comment: A couple commenters supported this technical clarification, noting that it is consistent with other similar approaches for calculations and will help prevent gaming. No commenters opposed the clarification.

Response: We thank these commenters for their support.

Comment: A commenter encouraged CMS to continue to take a uniform and consistent approach to data standards for contract consolidations.

Response: We thank this commenter for their support of a uniform and consistent approach to data standards for consolidations and find that the current methodology for consolidations and the proposed technical clarification align with this approach.

Comment: A commenter requested clarification that CMS will exclude missing data from the weighted average calculation, noting that some software will give missing values as the final output when missing data are included in calculations.

Response: CMS confirms that missing data would be excluded consistent with the proposed technical clarification.

Comment: A commenter requested CMS assess potential impacts and confirm the clarification accurately reflects plan performance and quality of care for impacted populations.

Response: Excluding missing data from the calculation of measure scores for the surviving contracts of consolidations for measures with low reliability or that do not have enough data to meet the measure technical specifications more accurately reflects plan performance and the quality of care provided.

After consideration of the comments we received and for the reasons outlined in the Contract Year 2026 proposed rule and our responses to comments, we are finalizing the technical clarification at §§ 422.162(b)(3) and 423.182(b)(3). As this is a technical clarification, CMS is applying it immediately on the effective date of the final rule and to the 2027 Star Ratings.

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.[106]

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 proposed 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 will 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 will split that period to accommodate the operational needs of CMS and NCQA as staff review initial and annual MOC submissions.

CMS expects there will be no change in the estimated burden from this changed timeline for SNPs submitting off-cycle MOC changes. Additionally, there will be no new collection of information for this rule, only maintenance of past expectations around the off-cycle MOC process.

CMS invited public comment on this proposal and received several comments in support. CMS received no comments opposing this proposal, but several commentors offered support with suggested modifications. The comments and responses are as follows:

Comment: Several commenters supported CMS' proposed change, but requested CMS continue to look at greater alignment with state Medicaid contracting windows where possible.

Response: CMS appreciates the commenters' support of this proposed change and agrees that the timing of MOC deadlines should align with state Medicaid contracting windows when possible. The shift in timing of the annual renewal and initial MOC submission process reflects feedback CMS has received over the years from plans and state Medicaid agencies. In some instances, CMS is restricted by the operational practicalities related to NCQA's review and approval of SNP MOCs in relation to finalizing all MA plan requirements for the upcoming contract year. However, CMS will continue to review the MOC submission process and its impact on plans and state partners.

Comment: Several commenters supported the proposal but suggested keeping the SNP MOC submission portal open year-round to give SNPs more time to make corrections and submit changes. They noted that this is particularly necessary when there are significant policy changes or mandates made at the state level. Commenters stated that an enhanced open portal timing would further reduce burden since plans are prohibited from making care management and some operational changes until NCQA has approved the SNP's off-cycle MOC submission. Another noted that the window should remain open from October 1st to March 31st of the next contract year.

Response: CMS appreciates the commenter's concerns and have taken plan burden into consideration when developing this proposal. As noted in the previous comment response, however, CMS is limited by operational considerations specific to NCQA's review process in relation to finalizing all MA plan requirements for the upcoming contract year. While this proposal represents the best balance of all these considerations, CMS will continue to review the MOC review process for future refinement opportunities.

Regarding the potential extension of the off-cycle window from October 1st to March 31st of the next contract year, this proposal is essentially providing the opportunity the commenter is

[106] For more discussion of the history of SNPs, please see Chapter 16B of the Medicare Managed Care Manual (MMCM).

seeking. The text of the proposal is written to align with current regulatory practices in mind as many of our current regulations are consistent with a contract year framework, which is why CMS framed the proposal around two separate portions of the same contract year.

After reviewing and responding to all comments, CMS is finalizing revisions to § 422.101(f)(3)(iv)(B) and (G) without modification.

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 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 met 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 (hereafter referred to as August 2018 HPMS memo) that provided technical guidance on how we would assess for substantially similar networks.[107] 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, in the Contract Year 2027 proposed rule, we proposed 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 proposed 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 noted that this proposed requirement would not affect a receiving integrated D–SNP's requirement to meet network adequacy standards per § 422.116, or potential compliance actions that may result from a failure to meet those requirements. We also proposed 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

[107] 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.*

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 (HRAs) 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 proposed 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 proposed 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 specifically tied the proposed amendment in § 422.60(g)(2)(ii) to § 422.112(b)(8)(i)(B), which currently requires MA coordinated care plans to provide a minimum 90-day transition period for basic benefits when an enrollee currently undergoing treatment switches to a new MA plan. This provision requires 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. A more detailed discussion of this proposal is available at 90 FR 54971 of the proposed rule.

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 proposed 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 was 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 also proposed to remove the language that requires the receiving plan to have substantially similar Medicare and Medicaid-covered benefits as the relinquishing integrated D–SNP. 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. As such, 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 did not propose 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 did not propose 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 welcomed comments on the changes we proposed at § 422.60(g)(2)(i) and (ii). Similarly, we solicited 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 did not define a minimum staffing capacity threshold in order to give integrated D–SNPs flexibility in implementing this proposed change. We invited comment on the feasibility of this proposed requirement and requested suggestions for potential refinement.

We received the following comments on this proposal and respond to them:

Comment: Many commenters, including MedPAC and MACPAC, generally supported the proposal to remove the requirement for the receiving D–SNP and the relinquishing D–SNP to have substantially similar networks and instead replace it with a period of continuity of care of 120 days as well as the requirement that the receiving D–SNP have care coordinator staffing capacity to receive dually eligible enrollees through passive enrollment. The commenters noted that these changes would allow for the passive enrollment option to be more readily used and facilitate continued enrollment in an integrated plan for eligible beneficiaries. Some commenters also noted that the proposed changes to passive enrollment would safeguard integrated coverage for dually eligible individuals and would allow passive enrollment to function as intended without imposing unrealistic alignment standards on States with complex delivery systems. A few commenters mentioned the effect of market changes and State re-procurement decisions on the landscape of integrated care and noted that passive enrollment between a non-renewing integrated D–SNP and a comparable D–SNP can help increase enrollment and retention in integrated D–SNPs.

Response: We appreciate the comments and support for the proposed changes to the passive enrollment process. We agree with the commenters that these changes will help streamline the passive enrollment process and help retain enrollment in integrated D–SNPs.

Comment: Some commenters opposed our proposal based on their assertion that CMS's proposal to remove the requirement for substantially similar networks due to not being able to implement such a requirement is an indication that passive enrollment should not be used, and that a slightly extended period for continuity of care does not make up for a future inability to see chosen providers. These commenters further reasoned that allowing passive enrollment could lead to override of an individual's plan enrollment decision, and that the noticing provided to enrollees alerting them that they are being passively enrolled in a new D–SNP with the option to opt out is not enough. A commenter also opined that there is no research to provide evidence that D–SNPs provide improvement in care

coordination for dually eligible enrollees.

Response: We acknowledge the commenters' perspectives on the proposal. We would like to reiterate that passive enrollment is an opportunity for enrollees in an integrated D–SNP to transition to another integrated D–SNP when their original plan is non-renewing or terminating. As we stated in preamble to the proposed rule (90 FR 54971) and as set forth in § 422.60(g)(1)(iii) and described in the April 2018 final rule, and in the August 2018 HPMS memo [108] that provided further technical assistance to D–SNPs on passive enrollment, such a transition would only occur 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. Under the notice requirements at § 422.60(g)(4), enrollees who are passively enrolled will receive a first notice from the integrated D–SNP receiving enrollment at least 60 days before the first day of enrollment in the receiving D–SNP, and a second notice at least 30 days before the first day of enrollment in the receiving D–SNP. Each of these notices will alert enrollees that they have the opportunity to opt out of the enrollment into the receiving integrated D–SNP. In the Contact Year 2027 proposed rule, we did not propose amendments to § 422.60(g)(5), which describes an enrollee's access to the special enrollment period (SEP) at § 423.38(c)(10). We stated that § 422.60(g)(5) would still be in effect. As such, this SEP would also be accessible to enrollees who are interested in switching their coverage (90 FR 54972). Enrollees in D–SNPs also have access to the one-time-per month SEP for dually eligible individuals and other LIS eligible individuals to elect Original Medicare and a standalone PDP and the integrated care SEP which allows full-benefit dually eligible individuals to elect an integrated D–SNP on a monthly basis. We believe that the passive enrollment mechanism, coupled with ample opportunity for an enrollee to switch coverage, does not amount to override of enrollee decision making.

Further, since the inception of the passive enrollment process at § 422.60(g)(1)(iii), CMS's decision to implement passive enrollment has been discretionary, not mandatory, and subject to a deliberative process. As we noted in the August 2018 HPMS memo, in order to implement D–SNP passive enrollment under § 422.60(g)(1)(iii), CMS must consult with the applicable State, CMS must determine that passive enrollment will promote integrated care and continuity of care, and the receiving integrated D–SNP must meet certain requirements. Though our proposal will amend some of the requirements, we did not intend to, nor do we believe that we proposed an amendment to the passive enrollment process that will, dilute our goal to promote integration and continuity of care. We continue to believe that 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.

Although research has not yet uniformly shown an advantage for dually eligible individuals enrolling in D–SNPs 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.[109] In their March 2024 Report to Congress, MedPAC highlighted a HEDIS measure to exemplify care coordination. MedPAC's review of HEDIS data on follow-up after emergency department visits for people with multiple high risk chronic conditions showed that coordination-only D–SNPs, HIDE SNPs and FIDE SNPs performed better than other MA plans for enrollees ages 65 years and older and HIDE SNPs and FIDE SNPs performed better than other MA plans for enrollees ages 18–64 years.[110]

Comment: We received many comments supporting our proposal to amend § 422.60(g)(2)(ii) to require that the D–SNP receiving passive enrollment provide continuity of care to all incoming enrollees for 120 days, with some commenters noting that the proposed amendment would reduce the risk of disrupting patient–provider relationships and help ensure that enrollees continue to receive essential medications and treatments during their plan transition.

Response: We thank commenters for their support.

Comment: We received some comments opposing our proposal to amend § 422.60(g)(2)(ii) to require that the D–SNP receiving passive enrollment provide continuity of care to all incoming enrollees for 120 days. The commenters cited State requirements, and that 120 days would be operationally difficult to achieve. Some of these commenters suggested changing the 120-day proposed requirement to a requirement of 90-to-120 day transition period, suggesting that a period of 90 to 120 days would enable receiving D–SNPs to work with transitioning enrollees without an across-the-board minimum exposure for non-contracted and potentially unmanaged care. A commenter opined that an additional 30-day requirement of continuity of care beyond the currently required 90 days per § 422.112(b)(8)(i)(B) could result in unaccounted for cost trends for the receiving D–SNP. Some commenters requested that CMS further define expectations related to continuity of care and provide clear guidance on how D–SNPs should operationalize continuity requirements, especially in States with multiple Medicaid product types to help ensure that passive enrollment policies advance integration goals without causing confusion or disruption for beneficiaries. For example, one commenter questioned whether, during the continuity of care period, D–SNPs receiving passive enrollment would be required to enter into single case agreements with providers unwilling to join their network.

Commenters further requested that CMS remind all MA plans of their obligations regarding continuity of care under this policy and take enforcement action when MA plans fail to comply. Finally, some commenters suggested that CMS consider strengthening the continuity of care policy by mandating a requirement for the relinquishing D–SNP to provide timely exchange of

[109] 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.*

[110] MedPAC. Report to Congress: Medicare Payment Policy, Chapter 14, March 2024. Retrieved from: *https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_Ch14_MedPAC_Report_To_Congress_SEC.pdf.*

clinical and care management information to the receiving D–SNP, including current treatment plans, authorizations, medications, etc.

Response: We welcome these perspectives. We remind commenters that our proposal relates to passive enrollment under a narrow set of circumstances when a State has a non-renewing or terminating integrated D–SNP with full-benefit dually eligible enrollees and seeks to transition these enrollees to another comparable integrated D–SNP with the goal of maintaining integrated coverage. Furthermore, we would like to make the distinction that our proposed amendment to the passive enrollment process at § 422.60(g)(2) is specific to D–SNPs and would not affect enrollees in other types of MA plans, including I–SNPs. We understand that under the Financial Alignment Initiative (FAI), full-benefit dually eligible individuals in some States were able to be passively enrolled into Medicare-Medicaid Plans (MMPs) from different types of plans. That authority was specific to MMPs under the FAI and is separate from the existing D–SNP passive enrollment regulation at § 422.60(g)(2), which we proposed to amend. Section 422.60(g)(2) only applies to integrated D–SNPs where the D–SNP is non-renewing or terminating and the State affirms its interest in transitioning these enrollees to another comparable integrated D–SNP with the goal of maintaining integrated coverage.

Given that the integrated D–SNP is terminating or non-renewing, there is no opportunity for an enrollee to remain in that D–SNP. We defer to D–SNPs receiving passive enrollees on approaches to contract with providers during the continuity of care period, but a single case agreement would be one such option. We appreciate the commenters' perspectives on potential unforeseen cost trends associated with the proposed 120-day continuity of care requirement. In the August 2018 HPMS memo, we stated that the applicable MA plan must meet certain requirements related to, among other things, coverage, cost, and operational capacity, and agree to receive passive enrollments. If a potential receiving D–SNP does not believe it is able to meet these requirements, it is under no obligation to accept passive enrollment if presented the option.

As stated earlier in this section, enrollees subject to passive enrollment would receive notices 60 days and 30 days in advance of the effective date of enrollment in the receiving integrated D–SNP, providing notice of their ability to opt out of the passive enrollment and choose different coverage. Further, as we discussed earlier in this preamble and in the preamble to the Contract Year 2027 proposed rule, we did not propose amendments to § 422.60(g)(5), which describes an enrollee's access to the SEP at § 423.38(c)(10). As such, this SEP would also be accessible to enrollees who are interested in switching their coverage (90 FR 54972). Enrollees in integrated D–SNPs also have access to the one-time-per month SEP for dually eligible individuals and other LIS eligible individuals to elect Original Medicare and a standalone PDP and the integrated care SEP, which allows full-benefit dually eligible individuals to elect an integrated D–SNP on a monthly basis. An individual passively enrolled has ample opportunities to make a different election should they choose not to enroll or remain enrolled in the receiving integrated D–SNP. Any integrated D–SNP that agrees to accept passively enrolled full-benefit dually eligible individuals will be required to comply with the continuity of care requirements.

Finally, we appreciate the comment regarding mandating a requirement to provide timely exchange of clinical and care management information. Such a requirement does not currently exist and was not proposed in the Contract Year 2027 proposed rule, but we note that § *422.119* requires an MA plan to implement and maintain a standards-based application programming interface (API) that—with enrollee approval and direction—allows third party applications to retrieve certain information as specified in § 422.119(b). Additionally, in some instances, State Medicaid agency contracts (SMACs) may require an exchange of information as well. While we are not finalizing any additional requirements under this rule, we may take this comment into consideration in future rulemaking.

Comment: Some commenters suggested that CMS extend the proposed continuity of care provisions beyond 120 days for residents of nursing facilities and assisted living communities, or other high-need groups.

Response: While we appreciate the request for lengthening the proposed continuity of care requirement to beyond 120 days, we believe increasing the existing 90-day continuity of care requirement to 120 days allows D–SNPs receiving passive enrollment sufficient time to maintain an existing course of treatment and educate providers outside of their networks about joining the D–SNP provider network.

Comment: We received some comments that supported our proposal to remove the requirement that receiving integrated D–SNPs meet the requirement in current § 422.60(g)(2)(ii) to have provider networks and facility networks that are substantially similar to those of the relinquishing integrated D–SNP. Some commenters noted that removing the substantially similar network requirement would remove the imposition of unrealistic alignment standards on complex delivery systems, and that this change represents a practical, beneficiary-centered way to maintain continuity of enrollment in integrated care when the D–SNP landscape changes within a State, minimizing disruptions and preserving the benefits of aligned Medicare-Medicaid coverage and care coordination.

Response: We thank the commenters for their support of this proposed revision. We agree that the proposed changes to § 422.60(g)(2)(ii) will allow D–SNPs to use passive enrollment as intended and safeguard integrated coverage for full-benefit dually eligible individuals when their existing D–SNP terminates or does not renew, and CMS determines, after consulting the State Medicaid agency, that passive enrollment will promote integrated care and continuity of care.

Comment: Similarly, we received some comments that opposed our proposal to remove the requirement that receiving integrated D–SNPs have provider and facility networks that are substantially similar to those of the relinquishing integrated D–SNP. A few commenters encouraged CMS to consider how passive enrollment may cause enrollees to lose access to their existing provider networks, asserting that the value of passive enrollments does not outweigh the value of beneficiary access to the facility network they chose, and that enrollee choice should be maximized during any passive enrollment. Another commenter expressed how this provision may affect a State, noting that a State may have focused on aligning the Medicaid and Medicare provider networks in a way that ensures dually eligible enrollees have continued access to services as they transition from Medicaid into Medicare and that the provider networks are fully available to the populations.

Response: We appreciate the commenters' perspectives on this issue. Our intention in proposing changes to the D–SNP passive enrollment process is to provide a process by which full-benefit dually eligible enrollees are able to maintain access to integrated care. As passive enrollment would only be used in situations where an enrollee's

integrated D–SNP is terminating or non-renewing, and considering the required opt out language and the SEPs that were discussed previously in this section, we believe that those enrollees who wish to select their enrollment based on specific providers or facilities will still be able to do so.

We note that more States are including provisions in their SMACs that address alignment of Medicaid and Medicare provider networks between a Medicaid MCO and its affiliated D–SNP. This alignment of provider networks is distinct from the existing substantially similar network language that we proposed to remove at § 422.60 and replace with an extended continuity of care period. The substantially similar network requirement sought to compare networks between different MA organizations offering integrated D–SNPs whereas the alignment the commenter referenced is specific to the provider network between affiliated entities. As such, we do not believe that the change in the D–SNP passive enrollment provision will have any impact on how States are assessing the alignment of Medicaid and Medicare provider networks.

Comment: We received some comments in support of our proposal to require that an integrated D–SNP receiving passive enrollment have the care coordinator staffing capacity to receive dually eligible enrollees through passive enrollment. Some commenters noted that effective care coordination is essential and that flexibility in staffing models allows D–SNPs to tailor care coordination approaches to the unique needs of dually eligible enrollees, State-specific integration requirements, and existing Medicaid managed long-term services and supports (LTSS) delivery systems, while still ensuring that D–SNPs are appropriately resourced to support new enrollees. Commenters noted that integrated D–SNPs receiving passive enrollment would need adequate notice of the impending passive enrollment in order to meet any staffing update requirements and recommended that CMS provide notice of at least 90 days to the receiving D–SNP prior to the passive enrollment effective date, which would allow sufficient time to increase care coordinator staff levels. Other commenters requested that CMS provide additional information on how it would measure and evaluate adequate care coordination capacity under the proposed requirement.

Response: We appreciate the commenters' support of this proposal. We agree that if a D–SNP were to receive passive enrollment, it should be appropriately resourced to support new enrollees and to tailor care coordination approaches to the unique needs. As noted earlier in this preamble and outlined in the August 2018 HPMS memo, CMS's decision to allow passive enrollment for D–SNPs under § 422.60(g)(1)(iii) is intended to be a deliberative process done in consultation with the respective State. We decline the suggestion for CMS to provide a 90-day notice to potential receiving D–SNPs because we do not find it necessary. Potential receiving D–SNPs will be in communication with CMS and the State to determine if the receiving D–SNP meets the regulatory criteria, has the capacity, and agrees to take on the additional enrollment. We do not intend to establish specific standards for care coordination, but we do highlight the necessity of care coordination when transitioning new enrollees who may or may not have high level of need.

Comment: A few commenters opposed our proposal to require that an integrated D–SNP receiving passive enrollment have the care coordinator staffing capacity to receive dually eligible enrollees through passive enrollment. These commenters noted that there are already care coordination requirements outlined at § 422.107(c) and the potential for additional care coordination requirements that State Medicaid agencies include as part of their SMAC arrangement or establish as an expectation in their policy guides. Another commenter suggested that CMS refrain from issuing policies that dictate care coordination staffing ratios. Commenters further requested that CMS clarify the definition of ''care coordinator staff.''

Response: We appreciate the thoughtfulness of the commenters' responses to this proposed provision. We note that our proposal did not define a minimum staffing capacity threshold to give integrated D–SNPs flexibility in implementing this proposed change, and we are not intending to prescribe a specific standard or ratio at this time. Further, as the commenters noted, there are already care coordination requirements outlined at § 422.107(c). It was not our intention to amend how care coordination requirements are implemented by D–SNPs as required per § 422.107(c), including how many staff would be enough to fit the needs of the D–SNP's beneficiaries. We did not propose nor are we finalizing any additional language in this regard.

Comment: A few commenters specifically objected to our overall proposal to amend the passive enrollment regulation at § 422.60(g) based on their understanding of how it would affect enrollment in institutional special needs plans (I–SNPs) or enrollees that reside in nursing facilities and assisted living communities. The commenters noted that passively enrolling these enrollees into D–SNPs without comparable networks would undermine these investments and disadvantage I–SNPs that have demonstrated strong performance in serving high-need populations. Commenters also suggested that CMS use tags on enrollment processes as an exclusion criterion for passive enrollment. Commenters advised that if applied, then the enrollment flag or facility site of care should be used to ensure that beneficiaries residing in nursing facilities or assisted living communities are only passively enrolled into plans that can maintain continuity of care within their current care setting. In addition, some commenters recommended that CMS simplify opt-out processes and allow beneficiaries who have opted out of passive enrollment to remain in their chosen plan without having to re-opt-out annually.

Response: We thank the commenters for their perspectives and appreciate the consideration paid to vulnerable populations. As we discussed previously in this preamble, we would like to make the distinction that our proposed amendment to the passive enrollment process at § 422.60(g)(2) is specific to D–SNPs and would not affect enrollees in other types of MA plans, including I–SNPs. We understand that under the FAI, full-benefit dually eligible individuals in some States could be passively enrolled into MMPs from different types of plans. That authority was specific to MMPs under the FAI and is separate from what we proposed in the Contract Year 2027 proposed rule, which only applies to integrated D–SNPs where the D–SNP is non-renewing or terminating and the State affirms its interest in transitioning these enrollees to another comparable integrated D–SNP with the goal of maintaining integrated coverage. Under § 422.60(g), CMS implements D–SNP passive enrollment only after consulting with the State Medicaid agency that contracts with the D–SNP, and requires the MA organization receiving passive enrollment to provide two notices of opt-out opportunities to enrollees at least 30 and 60 days prior to the enrollment effective date. Under our proposed amendment to § 422.60(g)(2), the MA organization must also provide continuity of care with a minimum

transition period of 120 days. We do not believe an opt-out flag is needed since we expect any passive enrollment under § 422.60(g)(1)(iii) would be a one-time occurrence in response to an integrated D–SNP non-renewing or terminating. Individuals passively enrolled have multiple opportunities to switch their enrollment to align with their preferred provider or facility, if they so choose, as detailed earlier in this section.

Comment: Some commenters suggested ideas for involving the State Medicaid agency in passive enrollment. Some of these commenters recommended that CMS clarify the flexibilities available to State Medicaid agencies when permitting passive enrollment, including opportunities for the States to establish higher standards for D–SNPs to participate in passive enrollment. Other commenters advised CMS to amend the proposal to allow passive enrollment if State-specific requirements for continuity and transitions of care, detailed in SMACs, are met. The commenters further suggested that CMS defer to States for individual beneficiary assignments, as States are in the best position to understand which D–SNP provides the least disruptive transition option for its members. Some of the commenters recommended that CMS establish clear criteria for integration, such as aligned enrollment, robust Medicaid contracts, coordinated care management, and shared data systems. The commenters believed that passive enrollment should be permitted when the State Medicaid agency confirms that the receiving D–SNP maintains or improves integration compared to alternatives. Commenters also encouraged CMS to collaborate closely with States to ensure enrollees are informed of any enrollment changes due to the passive enrollment process and have meaningful opportunities to select their preferred plan, such as through State-based actions to waive any Medicaid managed care lock-in policies and issuing notices that outline the remaining integrated D–SNP options.

Response: We appreciate these suggestions. As we mentioned earlier in this preamble, since the inception of the passive enrollment process at § 422.60(g)(1)(iii), CMS's decision to implement passive enrollment has been discretionary, not mandatory, and subject to a deliberative process. We expect the circumstances for passive enrollment under § 422.60(g)(1)(iii) to generally occur when a State selects a new Medicaid MCO that has an affiliated D–SNP. When the State selects a new Medicaid MCO, an existing Medicaid MCO with an affiliated D–SNP may not be selected. In this circumstance, the State may want to passively enroll full-benefit dually eligible individuals from the relinquishing D–SNP into the receiving D–SNP. As we noted in the August 2018 HPMS memo that provided further technical assistance to D–SNPs on passive enrollment, in order to implement D–SNP passive enrollment under § 422.60(g)(1)(iii), CMS must consult with the applicable State, CMS must determine that passive enrollment will promote integrated care and continuity of care, and the receiving integrated D–SNP must meet certain requirements. In light of these requirements and our own longstanding practice, we have every intention of working with States to ensure that passive enrollment is in line with State goals and promotes integrated care. To this end, we note that the proposed amendment at § 422.60(g)(2) does not preclude a State from including in their SMAC additional criteria for passive enrollment from an integrated D–SNP that meets the criteria at § 422.60(g)(2). The additional SMAC criteria could include some of the suggestions advanced by the commenters. Further, a State could include such criteria in its request for proposal that is used to select Medicaid MCOs.

Comment: We received several comments suggesting that we include specific information regarding provider or facility types that would be included in the proposed continuity of care requirement. These comments included setting specific requirements for physical therapists, occupational therapists, speech language pathologists, facility-based rehabilitation, home health and hospice providers. A commenter suggested that passive enrollment should emphasize flexibility to allow States and U.S. Territories, particularly those facing ongoing provider shortages in key service areas, such as behavioral health, long-term services and supports, or specialty care, to better protect continuity of care and avoid passive enrollment into plans with weaker or less adequate networks. A commenter suggested CMS clarify that, for therapy, continuity of care includes continuity of the therapeutic relationship, providers, and locations subject to medical necessity and consistent with the plan of care. Other commenters suggested that CMS implement stronger requirements around wait-times for new appointments and/or provider availability. The commenter further suggested that CMS could require any D–SNPs receiving passive enrollment to conduct a provider disruption analysis and share it with the State Medicaid agency prior to passive enrollment. Other commenters requested that CMS require D–SNPs to make reasonable efforts to contract with providers with which they have entered into continuity of care arrangements, to improve the provider network.

Response: We appreciate these commenters' perspectives. We note that the continuity of care period included in the proposed amendment to § 422.60(g)(2)(ii) would require any integrated D–SNP receiving passive enrollment to provide continuity of care consistent with § 422.112(b)(8)(i)(B) for a minimum of 120 days. Section 422.112(b)(8)(i)(B) applies to any active course(s) of treatment when an enrollee has enrolled in an MA plan after starting a course of treatment, even if the service is furnished by an out-of-network provider. Under our proposal, the integrated D–SNP receiving passive enrollment must not disrupt or require reauthorization for an active course of treatment for new plan enrollees for a period of at least 120 days. To that end, any integrated D–SNP receiving passive enrollment should not impose new administrative hurdles (*e.g.,* new evaluations solely for coverage purposes) that functionally delay care transitions and undermine continuity of care. We emphasize that enrollees who are passively enrolled from a non-renewing or terminating integrated D–SNP into a comparable integrated D–SNP may opt out of the passive enrollment or choose other coverage via an SEP. We believe that the specific suggestions for establishing additional provider network and continuity of care requirements are out of scope for this rulemaking and we are not making any changes to the final rule related to those suggestions.

Comment: A few commenters suggested that CMS establish additional opportunities around when a dually eligible individual who is passively enrolled into a D–SNP can enroll in another plan, and that CMS establish processes to monitor functional outcomes for these dually eligible enrollees. These comments included suggestions for CMS to allow movement from integrated plans to Original Medicare, rather than only to another integrated D–SNP, or to create additional SEPs to allow enrollment in MA. A commenter specifically requested that CMS clarify in regulation that the exemption at § 422.60(g)(3)(ii) applies to individuals who have affirmatively selected a standalone prescription drug plan. Other commenters emphasized the continued

importance of enrollees having sufficient notification about upcoming passive enrollments, the opportunity to make active plan selections during the passive enrollment process and through any applicable SEP.

Response: We agree with the commenters' perspectives about the importance of advance notification to enrollees during the D–SNP passive enrollment process as well as the opportunities to make other coverage selections. As articulated earlier in this section, D–SNP passive enrollment under § 422.60(g)(1)(iii) is only implemented after CMS consults with the State Medicaid agency that contracts with the D–SNP, and requires the MA organization receiving passive enrollment to provide enrollees with two separate notices, at least 30 and 60 days prior to the enrollment effective date, of the opportunity to opt out. If a passively enrolled full-benefit dually eligible individual wanted to make a change after the effective date of enrollment into the receiving integrated D–SNP, they could do so through the one-time-per month SEP for dually eligible individuals and other LIS eligible individuals to elect Original Medicare and a standalone PDP or the integrated care SEP which allows full-benefit dually eligible individuals to elect an integrated D–SNP on a monthly basis. Further, as we discussed earlier in this preamble and in the preamble to the Contract Year 2027 proposed rule, we did not propose amendments to § 422.60(g)(5), which describes an enrollee's access to the SEP at § 423.38(c)(10). As such, this SEP would also be accessible to enrollees who are interested in switching their coverage (90 FR 54972).

Comment: We received several comments offering support for our proposal that receiving D–SNPs operate as applicable integrated plans. Other suggestions included establishing a definition for ''new integrated plan'' and allowing all D–SNPs that meet strong integration standards, not just AIPs, to be eligible for passive enrollment, arguing that non-AIP D–SNPs can still provide significantly better coordination of Medicare and Medicaid services than other MA plans or Medicare FFS. Commenters also recommend that CMS clarify how the level of integration would be assessed if provider network adequacy and benefits are no longer criteria for passive enrollment and suggested adding to the proposed requirement that the receiving D–SNP must offer a substantially similar service array. A commenter recommended that CMS consider distributing enrollment among remaining qualified D–SNPs when a D–SNP exits the market.

Response: We proposed to amend § 422.60(g)(2)(i) to describe the integrated D–SNPs that can receive passive enrollment as plans that operate as an AIP as described at § 422.561 in an effort to use consistent and accurate language throughout our processes and documentation. We proposed this change since, as stated in the Contract Year 2027 proposed rule (90 FR 54970) and earlier in this section, AIPs meet higher standards of integration, quality, and performance benchmarks than non-AIPs, and have 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 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 HIDE SNPs that are not AIPs or coordination-only D–SNPs that are not also AIPs. Under our proposal, any integrated D–SNPs that meet the requirements in proposed § 422.60(g)(2) could receive passive enrollment from the non-renewing or terminating D–SNP. Additionally, in the August 2018 HPMS memo that provided further technical assistance to D–SNPs on passive enrollment, we did not state that only one plan may be selected to receive enrollees through passive enrollment. As we work with the State through the process, it could be possible for multiple integrated D–SNPs to receive passive enrollment.

Further, as we discussed in the Contract Year 2027 proposed rule, since integration levels are defined both in statute at section 1859(f)(8)(D) of the Act 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 or service array 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 (90 FR 54972). For example, if a HIDE SNP that is an AIP is non-renewing in the upcoming plan year, if the State agrees to a passive enrollment process, the receiving D–SNP would most likely also be a HIDE SNP that is an AIP. In the same State, the array of benefits offered by HIDE SNPs that are AIPs would most likely not be meaningfully different.

Comment: We received a few comments that were outside of the scope of this proposal. Commenters suggested that CMS should require D–SNPs serving beneficiaries with serious mental illness to include licensed mental health professionals—whether mental health counselors, marriage and family therapists, clinical social workers, or other qualified behavioral health specialists—directly in care coordination teams or ensure immediate access to behavioral health consultation for care managers. Some commenters suggested using Medicaid managed care contracts to require Medicaid managed care plans to offer HIDE SNPs. Other commenters requested more information about default enrollment. The commenters opined that there is very little public data about default enrollment including total numbers of individuals default enrolled and whether default enrollment opt-out notices follow language and disability preferences of the enrollee. Commenters request data to understand whether default enrollment is working for people and truly reflecting their preferences.

Response: We thank the commenters for their input. While we consider the comments outside the scope of this rulemaking, we take the opportunity to point commenters to information we made available regarding default enrollment. We provide data on the number of D–SNPs approved to participate in default enrollment under § 422.66(c)(2) and the annual number of individuals default enrolled *https://www.cms.gov/medicare/enrollment-renewal/managed-care-eligibility-enrollment.*

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed amendments to § 422.60(g)(2) without modification.

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 422.514(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 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 lowering the risk of inappropriate billing.

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 the suggestions put forth by commenters. 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 continued to receive feedback from stakeholders on some challenges in implementing these provisions in States without mandatory Medicaid managed care for the dual eligible population. For example, 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. The requirements at § 422.514(h) do not apply to MA organizations in a State that only offers coordination-only D–SNPs if these MA organizations, their parent organizations, or any entity that shares a parent organization with the MA organization does not also contract with the State as a Medicaid MCO that enrolls full-benefit dually eligible individuals. However, the § 422.514(h) requirements do apply to a State's HIDE SNPs if the MA organization also contracts with the State as a Medicaid MCO that enrolls full-benefit dually eligible individuals. In the Contract Year 2027 proposed rule, we provided a specific example in Pennsylvania to describe how § 422.514(h) requirements would potentially be disadvantaging to MA organizations offering coordination-only D–SNPs and HIDE SNPs that both enroll full-benefit dually eligible individuals in the same service areas. Please refer to 90 FR 54974 for the full discussion, and to our response to comments later on in this preamble which provide a correction to this example.

In 2027, in a State 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 the State 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 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.

In the Contract Year 2027 proposed rule, we proposed 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. In the Contract Year 2027 proposed rule at 90 FR 54974, we explained that 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 start disenrolling those members in 2030 as currently required under § 422.514(h).

We proposed to amend SMAC requirements at § 422.107(d)(1) through adding a new (i). For any SMACs that allow coordination-only D–SNPs (as established under § 422.107(d)(1)) to enroll full-benefit dually eligible individuals, 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 to enroll full-benefit dually eligible individuals who are enrolled in Medicaid FFS.

At § 422.514(h)(3), we proposed to add new (iii) and (iv). For any SMACs that permit full-benefit dually eligible individuals to enroll in (a) a coordination-only D–SNP per the 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. We explained that our belief was that 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

proposed adding a new (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 considered 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 did not propose 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 solicited 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.

In the Contract Year 2027 proposed rule, we stated our position that 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. The intent of our proposed changes was to remove the disadvantage some 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, our proposed changes were intended to 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 FFS enrollees. We explained in the Contract Year 2027 proposed rule that 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 (MSPs), 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 plan benefit packages 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 proposed 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 acknowledged in the Contract Year 2027 proposed rule that this proposal is a change from what we previously stated in response to comments in the April 2024 final rule. We also acknowledged 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 solicited 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 stated that we were 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 in the Contract Year 2027 proposed rule we identified a few States that we expected would benefit from our proposals, we invited commenters to identify other States that could benefit or be negatively impacted. As outlined earlier in this section, we also solicited 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. Further, we solicited 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 also stated our interest in perspectives on how limiting D–SNPs in the U.S. Territories would affect enrollees and the consumer choice in U.S. Territories.

We received the following comments on this proposal and respond to them below:

Comment: Many commenters, including MACPAC, expressed their support for our proposal 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. Commenters opined that this proposal accommodates diversity in State Medicaid managed care requirements while preserving opportunities for integrated care for all dually eligible individuals. Commenters expressed that while significant integration cannot be achieved for dually eligible enrollees in Medicaid FFS, D–SNPs might still provide helpful support to Medicaid FFS enrollees, including in obtaining Medicaid-covered services and navigating Medicaid appeals and grievances processes. MACPAC explained that the proposal recognized CMS's efforts to accommodate States' varying managed care landscapes and the challenges States and plans face as they work toward greater integration of Medicare and Medicaid benefits.

Response: We thank the commenters for their support for this proposal. As we stated in the Contract Year 2027 proposed rule, our intention in proposing this exception was to 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 unaligned members in 2030 as currently required under § 422.514(h). We appreciate the commenters' confirmation of our understanding that the varied Medicaid managed care landscapes necessitate an exception for when Medicaid FFS is available and exclusively aligned enrollment cannot be achieved.

Comment: Some commenters objected to the proposal to amend §§ 422.107(d)(1) and 422.514(h). These commenters expressed their belief that this proposal would reduce the scope of or limit enrollment in coordination-only D–SNPs or that this proposed language could result in a D–SNP having more than one health plan under the same MA organization operating in the same service area with different networks, offering different benefits, and requiring different premiums, causing market confusion for dually eligible individuals.

Response: We thank the commenters for their attention to this proposal, and we appreciate the opportunity to clarify aspects of what we proposed. We would like to reiterate that the intention of this proposal is to address the challenges that some MA organizations may have in complying with the requirements at § 422.514(h) in States where there is no mandatory Medicaid managed care program for all full-benefit dually eligible enrollees. As our stated goal has been to promote integrated care, the purpose of the proposal put forth in the Contract Year 2027 proposed rule is to avoid the need for MA organizations in States without mandatory Medicaid managed care to cease enrolling full-benefit dually eligible individuals who are in Medicaid FFS starting in 2027 and disenroll those members in 2030 as would be required under existing § 422.514(h). Further, under our proposal at § 422.514(h)(3), 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. Also, the proposed amendment to § 422.107(d)(1) would permit coordination-only D–SNPs that are affected by the requirements at § 422.514(h) to enroll full-benefit dually eligible individuals who are enrolled in Medicaid FFS. We respectfully disagree with the commenters' assumptions that the proposed rule would limit coordination-only D–SNPs in any way. In fact, we believe that this policy would have positive implications for coordination-only D–SNPs that are affected by the current § 422.514(h) language. We also emphasize that the requirements at § 422.514(h) do not apply to MA organizations in a State that only permits plans to offer coordination-only D–SNPs if these MA organizations, their parent organizations, or any entity that shares a parent organization with the MA organization does not also contract with the State as a Medicaid MCO that enrolls full-benefit dually eligible individuals.

Comment: We received a few comments from States and advocates on how the proposed provisions would affect populations that are excluded from mandatory Medicaid managed care enrollment, or who have the choice to enroll in Medicaid managed care, in a particular State. Commenters were supportive of the proposal to allow these populations to enroll, or continue to be enrolled, in a D–SNP affected by requirements of § 422.514(h), but noted that the ''majority of'' threshold proposed at § 422.514(h)(3)(iii) may not have the intended impact for beneficiaries in States where carve-outs are for a small population, and would be unable to meet the ''majority of'' threshold.

Response: We appreciate the responses from commenters illuminating how some States carve certain populations out of mandatory Medicaid managed care. Our intention in proposing this provision was to remove the disadvantage that MA organizations that offer coordination-only D–SNPs with an affiliated Medicaid managed care plan and HIDE SNPs could encounter starting (a) in 2027, when they would need to stop enrolling full-benefit dually eligible

individuals into the D–SNP that enrolls Medicaid FFS enrollees and (b) in 2030, when they would need to disenroll full-benefit dually eligible individuals from the D–SNP that enrolls Medicaid FFS enrollees. We agree that the inclusion of ''majority of'' in the proposed language at § 422.514(h)(3)(iii) could cause HIDE SNPs in States with small populations of full-benefit dually eligible individuals carved out of mandatory Medicaid managed care to not qualify for the proposed exception. For example, States that have carved-out individuals with intellectual and development disabilities from mandatory Medicaid managed care may have a coordination-only D–SNP or HIDE SNP enrolling the carved-out population. Because the carved-out population is relatively small, the HIDE SNP would not likely meet the proposed ''majority of'' requirement, and these D–SNPs would need to cease enrolling these 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). In light of these concerns, we are modifying the language proposed in § 422.514(h)(3)(iii) that would require a ''majority of'' HIDE SNP enrollees to be full-benefit dually individuals enrolled in Medicaid FFS in order to qualify for the proposed exception. We provide more detail on this proposed modification below.

Comment: We received many comments on our proposed amendment to § 422.514(h)(3), which would add new paragraph (iii) stipulating in part that the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization that has a HIDE SNP with a majority of individuals enrolled in Medicaid FFS, would be able to offer one or more additional D–SNPs for full-benefit dually eligible individuals in the same service area. Commenters expressed their belief that the proposed exception at § 422.514(h)(3)(iii) extends beyond the stated intent in the preamble and may create confusion for States and health plans, since the proposed amendment did not include corresponding limitations or qualifiers.

Some commenters requested clarification on the use of the term ''majority,'' while other commenters suggested removing the ''majority'' threshold altogether. Commenters who suggested its removal stated that such a requirement could create operational challenges for D–SNPs whose enrollment fluctuates near the threshold or it could create unintended incentives for D–SNPs to avoid transitioning eligible members into integrated D–SNPs. Other commenters suggested that we revise the ''majority'' threshold requirement to avoid impeding aligned enrollment efforts if States transition their Medicaid FFS enrollees to Medicaid managed care.

Response: We thank the commenters for their thoughtful opinions and questions. As we explained in the Contract Year 2027 proposed rule, our intention with the proposed language at §§ 422.514(h)(3)(iii) and 422.107(d)(1)(i) was to 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 for full-benefit dually eligible individuals 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) (90 FR 54974). We proposed that this exception would apply where enrollment of full-benefit dually eligible individuals represents a majority of the HIDE SNP's enrollees, to avoid the proposed exception applying to HIDE SNPs with only small proportion of enrollees in Medicaid FFS.

Upon consideration of the numerous comments received on the impact of the proposed ''majority'' threshold for HIDE SNPs and to clarify the scope of the proposal, we are modifying some of the language at § 422.107(d)(1)(i) and finalizing as proposed other portions of § 422.107(d)(1)(i). First, we are finalizing as proposed the language at § 422.107(d)(1)(i) providing that in order to trigger the stipulation requirement described in § 422.107(d)(1)(i), the SMAC must include language allowing enrollment of full-benefit dually eligible individuals into the D–SNP. Second, we are finalizing as proposed the language at § 422.107(d)(1)(i) that the SMAC must stipulate that such full-benefit dually eligible individual 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. Third, based on comments we received, we are modifying the proposed language at § 422.107(d)(1)(i) to specify that such an exception is available to a HIDE SNP as well as a coordination-only D–SNP that operates in a State where the State Medicaid agency does not mandate enrollment in Medicaid managed care for all full-benefit dually eligible individuals. We believe that this language appropriately addresses D–SNPs that are subject to § 422.514(h) requirements and operate in a State with voluntary Medicaid managed care and addresses the concerns expressed by commenters on this proposal.

In response to numerous comments we received and to more effectively achieve the intent of the proposal, we are modifying some of the language at § 422.514(h)(3)(iii) and finalizing as proposed other portions of § 422.514(h)(3)(iii). We are finalizing as proposed that the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization subject to this new exception may offer one or more additional D–SNPs for full-benefit dually eligible individuals who are enrolled in Medicaid FFS. We are modifying the provision by removing the threshold requirement that the majority of HIDE SNP enrollees must be enrolled in Medicaid FFS in order to qualify for the new exception. We are replacing the majority threshold with language specifying that (1) if the MA organization subject to § 422.514(h)(1) holds a State Medicaid agency contract with a State that does not mandate enrollment in Medicaid managed care for all full-benefit dually eligible individuals and (2) if the State Medicaid agency contract allows enrollment of full-benefit dually eligible individuals who are enrolled in Medicaid FFS, the MA organization may enroll, in a coordination-only D–SNP or HIDE SNP, full-benefit dually eligible individuals who are enrolled in Medicaid FFS. This modification will remove the proposed majority threshold that raised concerns for the commenters, while ensuring that the exception is only available to the extent a D–SNP operates in a State that does not require mandatory Medicaid managed care for all of its dually eligible enrollees and is allowed, via the State Medicaid agency contract, to enroll Medicaid FFS enrollees. This change is consistent with our intent, as stated in the proposed rule, to allow HIDE SNPs and coordination-only D–SNPs to continue enrollment of dually eligible individuals in a D–SNP in service areas where those individuals are enrolled in Medicaid FFS (90 FR 54974). As we stated in the proposed rule, we did not want to inadvertently prevent integrated D–SNPs from continuing to enroll full-benefit dually eligible individuals who are enrolled in Medicaid FFS. Additionally, in response to public comments seeking clarification on which enrollees D–SNPs subject to this exception may enroll, we are adding language stating that (3) D–SNPs may not enroll full-benefit dually eligible individuals who are 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. This language mirrors the language we are finalizing at § 422.107(d)(1).

We are making these modifications in light of concerns raised by many commenters that the ''majority of'' threshold was ambiguous and difficult to achieve. Having considered these comments in light of the intent of the exception as described in the proposed rule, we have determined that the modified language for § 422.514(h)(3)(iii) would more effectively result in the desired outcome, as it would allow enrollment of smaller populations that States exclude from Medicaid managed care enrollment, or who have a choice to enroll in Medicaid managed care. Commenters noted that such enrollees may only represent a minority of coordination-only D–SNP or HIDE SNP enrollees and thus tying the new exception to a ''majority of'' enrollees in Medicaid FFS would exclude such full-benefit dually eligible individuals from enrolling into a HIDE SNP as set forth in State policy. As stated in the proposed rule, our goal is to 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 avoid the need to disenroll those members in 2030 as currently required under § 422.514(h) in States that do not mandate enrollment in Medicaid managed care. (90 FR 54974) Furthermore, the requirements set forth in the SMAC will ensure that only coordination-only D–SNPs and HIDE SNPs with Medicaid FFS enrollment operating in States that do not mandate Medicaid managed care for all full-benefit dually eligible individuals and are approved by the State would have the option to use the exception finalized at 422.514(h)(3)(iii) for Medicaid FFS enrollees. Moreover, consistent with CMS's stated intent to allow D–SNPs to continue enrolling Medicaid FFS enrollees, the exception would not allow for the enrollment of individuals enrolled in unaligned Medicaid managed care. Thus, we do not believe it is necessary to limit the exception to HIDE SNPs that have a majority of its enrollees in Medicaid FFS.

Taken together, the modifications that we are finalizing at §§ 422.107(d)(1)(i) and 422.514(h)(3)(iii) more effectively alleviate the concerns documented in the Contract Year 2027 proposed rule with regard to § 422.514(h) requirements potentially disadvantaging MA organizations offering coordination-only D–SNPs and HIDE SNPs that enroll full-benefit dually eligible individuals in the same service areas where those individuals are enrolled in Medicaid FFS (90 FR 54974). Based on the numerous comments we received, we would like to reiterate that this exception is only applicable to 1) D–SNPs that are subject to the requirements of § 422.514(h) and that 2) operate in a State that does not mandate that all full-benefit dually eligible individuals enroll in Medicaid managed care.

Comment: Other commenters questioned our inclusion, in the Contract Year 2027 proposed rule, of Pennsylvania as an example of a State that does not mandate Medicaid managed care for full-benefit dually eligible individuals. Commenters clarified that although the State does not have 100-percent mandated Medicaid managed care, most Medicaid beneficiaries are enrolled in mandated managed care, and very few Medicaid beneficiaries are in FFS. Those enrolled in Medicaid FFS are limited to individuals under a particular Medicaid waiver authority, enrolled in PACE, or residents of State hospitals and intermediate care facilities.

Response: We thank the commenters for their clarification of Pennsylvania's landscape. As discussed earlier in this section, we are modifying the scope of the provisions to apply to coordination-only D–SNPs and HIDE SNPs that are subject to the requirements of § 422.514(h) and that operate in a State that does not mandate enrollment in Medicaid managed care for all full-benefit dually eligible individuals. As finalized, the exception at § 422.514(h)(3)(iv) would allow MA organizations that offer both a coordination-only D–SNP and HIDE SNP in Pennsylvania to continue to enroll full-benefit dually eligible individuals that are in Medicaid FFS should the State allow such enrollment in the SMAC.

Comment: We received other comments seeking clarification on the intended impact of this proposal. Some commenters sought clarification on what was proposed in the Contract Year 2027 proposed rule, including whether CMS intends for the proposed language at § 422.514(h)(3)(iii) to allow enrollment of full-benefit dually eligible individuals in Medicaid FFS to also include full-benefit dually eligible individuals who are enrolled in a Medicaid MCO through a parent company that differs from the coordination-only D–SNP or HIDE SNP.

Response: We appreciate the opportunity to clarify what types of enrollees would be eligible for enrollment under this exception. As we discussed earlier in this preamble, if the State Medicaid agency contract allows enrollment of full-benefit dually eligible individuals who are enrolled in Medicaid FFS, the MA organization may enroll, in a coordination-only D–SNP or HIDE SNP, full-benefit dually eligible individuals who are enrolled in Medicaid FFS. Additionally, we are also finalizing language at § 422.107(d)(1)(i) and adding similar language at § 422.514(h)(3)(iii) stating that D–SNPs may not enroll full-benefit dually eligible individuals who are 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. We further note that this language would allow eligible D–SNPs to enroll new Medicaid FFS enrollees and continue enrollment for any current enrollees who also have Medicaid FFS.

Comment: We received a few comments seeking clarification or making recommendations about whether this proposed exception at § 422.514(h)(3)(iii) would be a permanent exception. Commenters questioned whether the proposed flexibilities end in 2030 and suggested that this proposal be a time-limited transition mechanism, rather than a permanent policy solution.

Response: While we appreciate the commenters' interest in making the proposed exception at § 422.514(h)(3)(iii) a time-limited transition mechanism, our proposal was to make this exception permanent. We appreciate the consideration that commenters paid to evolving landscapes in States and how this may affect future enrollment. As we discussed previously in this preamble, coordination-only D–SNPs and HIDE SNPs subject to § 422.514(h)(3)(iii) will be allowed to retain full-benefit dually eligible enrollees in Medicaid FFS and newly enroll full-benefit dually eligible enrollees in Medicaid FFS to the extent that such enrollment is allowed via the State Medicaid agency contract per § 422.107(c)(2) and the contract is with a State that does not mandate Medicaid managed care for all full-benefit dually eligible individuals. States retain the option to stipulate enrollment and eligibility requirements in their State Medicaid agency contracts. Nothing in this final rule precludes a State from adding requirements to their State Medicaid agency contracts through § 422.107(c) that would prohibit or

place a time limit on the enrollment of full-benefit dually eligible individuals enrolled in Medicaid FFS by the D–SNP.

Comment: We received several comments in response to our proposal to add specific language at § 422.514(h)(3)(iv) regarding the proposed requirement that MA organizations with D–SNPs subject to paragraph (h)(3)(iii) must comply with responsibilities at existing § 422.562(a)(5). Also, commenters responded to our request for comment on whether to 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 in § 422.562(a)(5). A few commenters requested that we provide more specificity regarding potential reporting requirements. Many other commenters were opposed to the suggestion of additional reporting requirements, with a commenter stating that there could be confusion among plans as to what is required, given that § 422.562(a)(5)(i)(A) is currently applicable to all D–SNPs. A commenter objected to our proposal to add language at § 422.514(h)(3)(iv), stating their belief that such an action would require CMS to pursue Congressional action to redefine these Medicaid FFS coordination-only D–SNPs and HIDE SNPs separate from D–SNPs in statute.

Response: We thank the commenters for their consideration of the proposed regulation text at § 422.514(h)(3)(iv) and the request for comment considering potential reporting requirements for obligations proposed in § 422.514(h)(3)(iv). Our intention in proposing to add text at § 422.514(h)(3)(iv) stating that MA organizations with D–SNPs subject to proposed § 422.514(h)(3)(iii) must comply with responsibilities at § 422.562(a)(5) was to underscore the obligation that D–SNPs have to assist an enrollee in their plan 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. This obligation applies to all D–SNPs and their enrollees regardless of enrollment in Medicaid managed care or Medicaid FFS. Upon further review, we agree with commenters that adding a reference to § 422.562(a)(5) at § 422.514(h)(3)(iv) would be redundant since all D–SNPs are subject to the existing requirements at § 422.562(a)(5), so we are not finalizing our proposal to add that language in § 422.514(h)(3)(iv). We further appreciate the comments received in response to our request for comment on whether to 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 in § 422.562(a)(5). We are not taking any action on this comment solicitation in this rulemaking, but we may consider exploring opportunities for potential future rulemaking on this topic.

Finally, we appreciate the viewpoint that the proposed regulatory amendment may be perceived as defining coordination-only D–SNPs and HIDE SNPs with Medicaid FFS enrollees as a separate type of D–SNP. However, we do not believe this to be the case. Through this proposal, we are providing an exception for coordination-only D–SNPs and HIDE SNPs that are subject to the requirements of § 422.514(h) and that operate in a State that does not mandate all full-benefit dually eligible individuals to enroll in Medicaid managed care. We are neither proposing nor finalizing another category of integration. As such, we respectfully disagree with commenters that Congressional action would be needed.

Comment: We received many other comments seeking clarification on the intended impact of this proposal. Some commenters sought clarification on how this proposed policy would be operationalized, if finalized. Commenters sought clarification on who is eligible to enroll in a D–SNP under this proposed exception, including how individuals enrolled in prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs) would be factored in. Other commenters sought information on how these proposed changes would affect how many PBPs a MA organization could have, whether plans would be allowed to consolidate existing coordination-only D–SNP PBPs into their HIDE–SNP PBPs in their Medicaid MCO service areas, whether plans would be required to create new coordination-only D–SNPs or MA organization contracts or use existing coordination-only D–SNPs and MA organization contracts to take advantage of the proposed exception in addition to whether MA organizations could expand their coordination-only D–SNPs into areas outside of their Medicaid MCO service area. We also received questions regarding crosswalking enrollees between coordination-only D–SNPs and HIDE SNPs, and how proposed changes would affect segmented PBPs. Commenters expressed concern that the proposed language could be read to impose an overall limit on enrollment of individuals in coordination-only D–SNPs and non-affiliated Medicaid MCOs, including those in non-overlapping service areas.

Response: We appreciate the questions raised by the commenters. We would like to reiterate that 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 dually 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. If a D–SNP, or the D–SNP's parent organization, does not contract with the State as a Medicaid MCO, then the D–SNP would not be affected by the provisions in § 422.514(h) and would be able to enroll anyone eligible for their plan per the provisions at § 422.107(c)(2). To the extent that a State does not require enrollment of all full-benefit dually eligible individuals into Medicaid managed care and to the extent that enrollment of full-benefit dually eligible enrollees in Medicaid FFS is allowed via the State Medicaid agency contract per § 422.107(c)(2), the MA organization would be permitted to have coordination-only D–SNPs or HIDE SNPs that enroll or continue to enroll such individuals who are in Medicaid FFS. We therefore disagree with concern that the proposed language could be read to impose an overall limit on enrollment of individuals in coordination-only D–SNPs and non-affiliated Medicaid MCOs, including those in non-overlapping service areas.

We appreciate commenters' concern regarding the application of this proposed exception. We note that we will respond to some of the more detailed operational questions in an updated version of the Frequently Asked Questions (FAQs) and

Enrollment Scenarios for § 422.514(h).[111] However, we appreciate the opportunity to offer some clarification in terms of scope. In response to comments in the April 2024 final rule, we noted that we believed that applying the provisions at § 422.514(h) to D–SNPs where there is an affiliated PIHP or PAHP could create incentives that are disruptive yet do not significantly further the goals of our proposals. As a result, we did not extend the enrollment limitation policies in § 422.514(h)(1) and (2) beyond Medicaid MCOs or beyond D–SNPs that enroll full-benefit dually eligible individuals, meaning that an MA organization offering a D–SNP in the same area where it, its parent organization, or an entity (or entities) that share a parent organization with the MA organization contracts with the State only as a PIHP or PAHP, would not be subject to the enrollment limitations at §§ 422.503(b)(8), 422.504(a)(20), or 422.514(h). Following the reasoning from the April 2024 final rule, D–SNPs with an affiliated PIHP or PAHP not subject to § 422.514(h) would have no need to take advantage of the proposed exception at § 422.514(h)(3)(iii).

We would also like to take this opportunity to note that if the exception we are finalizing at § 422.514(h)(3)(iii) is applicable to a D–SNP, the State in the State Medicaid agency contract should, through existing requirements at § 422.107(c)(2), specify if there must be a separate PBP for enrollees who are enrolled in Medicaid FFS.

Comment: A few commenters recommended that CMS provide technical assistance to States and urged CMS to produce enrollee-facing materials for individuals to understand their D–SNP enrollment choices.

Response: We thank the commenters for their suggestion. We intend to continue to provide technical assistance on all aspects of D–SNP policy, including implementation of § 422.514(h), to interested States. We will update CMS-produced enrollee-facing materials with appropriate information reflecting the exceptions to § 422.514(h) finalized in this rule.

Comment: Numerous commenters supported the proposed exception at § 422.514(h)(3)(v), which would exempt MA organizations operating in U.S. Territories that have not adopted MSP from the requirements at § 422.514(h)(1)(i). Some commenters noted that this proposed exception recognized the unique Medicare and Medicaid landscapes in the U.S. Territories, including them not having adopted MSP and using their MA rebate to reduce Part B premiums and provide supplemental benefits. Several commenters mentioned that the proposed exception would maintain beneficiary choice, minimize beneficiary disruption, preserve operational flexibility in the Puerto Rico D–SNP market, in particular. A few of these commenters suggested that CMS consider other standards to trigger the exception to § 422.514(h)(1)(i), allowing the proposed exception to still apply should Puerto Rico adopt MSP in the future. A commenter offered the example of CMS applying the proposed exception in regions where state or local law requires D–SNPs to be fully integrated.

Response: We appreciate these perspectives and agree that the unique landscape in the U.S. Territories, including Puerto Rico, necessitates the proposed exception from the requirements at § 422.514(h)(1)(i). Without the proposed exception, beginning in contract year 2027, the MA organizations offering D–SNPs to full-benefit dually eligible individuals in the U.S. Territories that have not adopted MSP could 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 believe that triggering the proposed exception to § 422.514(h)(1)(i) based on participation in MSP is appropriate since should a U.S. Territory, such as Puerto Rico, adopt MSPs there would be less need for D–SNPs to differentiate their plan benefit packages by level of Part B premium reduction amount and supplemental benefits. We are not persuaded to change the requirements for the proposed exception. We clarify that for purposes of this exception, U.S. Territory means any Territory of the United States, including the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

Comment: A commenter opposed the exception proposed in § 422.514(h)(3)(v), explaining that MA organizations that do not adopt MSP may have higher premiums and cost sharing, making care less affordable for dually eligible individuals. The commenter further stated that allowing MA organizations to offer multiple D–SNPs in the same service area could cause market confusion and lead to less robust plan benefit packages, forcing individuals to choose between the benefits they need in different plans based on affordability rather than one plan that offers all services needed.

Response: Given the unique landscape of the U.S. Territories with no adoption of MSPs, we believe more flexibility is needed to differentiate D–SNP plan benefit packages. We believe the benefits of additional differentiation by level of Part B premium reduction and supplemental benefits outweigh the additional plan benefit packages full-benefit dually eligible individuals would need to review. We will continue to monitor the D–SNP market in the U.S. Territories and consider future rulemaking, as needed.

Comment: Additionally, we received several comments that were out of scope of this proposal, including suggestions on how to support the success of D–SNPs in rural and remote areas, enrollment periods, arguments against exclusively aligned enrollment, upcoding and truncating services, requiring States to align enrollment timelines during the transition to integrated enrollment, and incorporating Federal quality reporting. We received a suggestion that the Medicaid FFS model should be required to coordinate care, but that the State remain responsible for coverage and reimbursement.

Response: We thank the commenters for their questions and concerns and appreciate the breadth of engagement. We appreciate the recommendations; however, these comments are outside the scope of this rulemaking. We will consider exploring opportunities for potential future rulemaking to address some of these issues.

After considering the comments we received and for the reasons outlined above and our responses to comments, we are finalizing our proposal with a few modifications. First, we are finalizing proposed language at § 422.107(d)(1)(i) with modifications to specify that such an exception is available to a HIDE SNP as well as a coordination-only D–SNP that operates in a State where the State Medicaid agency does not mandate enrollment in Medicaid managed care for all full-benefit dually eligible individuals. Second, we are finalizing portions of the language at § 422.514(h)(3)(iii) as proposed; this exception would allow an eligible 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 who are enrolled in Medicaid fee-for-service. We

[111] Frequently Asked Questions (FAQs) and Enrollment Scenarios for § 422.514(h). Found at: *https://www.cms.gov/files/document/cy2025madsnpsfaqs.pdf.*

are also finalizing other modifications: we are removing the language referring to a ''majority of'' enrollees and replacing it with language specifying that (1) if the MA organization subject to § 422.514(h)(1) holds a State Medicaid agency contract with a State that does not mandate enrollment in Medicaid managed care for all full-benefit dually eligible individuals and (2) if the State Medicaid agency contract allows enrollment of full-benefit dually eligible individuals who are enrolled in Medicaid FFS, the MA organization may enroll in a HIDE SNP or coordination-only D–SNP, full-benefit dually eligible individuals who are enrolled in Medicaid FFS. We are also adding language stating that (3) D–SNPs may not enroll full-benefit dually eligible individuals who are 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. Third, we are not finalizing the proposed language at 422.514(h)(3)(iv). Fourth, we are finalizing our exception to § 422.514(h)(3)(v) as proposed, which will be located at § 422.514(h)(3)(iv).

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 State Medicaid agency contracts (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. The timeline and duration for these procurements is distinct to each State and may operate off-cycle from MA contracting at the Federal level, meaning that 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.

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 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 first proposed 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 was 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 proposed 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 proposed 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 stated 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 noted that our proposed amendments to §§ 422.510(a)(4)(xvii) and (b)(2)(i)(D) did not preclude a MA organization from seeking termination of a contract by mutual consent, per § 422.508.

We noted 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 stated 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 proposed 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 requested comment on this proposal, including but not limited to whether this package of provisions would accomplish the goals we have laid out in this preamble and whether there should be any other additional modifications to consider.

We received the following comments on this proposal and respond to them below:

Comment: Many commenters supported CMS' proposal to codify in regulation at § 422.510(a)(4) 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). Commenters expressed their appreciation for CMS clarifying the administrative process in such situations and stated that the proposed provision would provide clarity and codify necessary Federal authority when State contract terminations occur off-cycle from MA contracting.

Response: We thank the commenters for their support of this proposal and agree that the proposed language provides clarity on the administrative process when an MA organization is no longer eligible to offer a D–SNP due to not holding the required SMAC.

Comment: A few commenters opposed our proposal, stating that immediate terminations would cause disruption of care for vulnerable populations and create obstacles for beneficiaries to transition to new plans. Commenters further opined that CMS should establish reasonable transitional periods to ensure beneficiaries' continued access to medical services.

Response: We appreciate the commenters' concern for possible disruption of care and beneficiary well-being. We would like to reiterate that the purpose of this proposal was to codify that loss of a SMAC is a valid basis for contract termination under CMS authority per section 1859(f)(3)(D) of the Act. As we discussed in the preamble to the Contract Year 2027 proposed rule, in some instances where a SMAC was terminated by a State during the plan year, CMS has worked with the respective State and the MA organization whose SMAC is being terminated to mutually terminate the contract per § 422.508. This is a process by which CMS, the State and the D–SNP are able to mutually 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. (90 FR 54976). This process will continue to be available. Our goal in adding new (xvii) at § 422.510(a)(4) is to establish a an express pathway by which CMS may immediately terminate contracts based on termination of a SMAC, since, as discussed in preamble to the Contract Year 2027 proposed rule, an MA organization with a terminating SMAC is not required to seek a mutual termination of its MA contract with CMS. (90 FR 54977). Our proposed language does not preclude an eligible plan from seeking mutual termination, per § 422.508. 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 and could limit potential disruption of beneficiary access to integrated care.

Further, we would like to take the opportunity to clarify that while we refer to this process as an ''immediate termination,'' as stated previously in this section and in the Contract Year 2027 proposed rule, we generally receive advance notice when a State is terminating or ending a Medicaid MCO contract or their SMAC contract. In instances where an MA organization does not agree to a mutual termination, or where the timeline of a mutual termination would pose risks to beneficiaries, an immediate termination allows us to accommodate an orderly shutdown of operations. An immediate termination does not mean that a termination would occur without notice but rather allows for a more expedited process when necessary to protect enrollee health and safety.

Comment: A few commenters expressed their view that the provision that was proposed was too broad. Commenters believed that there was not a clear enough connection between the preamble language and the regulatory text, stating that the preamble language

that used Medicaid MCO procurement timelines presented a narrower scope than the language proposed in regulation at § 422.510(a)(4)(xvii).

Response: We thank the commenters for their feedback on this, though we respectfully disagree. In the Contract Year 2027 proposed rule, we emphasize that D–SNPs are statutorily required to have a SMAC to operate in a State per section 1859(f)(3)(D) of the Act. In the preamble to the Contract Year 2027 proposed rule, we used Medicaid MCO procurement timelines as an example to illustrate how the relationship between the State and the D–SNP and the provision and continuation of SMAC, are sensitive to State policy changes and operational choices. (90 FR 54976) However, our use of State procurement decisions as an example of a scenario in which a D–SNP may lose its SMAC does not mean that that is the only process by which a SMAC can be terminated, or in turn, an MA contract can be terminated. Ultimately, per § 422.107(a), a SMAC is a contract between an MA organization and the State Medicaid agency. If the State or the MA organization terminate the contract, then the MA organization is statutorily prohibited from operating that D–SNP in the State.

Further, in the Contract Year 2027 proposed rule, we pointed to 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 to draw attention to previous preamble that discussed how States have significant control over the availability of D–SNPs in their markets. (see 90 FR 54976 (citing 87 FR 27763)) Therefore, we do not believe there to be a mismatch between our proposed regulatory text and the preamble in the Contract Year 2027 proposed rule.

Comment: We received several comments objecting to the proposed provision, stating that while the regulatory language ties immediate termination to the loss of a SMAC, the preamble suggests that CMS intends to apply immediate termination authority when an affiliated Medicaid MCO contract is terminated, even where the SMAC itself remains in effect. Commenters suggested that termination of the affiliated Medicaid MCO contract would not necessarily prevent the D–SNP from continuing to meet its obligations to coordinate Medicare and Medicaid benefits under § 422.2 or from supporting CMS' broader goals of continuity of coverage and beneficiary stability. Other commenters suggested that this proposal should only apply to AIP D–SNPs.

Response: We thank the commenters for engaging with this proposal. As we explained in the Contract Year 2027 proposed rule, 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 (90 FR 54976). If the Medicaid MCO is terminated and is not an affiliated entity with a D–SNP, then it would not trigger a SMAC termination, since there would be no SMAC to terminate. Additionally, we respectfully disagree with the commenters that suggest that this proposal only be applicable to AIP D–SNPs. Per section 1859(f)(3)(D) of the Act, all MA organizations offering D–SNPs must have a contract with the State Medicaid agency to provide benefits, or arrange for benefits to be provided, for individuals entitled to Medicaid. Therefore, this policy would apply to all D–SNPs.

Comment: Many commenters opined on the concept of immediate termination. Commenters noted that immediate termination of a D–SNP contract has the potential to increase the risk of beneficiary confusion or disruption in care and access, and that alternatively, mutual termination allows CMS, States, and MA organizations to prepare for enrollee transitions and reduce care disruptions. Other commenters recommended that CMS wait until the end of the plan year for a contract termination to take effect, or at the very least, CMS should work closely with the State Medicaid agencies to determine a reasonable termination date and consider defining ''immediate'' as a mutually agreed upon termination date between CMS and the D–SNP. Other commenters encouraged CMS to avoid immediate contract terminations and only invoke the ability to immediately terminate a D–SNP contract after significant efforts have been made to collaborate with the State Medicaid agency and the respective MA plan.

Response: We appreciate the commenters' concern and share their interest in minimizing risk of beneficiary confusion or disruption in care and access. As discussed previously in this preamble, the preamble to the Contract Year 2027 proposed rule included reference to actual instances where a SMAC has been terminated by a State during the plan year, and CMS has worked with the respective State and the MA organization whose SMAC was being terminated to mutually terminate the contract per § 422.508. This is a process by which CMS, the State and the D–SNP are able to agree on a timeline for termination and notice to enrollees of such termination, in an effort to create a smooth transition to an alternative plan for the plan's enrollees (90 FR 54976). Our goal in proposing paragraph (xvii) at § 422.510(a)(4) is to codify an express pathway by which CMS may immediately terminate contracts based on termination of a SMAC, since, as discussed in preamble to the Contract Year 2027 proposed rule, an MA organization with a terminating SMAC is not required to seek a mutual termination of its MA contract with CMS (90 FR 54977). As stated previously in this section, an immediate termination allows for a more expedited process when necessary to protect enrollee health and safety and accommodate an orderly shutdown of operations.

Our intent is to minimize enrollee disruption to the extent possible and collaborate with the State Medicaid agency and the respective MA plan in instances where a contract must be terminated. Our proposed language does not preclude an eligible plan from seeking mutual termination, per § 422.508, which would be our preference, and we welcome working with State Medicaid agencies and plans to minimize enrollee disruption where possible.

Comment: We received many comments regarding the relationship between States and plans. Several commenters supported the overall proposal, noting that finalizing such a provision would improve a State's ability to engage in D–SNP oversight or empower States to have more control over which D–SNPs are offered in their State and support further Medicare-Medicaid integration and increased enrollment in integrated D–SNPs. These commenters noted that when plan performance leads to low quality of care, States should be able to terminate that D–SNP. A few commenters objected to our proposal, opining that the proposed provision could provide States with additional motivation to negotiate midyear changes to the terms of the SMAC with the penalty of rescinding the SMAC if the new terms are not accepted. The commenters strongly urged CMS to view this proposal considering the negotiation dynamics between health plans and States.

Response: We appreciate the commenters' thoughts on this matter. However, we would like to take this opportunity to underscore that this proposed language does not confer any new or different power on the State with regard to their ability to contract with D–SNPs. As discussed in preamble to the Contract Year 2027 proposed rule, 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 (90 FR 54976). Federal requirements for SMACs are codified in CMS regulations at § 422.107, but as stated at § 422.107(a), the SMAC is an agreement between an MA organization and the State Medicaid agency. At § 422.510(a)(4), we proposed 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). We note that under § 422.510(a)(4)(ix), CMS already has the authority to terminate a contract for failure to comply with regulatory requirements in 42 CFR part 422. Our goal in adding this new clause is to specifically 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. We did not propose nor are we finalizing any new language with regard to how SMACs are negotiated, carried out, or entered into.

Comment: A few commenters opposed our proposal to not apply noticing requirements if CMS executes an immediate contract termination. Commenters noted that noticing requirements could help to avoid beneficiary confusion, and immediate termination of a D–SNP contract could create significant beneficiary disruption, especially if termination occurs before enrollment transitions or communications are complete. Another commenter recommended that CMS include some form of beneficiary notification requirement even if that process must be abridged and aligned with State Medicaid notification requirements in the circumstance of an immediate contract termination. Commenters mentioned that contract terminations should be implemented with appropriate transition protections to preserve beneficiary stability.

Response: We thank the commenters for their responses and appreciate the attention regarding enrollees in a terminating D–SNP contract. We reiterate our previous responses to comments where we noted that our proposed language at § 422.510 does not preclude an eligible D–SNP from seeking mutual termination, per § 422.508, and we prefer working with State Medicaid agencies and D–SNPs on mutual terminations to minimize enrollee disruption, where possible. However, as an MA organization with a terminating SMAC is not required to seek a mutual termination of its MA contract with CMS, we proposed language that would codify CMS's ability to provide an immediate termination of the contract the D–SNP has with CMS. In an instance where an MA organization with a terminating SMAC does not seek mutual termination when the affiliated Medicaid MCO contract and/or SMAC terminates and CMS immediately terminates the MA organization's MA contract, pursuant to 42 CFR 422.510(b)(2)(iii), CMS notifies the MA organization's Medicare enrollees in writing of CMS's decision to terminate the MA organization's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the MA contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining Medicare services, including alternative MA organizations in a similar geographic area and original Medicare.

Comment: A couple of commenters suggested that CMS align the effective date of the Medicare contract termination with the SMAC termination date established by the Medicaid agency and consult with the Medicaid agency when such terminations occur.

Response: We thank the commenters for their consideration for the operational aspects of this policy proposal. We reiterate our previous responses to comments where we noted that our proposed language at § 422.510 does not preclude an eligible D–SNP from seeking mutual termination, per § 422.508, where applicable, and we welcome working with State Medicaid agencies and plans on mutual terminations to minimize enrollee disruption where possible. However, an MA organization with a terminating SMAC is not required to seek a mutual termination of its MA contract with CMS, and there are circumstances in which a State may immediately terminate a SMAC, such as where there is beneficiary harm. Thus, we proposed language that would codify CMS's ability to provide an immediate termination of the contract the D–SNP has with CMS, as it is our belief that a delay in D–SNP contract termination could disrupt access to Medicaid benefits for those who are eligible. (90 FR 54978)

Comment: A couple of commenters encouraged CMS to work with States to better structure Medicaid procurement opportunities. Commenters noted that State Medicaid procurement processes are not subject to Federal procurement rules or CMS oversight and can be opaque. Another commenter suggested that for a D–SNP designated as an AIP, where there is an aligned Medicaid MCO or D–SNP that is implemented after a procurement award, there be a run out period to prevent any unintended beneficiary disruption.

Response: We appreciate the opinions expressed by commenters. State Medicaid procurement processes are not subject to Federal procurement rules or CMS oversight, and thus these suggestions are outside of our purview. If a State requested our input on their Medicaid MCO procurement timelines and processes, we would provide any insight we may have at that time.

Comment: We received a few comments that were out of scope. Some commenters expressed concern regarding how the proposed provision would affect MA contract lockout periods for the terminated plan, suggesting that CMS should have the discretion to not impose a lockout period at all.

Response: We thank the commenters for their suggestion. We believe the commenters are referring to regulations, such as those at § 422.502, where CMS may deny an application for a new MA contract or service area expansion based on the applicant's substantial failure to comply with the requirements of the Part C program. The parameters for application denials are outside the scope of the proposed regulation.

After considering the comments we received and for the reasons outlined above and our responses to comments, we are finalizing language at § 422.510(a)(4)(xvii), (b)(2)(i)(D), and (c)(2)(iv) as proposed.

E. Limitation on D–SNP-Only Contracts Submitting Materials Under the Multi-Contract Entity and Multi-Plan 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. 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 managed care organization (MCO), prepaid inpatient health plan (PIHP), prepaid ambulatory health plan (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 proposed 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 stated that we do not expect this update to add burden for any MA organizations; the current process will not change.

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 proposed 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 received the following comments on our proposal and our responses are as follows:

Comment: Numerous commenters supported our proposal at §§ 422.2261(a)(3) and 423.2261(a)(3). They appreciated that it supports joint reviews of materials and integrated care. They stated it would allow States to provide better oversight of D–SNP-only contracts and take actions necessary to ensure enrollees receive quality materials. A commenter noted that the requirement would help ensure that MA organizations can better meet tight deadlines to provide materials to enrollees.

Response: We appreciate the commenters' support for our proposal to require that D–SNPs with exclusively aligned enrollment subject to § 422.107(e) submit all materials for the contract in HPMS under the MA organization's contract number. We believe that the proposal will help clarify the material submission process in HPMS for D–SNP-only contracts and help streamline the State and CMS material review process for these D–SNPs.

Comment: A few commenters suggested that CMS consider ways to encourage states to adopt consistent, streamlined review timelines to improve the timeliness of reviews. They noted inconsistent use of HPMS across States with some States implementing multi-step submission processes through both a State portal and HPMS. These commenters suggested that CMS consider a universal 45-day deeming period across all States and a 5-day file and use approach or a 10-day review period for all required materials. They also recommended increased education to States on how to use HPMS to improve their understanding and ability to review materials in HPMS as well as the ability for States to be exempt from the process if they choose.

Response: We thank the commenters for their perspectives. Only those States with D–SNP-only contracts can utilize the joint review process in HPMS if they choose to do so. States are not required to utilize this process. Each State Medicaid program is different, so the States that do participate in the process can determine which materials they want to review and if they want to review them in 10 days or 45 days, or as file and use which are the same review periods as for other MA materials per §§ 422.2261(b) and 423.2261(b). This is similar to the review process used for Medicare-Medicaid Plans under the Financial Alignment Initiative demonstration. Also, for States utilizing the joint review process, we provide education on the use of HPMS marketing module annually and are available to provide technical assistance to States throughout the year. We will continue to provide this training and focus on areas where we find further education is needed.

Comment: A commenter noted that for States that have multiple plan benefit packages (PBPs) for the D–SNP-only contract, materials are submitted to the State for the D–SNP PBP designated as an AIP. These States do not require submission of materials when the PBP is not an AIP. The commenter also stated that HPMS's review is at the PBP level and not at the contract level. The commenter articulated that submitting materials for AIP PBPs and non-AIP PBPs when States do not need to review the non-AIP PBP materials can create an administrative burden for both plans and the State. The commenter noted that it would welcome working with CMS to improve the process going forward.

Response: We appreciate the commenter's perspective on this issue. It is true that MA organizations with D–SNP-only contracts must submit materials under the contract ID number in HPMS for all PBPs within the contract and that States with D–SNP-only contracts to date have chosen not to review the non-AIP PBP materials. However, the plans still must submit materials for every PBP within the contract for State review because there is no technical mechanism within HPMS to have the State only review one PBP within a contract and not the other PBP. As a workaround, States have been approving the non-AIP PBP materials and noting that they did not review the remaining PBP materials since they are for a non-AIP PBP.

While this is an extra step for States, the majority of the material categories for D–SNP-only contract States are submitted at the contract level and not PBP level. For example, for the State of South Carolina, MA organizations with D–SNP-only contracts can submit materials for 12 out of 47 material categories at the PBP level. Materials for the other 35 categories are submitted at the contract ID level. In addition, for any non-AIP PBPs, D–SNPs only have to submit into HPMS those materials for which CMS review is required for MA plans. There are 5 material categories that CMS reviews for MA where plans can submit materials at the PBP level. Two of these material categories are for errata documents that MA plans rarely submit. As a result, we understand that while this process may be an extra step for States, the extent of the PBP level submissions is limited. We appreciate the commenter's offer to work with CMS to improve the process going forward.

Comment: A commenter requested that CMS not require MA plans to file national D–SNP marketing materials that do not include State-specific elements in HPMS under each individual contract number. The commenter stated that this approach would result in multiple submissions of identical materials under different contract numbers and material IDs, significantly increasing the volume of duplicate materials subject to CMS review without corresponding regulatory benefit. The commenter also opined that managing feedback from multiple States while attempting to produce a single unified material would be operationally challenging and burdensome. The commenter noted that even if all States were to agree on a single document version through separate reviews, it remains unclear how plans should reflect multiple material IDs. The commenter recommended that CMS consider adding unique category codes or creating an AIP D–SNP MCE contract number that could be used for national AIP D–SNP materials that do not contain State-specific content. If CMS finalized this regulation as proposed, the commenter suggested that CMS enhance HPMS to allow users to select multiple States from a dropdown menu and bundle submissions for standard templates, rather than requiring individual State submissions.

Response: We appreciate the commenter's perspective on this issue. For D–SNP-only contracts, States can only review those materials that are submitted under the D–SNP-only contracts that are located within their State. While a specific material may not contain State-specific content, we believe that every State has a right to review all materials submitted for the contract if they choose to do so. We understand that this may result in duplicate submissions of certain materials, however, organizations have a contract with both CMS and the State Medicaid agency for these exclusively aligned plans, and every State has different areas of focus for materials. If there are materials reviewed under multiple contracts that have no difference after review, the MA organization can add multiple material ID numbers to the bottom of the material. As a result, we disagree with adding unique category codes to HPMS or creating an AIP D–SNP MCE contract number. We will consider for the future the commenter's recommendation to allow MA organizations to select multiple States from a drop-down menu and bundle submissions for standard templates in HPMS.

Comment: A commenter questioned whether ''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'' will be the exact language used for the proposed requirements at §§ 422.2261(a)(3) and 423.2261(a)(3). The commenter believed the intent to be ''subject to § 422.107(e)'' was meant to be ''subject to § 422.107(e)(1)'' as the former largely focuses on the relationship between State Medicaid agencies and CMS, whereas the latter is specific to MA organizations with exclusively aligned enrollment.

Response: We thank the commenter for their question. We will be finalizing the regulation text as proposed as we believe that it is beneficial to use § 422.107(e) as it describes all aspects of D–SNP-only contracts, such as State access to HPMS which allows for joint reviews of materials, whereas § 422.107(e)(1) only includes some of

the steps that States must take for D–SNP-only contracts in the State.

Comment: A few commenters provided comments that were out of scope of this proposed provision. Commenters requested that CMS require all D–SNPs to register under their own contract number and not be grouped together with other D–SNPs or MA plans. The commenter suggested that such a structure would allow for greater transparency for States, as well as better monitoring for compliance and better-quality metric reporting. The commenters asserted that combining D–SNPs with other plans in the same contract number muddles data and accountability.

Response: We thank the commenters for their suggestion. We appreciate these recommendations; however, these comments are outside the scope of this rulemaking. We will consider exploring opportunities for potential future rulemaking to address some of these issues.

After considering the comments we received and additional review, we are finalizing the provisions proposed at §§ 422.2261(a)(3) and 423.2261(a)(3) with an update. In the Contract Year 2027 proposed rule, we inadvertently referred to the number for TPMO submissions in HPMS as the MCE number whereas it is a Multi-Plan number. We are correcting this technical error to clarify that MA organizations may not submit materials for the contract under the organization's MCE number and third-party marketing organizations may not submit materials under the Multi-Plan number as described in §§ 422.2262(d)(2)(i) and 423.2262(d)(2)(i). This change does not alter the intended scope of the regulatory requirement.

F. Request for Information: C–SNP and I–SNP Growth and Dually Eligible Individuals

In the Contract Year 2027 proposed rule (90 FR 54978 through 54984), we included a request for information regarding growth of chronic condition special needs plans (C–SNPs) and institutional special needs plans (I–SNPs) and dually eligible enrollment in those plans. This section summaries the RFI.

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 and the number of dually eligible individuals enrolled in C–SNPs increased from CY 2021 through CY 2025 as outlined at 90 FR 54979. Over the same timeframe, the number of C–SNPs with a high proportion of dually eligible enrollees increased as shown at 90 FR 54979 through 54980. Per § 422.514(d), we defined 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. At 90 FR 54979 through 54980, we provided 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.

2. Growth in I–SNPs With High Proportion of Dually Eligible Enrollees

At 90 FR 54981, we noted that compared to C–SNPs, the number of I–SNPs offered by MA organizations has remained relatively consistent in recent years. Dually eligible individuals represented the vast majority of I–SNP enrollees at approximately 90 percent of total enrollment each year. For a more detailed discussion of dually eligible individuals enrolled in I–SNPs, see 90 FR 54981.

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 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) 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. Through their annual SMACs, States are implementing intentional strategies to better coordinate care for dually eligible individuals.

As discussed in the Contract Year 2027 proposed rule at 90 FR 54982

through 54983, C–SNPs could be serving as a workaround to Federal and State integration efforts. Like D–SNPs, C–SNPs and I–SNPs must have approved MOCs and develop HRAs and individualized care plans (ICPs), but 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.[112]

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 eligible enrollees without meeting D–SNP requirements. In their comments on the Contract Year 2025 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.

4. Potential Policy Changes for Comment Solicitation

We solicited 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 solicited comment on establishing a SMAC requirement similar to the existing requirement for D–SNPs. We solicited comments on whether or not we should adopt a SMAC requirement for C–SNPs and/or I–SNPs with high concentrations of dually eligible individuals as well as potential Federal requirements for those SMACs.

Second, we solicited comments on methods to increase care coordination for dually eligible individuals enrolled in C–SNPs and I–SNPs. At 90 FR 54983, we stated that we were 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 solicited 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 solicited comment on three approaches to applying the D–SNP look-alike contracting limitations at § 422.514(d) through (g) to C–SNPs. We solicited 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 welcomed 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 requested 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 welcomed comments on the policy ideas outlined in this section to help inform potential future regulatory action.

Finally, we noted our interest 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). We invited 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 welcomed 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 invited 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 welcomed 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.

We received numerous comments in response to this request for information from a broad array of stakeholders, reflecting the strong interest in the issue of C–SNP and I–SNP growth and enrollment of dually eligible individuals in those plans. We appreciate commenters sharing these perspectives. While we will not be responding to the comments submitted in this final rule, we will consider the comments and suggestions for future rulemaking.

VII. Reducing Regulatory Burden and Costs in Accordance With Executive Order (E.O.) 14192

As noted previously, we sought public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other interested parties participating in

[112] 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.*

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).[113]

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),[114] 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).

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,[115] which are arrangements that are paid solely by the employer, reimburse employees only for their, their spouse's, and their dependents' medical care expenses [116] (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),[117] 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. Given that account-based entities do not offer such coverage, we proposed to revise § 423.56(b)(3) so that account-based entities are not required to provide the creditable coverage disclosures. Furthermore, 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) while the individual's plan that directly offers the prescription drug benefit coverage discloses that it does offer creditable coverage, the recipient of the information could find the dual messaging potentially contradictory and confusing. 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. 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. We proposed to exclude account-based plans from making these disclosures as

[113] *https://www.federalregister.gov/documents/2005/01/28/05-1321/medicare-program-medicare-prescription-drug-benefit.*

[114] *https://www.federalregister.gov/documents/2005/01/28/05-1321/medicare-program-medicare-prescription-drug-benefit.*

[115] 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.*

[116] 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.*

[117] *https://www.govinfo.gov/app/details/FR-2019-06-20/2019-12571.*

these account-based plans do not offer prescription drug coverage and to provide clarity for Medicare-eligible individuals regarding whether their coverage is creditable. The proposal also aligned 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 proposed 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.

We received comments from health plans, professional organizations, benefit specialist advisors, SHIPs, and a State Department of Insurance on our proposal to exclude account-based medical plans from creditable coverage disclosure requirements. The comments we received on this proposal and our responses follow.

Comment: Most commenters supported our proposal to exclude account-based medical plans from the creditable coverage disclosure requirements. Commenters cited several reasons for their support of this proposal. Commenters stated that these disclosures are not appropriate for account-based arrangements because such plans do not provide comprehensive prescription drug coverage and therefore do not function as substitutes for Part D coverage. Several commenters indicated that the proposal appropriately aligns disclosure requirements with the nature of the coverage offered.

Many commenters further noted that applying creditable coverage disclosure requirements to account-based medical plans creates confusion for beneficiaries and imposes administrative burden without a corresponding consumer benefit. One commenter explained that the purpose of creditable coverage disclosures is to inform beneficiaries about the equivalency of prescription drug coverage, and that extending these requirements to account-based arrangements goes beyond that intent and diminishes the usefulness of the disclosures.

A couple of commenters also stated that codifying the exclusion would promote greater consistency and clarity across stakeholders. A commenter representing beneficiary assistance programs reported that SHIP counselors frequently encounter beneficiary confusion resulting from disclosures associated with account-based plans and must spend significant time clarifying that these arrangements do not replace Part D coverage. The commenter stated that exempting account-based medical plans from the disclosure requirement would reduce unnecessary counseling complexity and improve efficiency. Another commenter noted that beneficiaries would remain protected because group health plans that provide prescription drug coverage, including those that also offer account-based arrangements, would continue to be subject to the creditable coverage disclosure requirements.

Response: We appreciate the commenters' support of this proposal and agree with the points the commenters raise.

Comment: One commenter supported the proposal but recommended that CMS revise § 423.56(b)(3) to clarify that any group health plan offering prescription drug coverage, including plans that also include account-based medical coverage, must comply with the disclosure and notification requirements in paragraphs (c) through (g) of that section.

Response: We appreciate the commenter's suggestion. We agree that group health plans offering prescription drug coverage, including those that also include account-based medical coverage, remain subject to the creditable coverage disclosure and notification requirements under § 423.56(c) through (g). We believe existing regulations sufficiently reflect this requirement and therefore are not making additional regulatory changes at this time.

Comment: A small number of commenters opposed the proposal to exclude account-based medical plans from the creditable coverage disclosure requirements. These commenters stated that disclosures help beneficiaries distinguish between coverage that does and does not satisfy Medicare requirements and expressed concern that exempting account-based plans could reduce beneficiary awareness of whether such coverage meets Medicare creditable coverage standards. One commenter noted that it is not obvious to beneficiaries that account-based arrangements used to pay for prescription drugs do not constitute creditable prescription drug coverage. Another commenter asserted that the administrative burden on account-based plans is minimal, as plan sponsors already know that these arrangements do not meet creditable coverage standards.

Response: We appreciate the commenters' concerns. As discussed above, account-based medical plans do not provide comprehensive prescription drug coverage and therefore do not satisfy Medicare creditable coverage standards. We agree that disclosures play an important role in informing beneficiaries; however, we believe that applying creditable coverage disclosure requirements to arrangements that are not, and cannot be, creditable has contributed to beneficiaries receiving potentially contradictory and confusing information. Beneficiaries will continue to receive creditable coverage disclosures from group health plans that provide prescription drug coverage, including plans that also offer account-based arrangements.

After consideration of the comments received on this provision by a broad range of stakeholders, we are finalizing this policy as proposed without modification.

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 dually eligible population. Such benefits may include nonskilled nursing services, personal care services, and other long-term care services and supports designed to keep dually 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.[118] CMS codified this standard at § 422.100(c)(2)(ii)(A).

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.

We noted in the Contract Year 2027 proposed rule that, in recent years, few MA plans have used § 422.102(e) to provide supplemental benefits. A table showing supplemental benefits offered through § 422.102(e) for contract years 2013–2026 can be found at 90 FR 54986. Our analysis of the bid data from 2013 to 2026 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.[119]

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 believed that § 422.102(e) was no longer needed and proposed 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 explained in the Contract Year 2027 proposed rule that we did 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. We anticipated that deregulating § 422.102(e) could streamline the bid submission process for D–SNPs and us by simplifying the avenues for offering supplemental benefits.

We solicited comments on our proposal. We requested 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 solicited comments on whether § 422.102(e) provides any advantages in D–SNPs offering supplemental benefits previously offered under VBID.

We received the following comments on this proposal and respond to them below:

Comment: Some commenters outlined support to remove § 422.102(e), referencing low utilization of the § 422.102(e) pathway and the availability of other pathways for D–SNPs to provide supplemental benefits, such as primarily health related supplemental benefits and SSBCI. A few of these commenters stated that removing the § 422.102(e) pathway would reduce regulatory complexity without constraining benefit design. While supporting the proposal, a commenter emphasized that when States do not provide Medicaid benefits for dually eligible individuals, D–SNPs need flexibility to provide additional benefits to enrollees with complex needs and such benefits cannot always be provided through primarily health related supplemental benefits or SSBCI. A commenter suggested that CMS develop a publicly shared document that displays benefits historically offered under § 422.102(e) with other supplemental benefits pathways and provide guidance for D–SNPs to operationalize any transition away from the § 422.102(e) pathway.

Other commenters opposed removing § 422.102(e), noting lack of D–SNP awareness of the § 422.102(e) supplemental benefits pathway and that removing the § 422.102(e) pathway could constrain innovation in State and D–SNP supplemental benefits design to advance more integrated D–SNPs. A commenter stated that the § 422.102(e) pathway may not have been used previously due to the VBID model and could be useful to D–SNPs now that the VBID model is no longer available. Another commenter recommended that CMS issue guidance to plans that reinterprets § 422.102(e) to allow additional supplemental benefits, such as food and grocery allowances, that are responsive to the needs of dually eligible individuals. The commenter also suggested that CMS consider ways to expand § 422.102(e) beyond its applicability to HIDE SNPs and FIDE SNPs. In addition, a commenter raised concerns that removing the § 422.102(e) pathway could negatively impact D–SNP enrollees.

Response: We appreciate the commenters perspectives on our proposal to remove § 422.102(e) as an additional pathway for D–SNPs to offer supplemental benefits. Although a small number of D–SNPs have offered supplemental benefits through § 422.102(e), we are persuaded by comments regarding the lack of awareness of § 422.102(e), the potential for § 422.102(e) to be an alternative to the recently ended VBID program, and the potential for § 422.102(e) to provide

[118] CMS, Announcement of Calendar Year 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, page 208. Retrieved from: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.*

[119] 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.*

a pathway to develop innovative supplemental benefits for dually eligible individuals. We will retain the § 422.102(e) supplemental benefits pathway and monitor utilization of this pathway in future bids to inform future rulemaking.

After considering the comments we received and for the reasons outlined previously and our responses to comments, we are not finalizing the proposal to remove § 422.102(e) and instead retaining § 422.102(e) as a pathway for D–SNPs to offer supplemental benefits.

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 30561). The notice, referred to as the Mid-Year Notice, was to list any supplemental benefits not utilized by the enrollee during the first six 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, CMS later determined that the frequency of utilization was higher than previously believed. CMS also developed concerns about the administrative and financial burden, especially on smaller MA organizations, and determined the new requirement was 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 proposed in the Contract Year 2027 proposed rule to rescind the Mid-Year Notice of Supplemental Benefits requirement established in §§ 422.111(l) and 422.2267(e)(42) (90 FR 54987).

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 reviewed this regulation in accordance with E.O. 14192 and determined that it was unnecessary and 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 necessitated 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 then required 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 predicted 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 risked 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 the proposal was 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 already 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 was to 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 six 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 [120] 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 using them, although CMS acknowledges that at this time, information on MA enrollee use of supplemental benefits is limited. It should be noted, however, that CMS is working to address this data gap; the Agency introduced the Supplemental Benefit Utilization and Costs section in the Part C Reporting Requirements for contract year (CY) 2024 and made additional changes effective for CY 2025 and subsequent years. This will allow CMS to review and compare a chronological sequence of CY data sets to help the Agency better understand supplemental benefit utilization trends in the Part C program.

Market competition naturally incentivizes MA organizations to ensure enrollees are aware of and use 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

[120] *https://www.commonwealthfund.org/publications/surveys/2024/feb/what-do-medicare-beneficiaries-value-about-their-coverage.*

supplemental benefits information and would create undue burden for MA organizations. Further, recent evidence suggests that enrollees are utilizing supplemental benefits when they need them. For the aforementioned reasons, CMS proposed to rescind the Mid-Year Notice requirement at §§ 422.111(l) and 422.2267(e)(42).

CMS invited public comment on the proposed removal of this regulatory requirement and received mixed comments. A discussion of the comments received, along with CMS's responses, follows.

Comment: Some commenters expressed concern that MA enrollees could be unaware of the full slate of supplemental benefits available to them, and that enrollees would not be informed of their supplemental benefits as a result of the removal of the Mid-Year Notice requirement.

Response: As discussed in the preamble, the Mid-Year Notice duplicates existing communication requirements such as the EOC. MA organizations are required to send an EOC annually to each individual enrolled in their MA plans. The EOC includes detailed information about the supplemental benefits covered by the plan such as benefit descriptions, copays, coinsurance, and eligibility criteria when applicable. Further, many MA organizations already communicate availability of supplemental benefits through their care coordination services, newsletters, and other enrollee education efforts.

Comment: Some commenters stated that enrollees do not always understand that they must meet particular eligibility requirements to receive certain supplemental benefits, and that a failure to rescind the Mid-Year Notice requirement would result in confusion when enrollees receive information about benefits for which they are not eligible.

Response: CMS agrees that a new, targeted communication method that presents an individualized menu of supplemental benefits options (*i.e.* the enrollee's unused supplemental benefits) but may not exclude benefits the enrollee is ineligible or not necessarily eligible for, could be confusing and would likely result in frustration for enrollees and increased costs for MA organizations. CMS believes that the EOC already makes clear distinctions between types of supplemental benefits and their corresponding eligibility criteria in a way that is easy to understand.

Comment: Some commenters stated that enrollees choose plans based on supplemental benefits, and MA plans receive rebates to fund those supplemental benefits. Thus, CMS should promote enrollee utilization of supplemental benefits to ensure government funds are responsibly spent.

Response: CMS is committed to ensuring that taxpayer money is spent responsibly, transparently, and appropriately across all CMS programs. Continuous oversight and thoughtful consideration for the use of government funds, including in MA, are an ongoing Agency priority. While, as these commenters stated, enrollees should be encouraged to use their supplemental benefits, CMS does not believe that the duplicative effort of sending a bulk of information to enrollees that they have already received six months earlier will achieve this result.

Comment: Some commenters gave their support for removal of the Mid-Year Notice requirement due to the logistical challenges and administrative and operational costs associated with its implementation and noted that the information sent would be largely duplicative of information sent six months earlier in the EOC. A subset of those commenters further noted that the complexity of these challenges would put smaller MA organizations at a disadvantage.

Response: CMS appreciates the feedback and acknowledges the challenges MA organizations, including small MA organizations, face when new regulatory requirements emerge. CMS also acknowledges the importance of maintaining an environment that gives smaller MA organizations a fair chance to compete, with the ultimate goal being a wide variety of plan choices for enrollees each year. As such, it is important to ensure that every new requirement can offer enough benefit to offset the burden it imposes.

Comment: A commenter stated that in some cases, the Mid-Year Notice would require great effort but produce little value. As an example, the commenter pointed out that some provider-led Institutional Special Needs Plans (I–SNPs) already ensure enrollees maximize their available supplemental benefits, and as a result, the enrollees of those SNPs are unlikely to have improved access to care and health outcomes because they received a Mid-Year Notice.

Response: CMS appreciates the thoughtful response by this commenter and acknowledges the commenter's assessment that if a MA plan such as an I–SNP is already designed to help enrollees maximize their use of supplemental benefits, it is unlikely that any improvement in health outcomes would result from the distribution of a Mid-Year Notice. This example demonstrates that aside from being duplicative of existing communication requirements, the requirement may also be overly broad because of its application to all MA plan-types.

Comment: Some commenters noted the dearth of available data on supplemental benefit usage and stated that CMS should obtain such data and use it for future policy refinements with respect to supplemental benefit communications. For example, a commenter pointed out the hypothetical potential for a discharge team to use electronic tools, suggestive of the interoperability infrastructure of which implementation began during the first Trump administration, to connect a patient with post-discharge support that could help reduce the likelihood of rehospitalization.

Response: Use of interoperability tools by providers for the purpose of connecting patients to supplemental benefits is intriguing, but beyond the scope of this rule. CMS appreciates the thoughtful nature of these comments and will take this input into consideration for future rulemaking.

After careful consideration of the comments received, CMS will move forward with the proposal, without modification, and rescind the Mid-Year Notice of Supplemental Benefits.

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. Additionally, on January 31, 2025, E.O. 14192, ''Unleashing Prosperity through Deregulation'' was issued, 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. In the Contract Year 2027 proposed rule (90 FR 54988), CMS proposed 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 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 received the following comments on this proposal, and our responses follow:

Comment: A commenter agreed with the proposal, as they were supportive of the aims of E.O. 14148 and the removal of sex-based terminology.

Response: CMS thanks the commenter for their support for our proposal.

Comment: Multiple commenters were opposed to the proposal and shared concerns about the proposed change to § 422.112(a)(8). Concerns included that the change would impede plans' ability to address social risk factors and other barriers that impact care delivery and management, as well as that the generality of the language would lead to inconsistent implementation which would potentially worsen health disparities. Several commenters noted support for enumerating groups that have experienced poor health care experiences and that it was a specific, inclusive, and helpful guide for plans.

Response: CMS appreciates commenters sharing their concerns. However, CMS disagrees with this position, as plans will still be required to ensure all enrollees, without exception, are provided with accommodations to access services, as they were required to do even before the April 2023 updates to § 422.112(a)(8). Further, this action does not prohibit plans (including special needs plans) from identifying health disparities, addressing barriers that impact care delivery, and developing strategies for different sub-populations to ensure high-quality care if they choose to do so. Plans can continue to develop their own lists of sub-populations of focus, continue quality improvement programs that work to improve health outcomes, and address disparities observed among their enrollees.

Comment: A commenter urged that CMS ensure that the language requiring culturally competent services for those with limited English proficiency or reading skills is implemented robustly, with this including requirements for qualified interpreter services, translated written materials, and other accommodations.

Response: CMS appreciates the commenter sharing this suggestion. CMS believes that plans can determine what strategies, such as translation or interpreter services, work best to ensure culturally competent care for their enrollees. Of note, plans are also held to the Health and Human Services Office for Civil Rights (OCR) notice of availability of language assistance services and auxiliary aids and services requirements (currently at 45 CFR 92.11).

After consideration of the public comments CMS received, and for the reasons outlined here and in the Contract Year 2027 proposed rule, CMS is finalizing as proposed revisions to § 422.112(a)(8).

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 Medicare Advantage (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.

Subsequently, CMS made and proposed additional changes to the UM Committee requirements, which are detailed in the Contract Year 2027 proposed rule. This includes changes made in April 2024, when 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).

Specifically, at § 422.137(c)(5) CMS finalized 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 finalized a requirement that the UM Committee must conduct an annual health equity analysis on 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). 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 a useful baseline of data. CMS also signaled the intent to consider further changes to these requirements in subsequent rulemaking based on comments received.

CMS implemented the additional UM Committee requirements in the April 2024 final rule based on the previous administration's health equity-related initiatives, which have since been revoked by E.O. 14148: ''Initial

Rescissions of Harmful Executive Orders and Actions.'' [121]

Moreover, as discussed in the Contract Year 2027 proposed rule, 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.[122]

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.

In the Contract Year 2027 proposed rule, CMS proposed to remove the requirement at § 422.137(c)(5) that the UM Committee include at least one member with expertise in health equity. In addition, CMS proposed 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 proposed 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.

CMS received the following comments on this section of the Contract Year 2027 proposed rule, and provided responses as follows:

Comment: Many commenters expressed support for CMS' proposal to rescind the requirements for MA organizations' UM Committees at § 422.137(c)(5), (d)(6), and (d)(7). The commenters stated that the analysis was duplicative, offered limited value, and could present a misleading picture of health equity due to inconsistences in data reporting. Commenters also indicated that simplifying and streamlining the requirements would reduce administrative costs and burden on MA organizations. A commenter stated prior authorization denial rates are not necessarily attributable to an enrollee's SRF status. Another commenter expressed concerns that statistics alone would not describe the entirety of MA plans approach to supporting beneficiaries access to care. Finally, a commenter expressed concerns that there would be data inconsistencies in the absence of reporting guidance defining data elements or a standard template.

Response: CMS appreciates the commenters' support and thanks them for their comments.

Comment: Many commenters supported the requirement that MA organizations release an annual health equity analysis of utilization management policies. These commenters stated that the burden associated with producing the analysis would be minimal and that the resulting data would provide important transparency, information, and accountability around the use of UM on different populations.

Numerous commenters further asserted that the analysis would strengthen CMS oversight of the MA program by helping to prevent inappropriate denials, barriers to care, harmful clinical delays, and clinician burnout. They emphasized that the reporting would support efforts to identify and address health disparities and improve access to care for underserved populations.

Several commenters expressed concerns about removing health equity reporting requirements when Medicare's population is increasingly diverse and disparities in access to care are well documented. Commenters also stated that MA organizations' prior authorization practices lead to inappropriate denials, care delays, and administrative burden. These commenters stated that the analysis would provide a deeper understanding of the real-world impacts of prior authorization and help ensure that MA organizations are meeting coverage requirements. A commenter stated that removing the requirement would allow a critical information gap to persist, while another commenter expressed concerns that eliminating the requirement would undermine prior authorization reform efforts.

Response: CMS considered commenters' views regarding transparency, oversight, and the importance of analyzing UM policies in an increasingly diverse Medicare population. As outlined in the Contract Year 2027 proposed rule and this final rule, CMS continues to believe that the burden associated with producing the annual health equity analysis is not minimal and that the analysis would not meaningfully strengthen oversight of UM practices in the MA program.

CMS' decision to rescind the requirements for MA organizations' UM Committees at § 422.137(c)(5), (d)(6), and (d)(7) reflects CMS' assessment that the requirements would have limited effectiveness in advancing health equity, while imposing additional administrative burden associated with collecting and publishing the data. This decision is also consistent 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 believes there are more efficient and effective ways to obtain information on the impact of UM requirements on MA enrollees, including through ongoing interoperability initiatives and other data collection mechanisms. CMS remains committed to ensuring that MA organizations comply with coverage and UM requirements and will continue to evaluate options for collecting data that more accurately reflect the experiences of all MA enrollees.

Comment: Several commenters urged CMS not to rescind the annual requirement for MA organizations to release an annual health equity analysis without first establishing an alternative data collection mechanism. These commenters recommended that CMS

[121] *https://www.federalregister.gov/documents/2025/01/28/2025-01901/initial-rescissions-of-harmful-executive-orders-and-actions.*

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

retain the health equity analysis requirement until service level determination and appeal data are fully operational.[123] Commenters also recommended that CMS adopt a less burdensome alternative methodology, collect baseline data through interoperability, or expand data reporting to better understand how prior authorization policies affect access to care across beneficiary populations.

Multiple commenters proposed specific alternative methodologies for monitoring MA organizations' UM policies and practices. Some commenters encouraged CMS to extend reporting requirements to Part D plans to improve understanding of how UM policies affect access to care and help inform beneficiaries' and caregivers' coverage decisions. A commenter further urged CMS to conduct a study examining whether utilization management policies contribute to poorer health outcomes. Another commenter encouraged CMS to require states to develop standardized tools to measure the impact of UM policies on access to Medicaid services for dually eligible individuals.

Response: CMS appreciates commenters' recommendations regarding ways to retain and strengthen the annual health equity analysis. While CMS acknowledges commenters' concerns about eliminating the reporting requirements without an alternative approach, the Agency does not believe that the annual health equity analysis, as finalized in prior rulemaking, is the most effective or efficient mechanism for establishing baseline data on the impacts of UM practices across MA enrollee populations. CMS is therefore rescinding the requirements while continuing to consider other approaches to obtaining more timely, standardized, and actionable data.

CMS also considered commenters' suggested alternative methodologies for monitoring MA organizations' UM policies and practices. CMS believes the proposed alternative analysis methodologies would offer limited practical utility and impose additional administrative burden on MA organizations. CMS is committed to taking steps to reduce the regulatory burdens imposed by the UM Committee requirements, consistent with the focus on streamlining regulations and reducing administrative burden. However, CMS may consider other approaches to monitoring UM policies and practices in future rulemaking.

Comment: Several commenters urged CMS not to remove the requirement that the UM Committee include at least one member with health equity expertise. The commenters stated that the requirement supports MA organizations' ability to monitor the impact of prior authorization on specific patient groups, identify disparities, and address any inequities in access to care.

Response: CMS carefully considered commenters' views regarding the inclusion of a UM Committee member with health equity expertise and the role such expertise may play in monitoring the effects of UM on specific patient populations. In the MA program, access to care is monitored through multiple oversight mechanisms, and MA organizations are already required to maintain policies, procedures, and safeguards to ensure timely access to covered items and services. Therefore, CMS does not believe that a prescriptive UM Committee composition requirement is necessary to monitor the impact of prior authorization on specific patient groups, address inequities in access to care, or ensure access to services for all MA enrollees.

After considering the public comments received, and for the reasons discussed in the Contract Year 2027 proposed rule and in this response to comments, the proposals to rescind the requirements for MA organizations' UM Committees at § 422.137(c)(5), (d)(6), and (d)(7), are being finalized as proposed, consistent with the cited E.O.s., and in response to interested parties' concerns about the requirements' rationale, feasibility, and administrative burden. This 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 also requested comments on ways to reduce administrative burdens associated with other UM Committee requirements for consideration in future rulemaking. CMS appreciates the comments and suggestions received and will take the feedback into consideration for future policy development.

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.

Consistent with E.O.s 14148 and 14192, CMS proposed to eliminate the regulatory requirement for QI programs under § 422.152(a)(5) for the reasons outlined in detail in the Contract Year 2027 proposed rule issued in November 2025 (90 FR 54990).

CMS did not propose to modify the QI Program requirements under § 422.152(a)(1) through (4), which are required 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 final rule aligns with the directives of E.O. 14192, to deregulate and reduce the administrative burden on MA organizations while preserving quality.

MA organizations 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 ensures 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 finalized deregulation reflects CMS' continued commitment to high-quality health care, while reducing

[123] In a December 16, 2025, HPMS memorandum, CMS announced its plans to conduct a voluntary pilot to collect service level data on MA plan initial determinations and appeals in 2026, with the intent to expand the data collection to all MA plans beginning in 2027.

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 received the following comments on this section of the Contract Year 2027 proposed rule, and responses follow:

Comment: Many commenters expressed concerns that removing requirements in MA quality improvement programs for the inclusion of activities to reduce disparities may exacerbate the prevalence of chronic illness and noted the well-documented correlation between health disparities and chronic illness. Commenters expressed concerns that removing this requirement would widen the health care gaps affecting marginalized and underrepresented populations. Some voiced concerns that if this requirement is revoked, insurers would use discriminatory practices to improve overall quality scores. They also urged CMS to continue naming specific groups that have historically experienced discrimination (such as people with disabilities, LGBTQI individuals, racial and ethnic minorities, rural residents, and those affected by persistent poverty) to provide necessary clarity, accountability, and direction to MA plans to ensure equitable access to care.

Response: CMS appreciates the commenters sharing their concerns. The QI Program requirements under § 422.152(a)(1) through (4) will remain in effect, including the requirement to have a chronic care improvement program (CCIP). Additionally, as discussed in the proposal, MA plans may continue with their current quality improvement initiatives and retain the ability to incorporate activities that address health disparities within their QI programs. CMS remains committed to sustained improvement in patient health outcomes.

Comment: Several commenters urged CMS to either keep the provision at § 422.152(a)(5) or come up with an alternative policy that would ensure quality care and health equity for MA enrollees from underserved communities.

Response: While CMS acknowledges the commenters' suggestion, the remaining QI Program requirements are sufficient to address the concerns regarding enrollee access to quality health care while reducing burden for MA organizations.

Comment: A commenter indicated that in Massachusetts, the requirement at § 422.152(a)(5) has functioned as a backstop against unfair or discriminatory prior authorization practices. They went on to urge CMS to strengthen the link between civil rights compliance and Star Ratings, using the ratings to reform utilization management to support timely, fair access to care.

Response: CMS appreciates the suggestion for reforming utilization management practices through the Star Ratings. However, this comment is outside the scope of this regulation.

Comment: Some commenters wrote in support of rescinding the provision at § 422.152(a)(5), noting that it would reduce administrative burden.

Response: CMS thanks the commenters for their support.

After consideration of the public comments received, and for the reasons set forth in the Contract Year 2027 proposed rule and in the above responses to comments, CMS is finalizing the removal of § 422.152(a)(5) as proposed.

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 expired at the end of plan year 2025, we proposed to remove § 422.752(d) as articulated in the Contract Year 2027 proposed rule (90 FR 54990).

We received the following comments on this proposal and respond to them below:

Comment: A few stakeholders commented on our proposal. A commenter noted that retaining an expired enforcement authority in regulation is unnecessary and potentially confusing and that removing this language would improve regulatory clarity while preserving CMS oversight tools. While not opposed to removing the expired enforcement authority, another commenter recommended that CMS work with Congress to extend the expiring statutory authority. This commenter explained that an intermediate sanction can be less disruptive for enrollees than an intermediate termination and reinstating the statutory authority would allow CMS to engage in enrollment sanctions for non-compliant D–SNPs in the future.

Response: We appreciate these comments in support of our proposal to remove § 422.752(d). We agree that the sanction authority was useful for States and new D–SNPs since it created a mechanism to suspend enrollment for D–SNPs when SMACs were delayed. While we appreciate the interest in extending the enforcement authority in statute, we have been able to work with all applicable States to include, where appropriate, language in the SMACs that provides the same result as the limited enrollment enforcement authority from CMS.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed removal of § 422.752(d) without modification.

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

exempt 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 proposed 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 proposed 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 changes to the regulatory text will adversely impact the LI NET sponsor, individuals' access to prescription drug benefits, the Medicare Trust Fund, or result in a paperwork burden.

The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for the proposal to waive requirements related to customer call center extended hours of operation for the LI NET program. They agreed that the removal of this requirement appropriately reflects the unique structure of the LI NET program and avoids duplicative requirements.

Response: We thank the commenters for their support.

Comment: Some commenters expressed concern that shorter call center hours may limit access to medications and prescription reimbursement assistance, especially for those with work, caregiving, or transportation constraints. Shorter hours may also inconvenience those with less flexible schedules. A few of the same commenters stated the importance of maintaining phone service for individuals without smartphones or internet access.

Response: While we acknowledge the concerns raised by the commenters, we do not believe enrollees' access to medications will be affected. As discussed previously, § 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. Consequently, LI NET enrollees have access to a call center as long as the enrollee's pharmacy is open. In addition, the number of calls made to the call center after 7:00 p.m. ET has historically been low due to the short-term nature of LI NET enrollment and the relatively open formulary employed by the LI NET program, which indicates that the call center hours of operation are sufficient to accommodate individuals with limited schedules or lacking internet access.

Comment: A commenter noted that the proposed LI NET call center hours waiver does not apply to every plan.

Response: We acknowledge this comment and agree that the waiver only applies to LI NET. All other plans must follow the extended call center hour requirements.

Comment: A commenter acknowledged the significance of telephonic and digital enrollment models in increasing beneficiary access and encouraged uniform safeguards and equivalent scrutiny to ensure beneficiary protection as it pertains to call centers and digital enrollment models.

Response: This comment is out of scope with respect to this proposal to waive requirements related to customer call center extended hours of operation for the LI NET program.

After consideration of the public comments we received, we are finalizing this proposal without modification.

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

A. Introduction

The MA program has grown considerably in the past two decades and now covers over half of all Medicare beneficiaries.[124] In light of this growth, CMS was 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) [125] [126] and other researchers.[127] [128] [129] CMS was particularly interested in changes that can enhance competition in the MA

[124] 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.*

[125] 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.*

[126] 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.*

[127] Kronick, R., & Chua, F. M. (2021). Industry-wide and sponsor-specific estimates of Medicare Advantage coding intensity. *Available at SSRN 3959446.*

[128] 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.

[129] 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.

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 (for example, 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,[130] [131] the Home Health Value-Based Purchasing Model,[132] and Prior Authorization of Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT),[133] 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,[134] which terminates effective December 31, 2025.[135] 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.[136]

Moreover, risk adjustment impacts competition between MA organizations and may impose inherent disadvantages on certain types of organizations over others.[137] 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.[138]

CMS, therefore, requested feedback in the CY 2027 Proposed Rule 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 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 sought 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,

[130] 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*.

[131] 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*.

[132] 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*.

[133] 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*.

[134] Centers for Medicare & Medicaid Services. *https://www.cms.gov/priorities/innovation/innovation-models/vbid*.

[135] 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*.

[136] 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*.

[137] 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.

[138] 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*.

incentivize positive health outcomes, and minimize administrative burden for plans and providers. In particular, CMS sought 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 was 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 solicited 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 were 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 also solicited 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 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?

C. Quality Bonus Payments in Medicare Advantage

In this RFI, we solicited 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 was 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[139] 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 was

[139] Request for Information on Consolidation in Health Care Markets. (June 2024). *https://www.regulations.gov/docket/FTC-2024-0022/document.*

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 prior to being finalized as Star Ratings measures used for payment. We, therefore, solicited 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 also solicited 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 solicited 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?
- 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?

Commenters broadly supported updating MA risk adjustment and the Quality Bonus Payment/Star Ratings framework to better align payments and incentives with beneficiary needs and meaningful outcomes. For risk adjustment, many urged CMS to improve payment accuracy and reduce incentives for coding intensity, including by strengthening the underlying data and better accounting for persistent chronic conditions while avoiding continued credit for conditions that are no longer clinically active. Commenters emphasized transparency, testing, and phased implementation to prevent unintended impacts on high-need populations and program stability.

For QBP/Star Ratings, commenters recommended refining measure selection, weighting, and program design to better reflect outcomes and beneficiary experience, improve alignment with other CMS quality programs, and reduce timing lags between measurement and payment. Some raised concerns about overall spending and whether QBP should be budget neutral, while others cautioned against abrupt changes that could disrupt plan benefits and supplemental offerings.

We appreciate the feedback received on MA risk adjustment and the Quality Bonus Payment/Star Ratings programs. We will consider these comments as we evaluate future policy directions for the MA program.

D. Well-Being and Nutrition

CMS requested comments on well-being and nutrition policy changes for the MA program, including tools and policies that improve overall health, happiness, and life satisfaction through complementary and integrative health approaches, as well as strategies to achieve optimal nutrition and preventive care, with particular emphasis on improving incentives to ensure MA organizations bear long-term risk for beneficiary health and well-being.

CMS received numerous comments in response to this RFI. Comments were overwhelmingly supportive of CMS's focus on nutrition and well-being in MA. Commenters expressed strong support for recognition of nutrition as foundational to preventive care, focus on well-being and nutrition policy development, and efforts to integrate nutrition interventions into Medicare Advantage programs. Comments reflected strong support for integrating nutrition and holistic well-being into Medicare policy, with emphasis on prevention, expanded coverage, and addressing social determinants of health. Comments recommend expanding access to nutrition-related services including medical nutrition therapy (MNT) for malnutrition, obesity, cancer, heart disease, and other conditions affecting nutritional status. Additional recommendations included home-delivered medically tailored meals, oral nutrition supplements for food-insecure populations, produce prescriptions, virtual and in-home visits from multidisciplinary teams, and education opportunities such as grocery store tours and cooking classes.

CMS thanks the commenters for expressing their support and sharing their recommendations for comprehensive health, nutrition, and preventive care in the MA program.

IX. Technical Changes to Terminology in Risk Adjustment and in Payments to Sponsors of Retiree Prescription Drug Plans

We proposed 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 proposed to 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 did not include a discussion of this provision in the COI section of this rule.

We did score this provision in the Regulatory Impact Analysis section because this technical change has no impact on program operations.

Comment: A few commenters stated that the technical change will create

barriers to care for gender-diverse beneficiaries. A commenter was concerned that the terminology change will create confusion across Medicare Advantage and Medicare Part D payer policies, leading to variability in the interpretation and application of coverage requirements by plans. This commenter also noted that the policy change may lead to confusion in practices because it is not consistent with coding and medical documentation.

Response: We recognize the concerns raised by the commenters. However, these terms have no discernable operational difference in meaning with regard to risk adjustment and applications for qualified retiree prescription drug plans.

After consideration of the public comments we received, we are finalizing the technical change as proposed.

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 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.

In the Contract Year 2027 proposed rule (90 FR 54894), we solicited public comment on each of these issues for the following sections of the rule that contained information collection requirements. Such comments were received for the provisions proposed under ICR #2 (Strengthened Documentation Standards for Part D Plan Sponsors) and ICR #4 (Appeals Process for Part D Program Integrity Prescription Drug Event Record Review Audits). A summary of the comments and our responses follow under the applicable ICR section of this final rule. Separately, we received a comment on our use of BLS's National Occupational Employment and Wage Estimates to calculate costs. A summary of that comment and our response follow under section X.A. (*Wage Data*) of this final rule.

While a number of requirements were finalized on April 15, 2025 (90 FR 15792) under CMS–4208–F (RIN 0938–AV40), the proposed information collection requirement in section VI.B.9. of the Contract Year 2026 proposed rule CMS–4208–P (89 FR 99340) titled ''ICRs Regarding Eligibility for Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102(f)(4)(iii)(C))'' was not finalized at that time. As indicated throughout this preamble, this provision is being finalized in this CMS–4208–F3 rule.

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 final rule, provides May 2024 wages. In this regard, table 6 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 6: 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

In response to the commenter's recommendation to use BLS's Employer Costs for Employee Compensation data, we use BLS's National Occupational Employment and Wage Estimates, which provide more job-specific details and categories of employees. In addition, the employer costs shown in both datasets are fairly comparable. For example, the BLS's ECEC dataset for September 2025 estimates the total hourly compensation for management, professional, and related occupations at $77.26/hour.[140] By contrast, BLS's OEW dataset for May 2024 for management occupations (occupational code 11–0000) reflects a mean hourly wage of $68.15. To account for the cost of fringe benefits and other indirect costs, we doubled the OEW mean hourly wage, yielding a total hourly compensation estimate of $136.30. Our use of BLS's OEW data yields a conservative estimate of labor costs while providing greater specificity in distinguishing wage estimates across job titles and occupational classifications. Accordingly, this rule relies on BLS's OEW data as the basis for the occupational wage estimates used in calculating the burden costs associated with the provisions in this final rule. We will continue to evaluate estimation methods and policy implementation timelines, as appropriate.

After consideration of the public comments we received, we are finalizing the proposed collection of information requirements using BLS's mean hourly wages doubled for fringe benefits and other indirect costs to estimate the adjusted mean hourly wages.

B. Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble of this final rule.

[140] U.S. Bureau of Labor Statistics, Employer Costs for Employee Compensation, *https://www.bls.gov/web/ecec.supp.toc.htm.*

1. ICRs Regarding Manufacturer Discount Program (§ 423.100 and §§ 423.2700 Through 423.2768)

As described in section II.C. of the Contract Year 2027 proposed rule, we proposed to codify the policies established under the Manufacturer Discount Program Final Guidance,[141] with certain refinements, as new subpart AA of part 423.

Codification of the Manufacturer Discount Program policies in this final rule have no impact on the requirements or burden estimates that are currently approved by OMB under control number 0938–1451 (CMS–10846). The collection of information requirements/burden in the Final Guidance are active and properly accounted for in CMS–10846 without the need for change. In this regard, our finalized provisions are not subject to the requirements of the PRA.

We received no comments regarding information collection requirements for the Manufacturer Discount Program. We are finalizing the regulatory policies for the Manufacturer Discount Program largely as proposed, with limited modifications, which are described in greater detail in section II.C. of this final rule.

2. ICRs Regarding Strengthened Documentation Standards for Part D Plan Sponsors (§ 423.505)

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, 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 the Contract Year 2027 proposed rule, CMS proposed 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 proposed 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 CMS to evaluate if the PDE record was covered and paid under the Medicare Part D benefit in compliance with CMS policy or policies.

CMS proposed 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 proposed 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 proposed 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 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.

As indicated, comments were received. A summary of the comments and our response follow.

Comment: A few commenters mentioned that the documentation standard proposed may cause increased administrative burden for Part D plan sponsors.

Response: We have included minor updates to the proposed language and addressed comments for documentation standards, including commenters' concerns surrounding burden for plan sponsors in this rule's provision for ''Strengthened Documentation Standards for Part D Plan Sponsors''. CMS provided clarification that plan sponsors (1) do not need to maintain audio recordings and that transcripts or call notes suffice, (2) only need to maintain communications that *they* have with pharmacists, prescribers, enrollees or other stakeholders entities and not communications between these entities, and (3) do not need to perform additional outreach if information available clearly illustrates how a decision for Part D coverage was made.

After consideration of the public comments we received, we are finalizing the proposed provisions with minor modifications in the original draft language to clarify plan sponsor expectations.

3. ICRs Regarding Removing Rules on Time and Manner of Beneficiary Outreach (§§ 422.2264(c) and 423.2264(c))

CMS is finalizing three deregulatory changes to §§ 422.2264(c) and 423.2264(c) to remove rules on the time and manner of beneficiary outreach. The changes are designed to improve the plan decision making process by

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

creating a more convenient, beneficiary-friendly outreach experience and to reduce burden on beneficiaries, plans, and agents/brokers. The 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 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), this rule removes 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 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), this rule removes 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 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), this rule removes 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).

d. Burden Summary

The following table summarizes our burden estimates.

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
§§ 422.2264(c)(2)(i) and 423.2264(c)(2)(i)	697 MA organizations (contracts)	(697)	0.25	(174)	88.82	(15,477)	0
§§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i)	697 MA organizations (contracts)	(697)	0.25	(174)	88.82	(15,477)	0
§§ 422.2264(c)(1)(ii)(D) and 423.2264(c)(1)(ii)(D)	697 MA organizations (contracts)	(697)	0.25	(174)	88.82	(15,477)	0
TOTAL	697 MA organizations (contracts)	(697)	0.25	(522)	88.82	(46,431)	0

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

4. ICRs Regarding Appeals Process for Part D Program Integrity Prescription Drug Event Record Review Audits (Part 423, Subpart Z)

The effort associated with our finalized requirements under part 423, subpart Z 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.

As indicated, comments were received. A summary of the comments and our response follow.

Comment: A few commenters mentioned that the appeals process may cause increased administrative burden for Part D plan sponsors.

Response: CMS has addressed comments for the appeals process, including commenters' concerns surrounding burden for plan sponsors in this rule's provision for ''Appeals Process for Part D Program Integrity Prescription Drug Event Record Review Audits''.

After consideration of the public comments we received, we are finalizing the proposed provisions without modification.

5. ICRs Regarding Eligibility for Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102(f)(4)(iii)(C))

The following changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

As outlined in the CY 2026 proposed rule, for each SSBCI, the plan must post the written policies and objective criteria on which the policies are based to a public-facing website. For web developers and programmers to annually post the required information on the plan website, we estimate it will take 2 hours at $130.68/hr (89 FR 99392). We estimate that there are 697 plans including local and regional CCPs, MSA, and PFFS. In aggregate, we estimate an annual burden of 1,394 hours (697 plans * 2 hr/plan) at a cost of $182,168 (1,394 hr * $130.68) Medicare Cost plans are excluded from the count since they are not permitted to offer SSBCI.

The following table summarizes our burden estimates.

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
§ 422.102(f)(4)(iii)(C)	697 MA organizations (contracts)	697	2	1,394	130.68	182,168	182,168

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates. We are finalizing our estimates in this rule based on the proposed methodology but with more current data for wages and MA contracts. Our original estimates used wage data and a count of MA contracts that are no longer accurate.

6. ICRs Regarding Passive Enrollment by CMS (§ 422.60)

The requirement and burden change for D–SNPs will be submitted to OMB for approval under control number 0938–TBD (CMS–10953). At this time, the OMB control number has yet to be determined. However, it will be assigned by OMB upon their approval of this collection of information request. The public can monitor the status of our request at *reginfo.gov* under Information Collection Review.

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 will 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.

To address this issue, we are finalizing an amendment at § 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 will 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 will minimize the number of enrollees whose provider relationships are disrupted as a result of passive enrollment.

Based on July 2025 total D–SNP enrollment, we estimated 6,168,649 D–SNP enrollees per 949 D–SNPs or a CY 2025 average of 6,500 enrollees per D–SNP (6,168,649 D–SNP enrollees/949 D–SNPs).[142]

We assumed 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 estimated that a sheet of paper weighs 0.16 ounces (10.0 lb/1,000 sheets × 16 oz/lb), and did not anticipate additional postage for mailings in excess of 1 ounce.

We estimated 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 assumed a maximum of 2 double-sided pages (generally, weighing less than 1 ounce) would 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 did not estimate any labor costs. Therefore, we estimated a total mailing cost by sponsors of $114,686 (6,500 enrollees/D–SNP * 2 mailings * 11 D–SNPs * $0.802/mailing).

We did not receive comments on the information collection requirements associated with our proposal and, therefore, are finalizing the information collection requirements without modification.

The following table summarizes our burden estimates.

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
Labor Related Costs							
§ 422.60(g)	11 D-SNP (contracts)	11	80	880	Varies	67,654	0
§ 422.60(g)	11 D-SNP (contracts)	11	20	220	Varies	19,540	0
Subtotal: Labor Costs	11 D-SNP (contracts)	22	Varies	1,100	Varies	87,194	0
Non-Labor Costs							
§ 422.60(g)	11 D-SNP (contracts)	11	N/A	N/A	N/A	114,686	114,686
Subtotal: Non-Labor Costs	11 D-SNP (contracts)	11	N/A	N/A	N/A	114,686	*114,686*
TOTAL	11 D-SNP (contracts)	11	varies	1,100	Varies	201,880	114,686

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 changes will be submitted to OMB for approval 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 final rule.

We are amending §§ 422.107(d)(1) and 422.514(h) to allow D–SNPs that serve full-benefit dually eligible individuals in a coordination-only D–SNP or HIDE SNP to continue enrollment of full-benefit dually eligible individuals in a D–SNP in the same service area where

[142] CMS, SNP Comprehensive Report, July 2025. Available 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-2025-07.*

those individuals are enrolled in Medicaid FFS. As discussed in section VI.C. of this final rule, we are revising specific 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. The provisions that we are finalizing at §§ 422.107(d)(1) and 422.514(h) will 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. Using BLS's May 2022 wage data, 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 (or a total of 8 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 finalizing in section VI.C. of this rule to §§ 422.107(d)(1) and 422.514(h) will allow D–SNPs that serve full-benefit dually eligible individuals in a coordination-only D–SNP or HIDE 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, will change which D–SNPs will 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 finalized exception. To account for the reduction in affected MA organizations under this finalized 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 estimate that amendments to §§ 422.107(d)(1) and 422.514(h) will 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 in finalizing the amendments to §§ 422.107(d)(1) and 422.514(h). The wage estimates reflect May 2024 BLS National Occupational Employment and Wage Estimates, whereas our estimates in the April 2024 final rule used BLS National Occupational Employment and Wage Estimates from May 2022.

Using BLS's May 2024 wage data, 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 estimated 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 estimated a burden reduction of minus 180 hours (420 hr revised − 600 hr active) and minus $15,673 ($51,355 revised − $67,028 active).

The following table summarizes our burden estimates.

§§ 422.107 and 422.514	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
Active Burden	50 MA organizations (contracts)	50	12	600	varies	67,028	0
Revised Burden	35 MA organizations (contracts)	35	12	420	varies	51,355	0
Change	(15) MA organizations (contracts)	(15)	No change	(180)	varies	(15,673)	0

We did not receive comments on the information collection requirements associated with this proposal and are finalizing the information collection requirements without modification.

8. ICRs Removing Account-Based Medical Plans From Entities Required To Provide Creditable Coverage Disclosures

The following changes will be submitted to OMB for approval under control number 0938–1013 (CMS–10198).

As described in section VII.A. (90 FR 54984) of the Contract Year 2027 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 finalized provision 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 the Contract Year 2027 proposed rule (90 FR 54984), 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 the Contract Year 2027 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 from feedback that CMS received 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 attempted 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.[143]

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 burden 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). We used the higher of our two cost estimates (namely, $90,266) to score our total burden estimates.

The following table summarizes our burden estimates.

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
§ 423.56(b)(3)	140,974 Group Health Plans	(7,049)	0.083	(585)	154.30	(90,266)	(90,266)

We received no comments on this proposal and therefore are finalizing this provision without modification.

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))

Section 422.137(c)(5) requires a member of the UM Committee to have expertise in health equity. CMS estimated 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 of 348 hours (697 contracts * 0.5 hr) and $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 estimated 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 estimated 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).

The following table summarizes our burden estimates.

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
§ 422.137(c)(5)	697 MA organizations (contracts)	697	0.5	348	81.72	28,438	0
§ 422.137(d)(6)	697 MA organizations (contracts)	(697)	8	(5,576)	139.00	(775,064)	(775,064)
§ 422.137(d)(7)	697 MA organizations (contracts)	(697)	0.1667	(116)	88.82	(10,303)	(10,303)
Total	697 MA organizations (contracts)	(697)	varies	(5,344)	varies	(756,929)	(785,367)

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

C. Summary of Information Collection Requirements and Associated Burden

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[143] 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 J2: 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 ($)
Labor-Related Burden									
§§ 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)	0
§§ 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)	0
§§ 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)	0
§ 422.102(f)(4)(iii)(C)	Post plan's SSBCI eligibility criteria on their public-facing website	0938-0753 (CMS-R-267)	697 MA organizations (contracts)	697	2	1,394	130.68	182,168	182,168
§ 422.60(g)	Passive Enrollment (plan burden)	0938-TBD (CMS-10953)	11 D-SNP (contracts)	11	80	880	varies	67,654	0
§ 422.60(g)(4)	Notice Development	0938-TBD (CMS-10953)	11 D-SNP (contracts)	11	20	220	88.82	19,540	0
§§ 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)	varies	(15,673)	0
§ 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	(5,344)	103.18	(756,929)	(785,367)
Subtotal: Labor-Related Burden			*7,757 (697 + 11 + 7,049)*	*(9,133)*	*Varies*	*(4,137)*	*varies*	*(639,937)*	*(693,465)*
Non-Labor Burden									
§ 422.60(g)	Passive Enrollment (mailing costs)	0938-TBD (CMS-10953)	11 D-SNP (contracts)	11	N/A	N/A	N/A	114,686	114,686
Subtotal: Non-Labor-Burden			*11 D-SNP (contracts)*	*11*	*N/A*	*N/A*	*N/A*	*114,686*	*114,686*
TOTAL			**7,757**	**(9,122)**	**varies**	*(4,137)*	**varies**	**(525,251)**	**(578,779)**

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XI. Regulatory Impact Analysis

A. Statement of Need

This final rule addresses several critical needs in the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), and Medicare cost plan programs that require regulatory action to ensure program integrity, beneficiary protection, and statutory compliance. The provisions finalized in this rule are intended to codify 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 codify 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 provided under statute. 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 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 modifications being finalized 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 final 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 final 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 final 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 final rule in order to arrive at the total impact. Table 7 summarizes the estimated transfers and costs associated with the various provisions in this final rule over a 10-year period. Further details are provided later in this RIA.

TABLE 7: SUMMARY OF THE TRANSFERS AND COSTS OF THE FINAL 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	1,360	1,340	1,430	1,620	1,780	1,800	1,890	18,560
Continuity in Enrollment for Full-Benefit Dually Eligible Individuals	-	-	-	-	5	5	5	5	7	7	7	41
TOTAL TRANSFERS	-	-	5,020	2,320	1,365	1,345	1,435	1,625	1,787	1,807	1,897	19,601
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	-	-20.5	-20.5	-20.5	-20.5	-20.5	-20.5	-20.5	-20.5	-20.5	-20.5	-205
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†	-	-0.5	-0.6	-0.6	-0.6	-0.6	-0.6	-0.6	-0.6	-0.6	-0.6	-5.7
TOTAL COSTS	-1.9	-23.4	-23.5	-23.5	-23.5	-23.5	-23.5	-23.5	-23.5	-23.5	-23.5	-236.1

* Figures in the Costs section of Table 7 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: Removing Rules on Time and Manner of Beneficiary Outreach; Eligibility for Supplemental Benefits for the Chronically Ill (SSBCI); 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.

1. Effects of Part D Redesign: Redesigned Part D Benefit

In the Contract Year 2027 proposed rule, we proposed to codify changes to the Part D benefit made by section 11201 of the IRA related to the deductible, the initial coverage limit, the coverage gap, the annual out-of-pocket (OOP) threshold, and alternative prescription drug coverage options.

The CMS Office of the Actuary estimated the impacts of the drug provisions of the IRA using the 2024 President's Budget as a baseline early in calendar year 2023. These estimates were made prior to many policy decisions to implement the law, and independently from other components of CMS. Since the majority of these provisions have already been implemented through program instruction,[144] this estimate should be taken only in its historical context, not as a reflection on the experience since the provisions' effectuation. Additionally, these estimates measure the overall impact of the IRA on Medicare, whereas this regulation codifies only certain provisions of the law. We will highlight certain components of this estimate where recent experience has diverged from our initial assumptions.

The IRA has a range of Medicare provisions, including restraining price growth and negotiating drug prices for certain drugs payable under Part B and covered under Part D, as well as redesigning the Part D benefit structure to decrease beneficiary out-of-pocket costs. The provisions of the IRA take effect over several years, resulting in very different effects by year. Much of the Part D benefit redesign became effective in 2025, for example, before the Negotiation Program provisions can have any offsetting effects.

To model the Negotiation Program provisions of the IRA, we first determined which drugs would be selected for negotiation in accordance with sections 11001 and 11002 of the IRA. Using 2022 experience for Part B and Part D claims, we ranked drugs by Part B and Part D expenditures and then applied the eligibility criteria specified in the IRA—verifying, in particular, that the ranked drugs had been on the market long enough to qualify for negotiation. From this list, we generated the potential list of drugs to be negotiated in each year for Part B and Part D.

To estimate the impact of negotiation and to measure the differences between the current prices and the ceiling price and other pricing parameters laid out in the IRA, we used 2021 data from a variety of sources, including PDE records, Medicaid Average Manufacturer Price data, and Part B ASP data. We assumed, after comparing the Medicare prices to the ceiling prices in each projection year, that Medicare would be able to negotiate slightly below the ceiling price in Part D. We then adjusted for generic and biosimilar launches that, should they happen after the selection process, would potentially limit the impact of the maximum fair price. Lastly, we adjusted for changes in the percentage of spending that the selected drugs would represent over time. The discounts relative to total 2021 Part D allowed cost, prior to manufacturer rebates and total Part B allowed cost, are shown in Table 8.

TABLE 8: CUMULATIVE NEGOTIATION DISCOUNT FROM ALLOWED COST

	2026	2027	2028	2029	2030	2031
Part B	0%	−1%	−5%	−6%	−9%	−12%
Part D	−9%	−16%	−20%	−23%	−24%	−25%

For Part D, the benefit is considerably enriched under the IRA redesign, and the most impactful changes took effect in 2025. To estimate these effects inclusive of the Negotiation Program impacts, we incorporated the negotiated price at the drug level into a beneficiary- and claim-level detailed model. Then, we recalculated the new benefit on the negotiated prices to determine the combined result under the defined standard benefit design by year. To protect beneficiaries from large premium increases, the IRA limits the premium change in years 2024 through 2029 before ultimately readjusting the base beneficiary premium percentage to a minimum of 20 percent in 2030 and later years. The major benefit changes and beneficiary premium protections by year are shown in Table 9.

[144] This includes the Medicare Drug Price Negotiation Program Guidance with respect to initial price applicability years 2026, 2027, and 2028; the Part D Redesign Program Instructions for CY 2025 and 2026 (as discussed in section II.A. of this final rule); and the Medicare Part D Manufacturer Discount Program Final Guidance for CYs 2025 and 2026 (as discussed in section II.C. of this final rule).

TABLE 9: NOTABLE IRA PART D BENEFIT AND PREMIUM CHANGES

	2023	2024	2025–2029	2030
Benefits	Reduced cost sharing for insulins and ACIP-recommended adult vaccines	No cost sharing in catastrophic phase	Removal of coverage gap, $2,000 annual out-of-pocket cap (indexed), new manufacturer discount	No benefit changes
Premium	Funded by retrospective government subsidy	Base beneficiary premium (BBP) limited to 6% increase from prior year	BBP limited to 6% increase from prior year	BBP equal to lesser of prior year's BBP increased by 6% or the BBP calculated under §1860D-13(a)(2), with BBP not less than 20% of bid and reinsurance costs.

To complete the modeling of the Negotiation Program, prescription drug inflation rebates, and benefit provisions, we applied the results from the Part D claim-level detailed simulation to our total Part D benefit model. This model also incorporated changes to the per capita cost trends to reflect: (i) the impact of most existing brand-name drugs moving to a CPI-level increase; (ii) the expected growth in new drug costs; and (iii) the expected induced utilization due to the enriched benefit. We assumed that drugs with a significant amount of spending in Part D would temper their price increases rather than pay the inflation rebates required by the IRA. Additionally, we reduced manufacturer rebates to compensate for the lower negotiated prices and lower price growth on existing drugs.

For drugs payable under Part B, we applied the negotiated price discounts to the OM spending for separately payable Part B drugs. We further adjusted these results to account for the impact to private health plan expenditures to obtain a total impact. While there are also inflation rebates required for certain drugs payable under Part B drugs under the IRA, price increases on existing drugs payable under Part B historically have been close to the CPI in aggregate, and therefore we did not project an effect for this provision in the drugs payable under Part B. We also incorporated other, less significant changes from the IRA, such as the lower cost sharing for insulins furnished under durable medical equipment and the temporary payment increase for biosimilar products.

Our assumptions on the impacts of the IRA differed from those used in other public estimates in a few critical ways. Most importantly, we assumed that the inflation rebates required by the IRA would result in manufacturers paying relatively small inflation rebate amounts for drugs covered under Part D and nothing for drugs payable under Part B. We assumed that manufacturers would prefer to have lower price trends that would incentivize greater use than pay publicly reported fees for price increases that exceed inflation. Under this assumption, the effects of the inflation rebate provisions of the IRA are changed because the difference in price is shared across the benefit rather than accruing directly to the government. In other words, lower list price trends will reduce prices paid at the pharmacy relative to the baseline, which results in lower beneficiary cost sharing and lower state clawback payments, thereby increasing the federal cost for the Part D benefit. To compensate for the loss of price increases, we expected manufacturers to reduce rebates offered to plan sponsors.

Additionally, we expected that the initial pool of drugs covered under Part D selected for negotiation would have a large proportion of heavily rebated drugs. In these cases, we expected that the price net of rebate will be substantially lower than the other ceiling prices described in the IRA. We further estimated that the effect of negotiation in the early years would be similar to the impact of shifting rebates to the point of sale. This shift reduces beneficiary cost sharing as the price at the point of sale is lower, but increases bid amounts and increases federal expenditures.

In summary, the total effects were to reduce government expenditures for Part B, to increase expenditures for Part D through 2030, and to decrease Part D expenditures beginning in 2031. Part B savings were primarily due to: (i) the substantial lowering of payments, relative to current payment, as a result of negotiated prices; and (ii) small impacts from other provisions. Part D ultimately generated cost savings at the end of the budget window, but many of the gains from negotiated prices and lower trends were initially spent on increased benefits and the loss of manufacturer rebates. The impact on benefits and premiums and the impact in total are shown in Table 10 using the 2024 President's Budget as a basis.

TABLE K4: PART B AND PART D IRA IMPACTS (In billions)

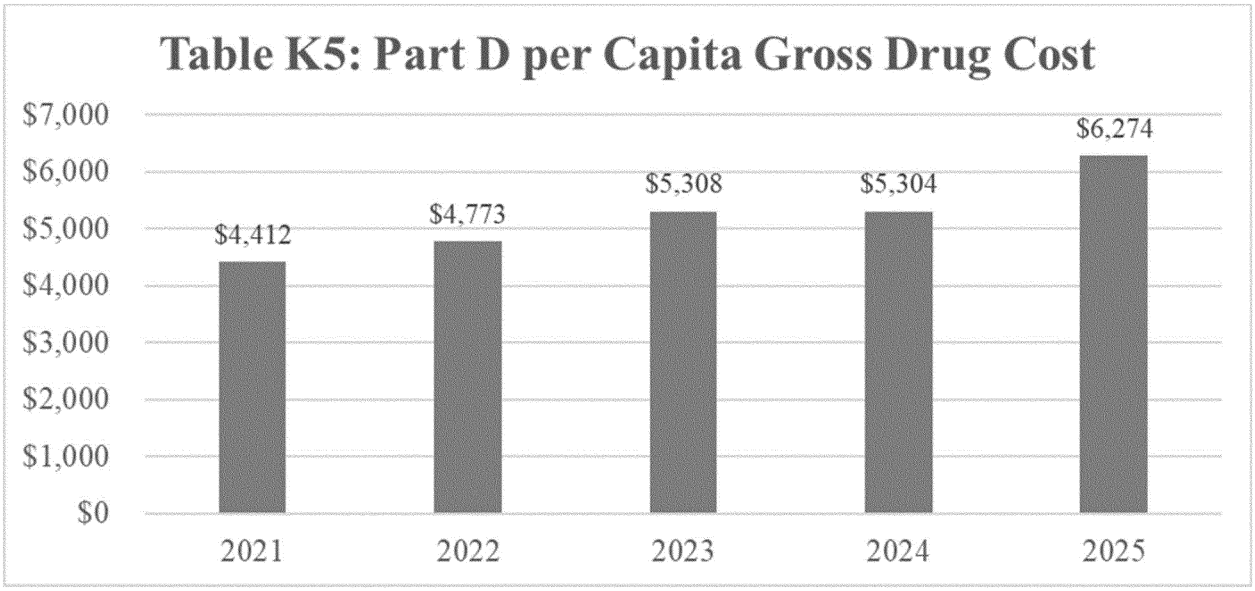
	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
Part B										
Total benefits	$0.1	$0.1	$0.1	−$0.2	−$0.3	−$5.8	−$8.4	−$14.7	−$21.4	−$28.4
Premium	0.0	0.0	0.0	−0.1	−0.1	−1.5	−2.1	−3.7	−5.3	−7.1
Total Federal impact	0.1	0.1	0.1	−0.2	−0.2	−4.4	−6.3	−11.0	−16.1	−21.3
Part D										
Total benefits	0.9	6.5	9.5	11.3	7.5	3.0	0.4	−4.5	−10.4	−12.5
Premium	0.0	−0.3	−0.6	−0.3	0.2	0.7	1.3	0.7	−0.1	−0.3
Inflation rebates	0.4	0.3	0.3	0.2	0.2	0.2	0.2	0.3	0.3	0.3
State transfer impact	0.0	−0.1	−0.4	−0.6	−1.7	−3.5	−5.1	−6.4	−7.6	−8.6
Total Federal impact[1]	0.4	6.6	10.2	11.9	8.8	5.6	3.9	1.0	−3.0	−3.9

[1]The Federal impact is calculated as the benefit impact less (i) the premium impact; (ii) the inflation rebate impact; and (iii) the State transfer impact.

Note: Totals do not necessarily equal the sums of rounded components.

Since we produced these estimates, both the Part B and Part D programs have had large increases in drug expenditures. Part D trends have accelerated dramatically, with the per capita gross drug cost increasing more than 18 percent in 2025 over 2024, driven by higher glucagon-like peptide-1 (GLP-1) and specialty drug usage. Meanwhile Part B drug trends have also increased, although the primary driver was skin substitutes that were not FDA-approved drugs. There are a variety of other causes contributing to observed changes in expenditures for both programs.

The Part D trends in per capita gross costs are shown in table 11. Much of the IRA Part D benefit redesign took effect in 2025, including limiting annual out of pocket expenditures to $2,000 per enrollee for 2025 (to be annually increased by the annual percentage increase, as described in section 1860D–2(b)(6) of the Act). While this new feature could have induced spending beyond the assumption we included in our initial estimate, it is worth noting that the 2024 benefit structure under the IRA also eliminated cost-sharing in the catastrophic phase of the benefit, effectively implementing an out-of-pocket maximum without a pronounced increase in costs. Additionally, some of the increase may be attributable to manufacturers reducing spending on patient assistance programs, which would cause more claims to run through the Part D program. Expanded indications for cancer drugs also contributed to the increase.



The observed discounts from maximum fair prices for selected drugs also differed from what we initially assumed. For initial price applicability year 2026, the projected negotiated discount impact on allowed costs—ingredient cost, dispensing fee, and sales tax—using 2025 experience data is 11.3 percent, while the projected impact for initial price applicability year 2027 is 18.2 percent. Compared with the original estimated effects shown in Table 8, the actual negotiated discounts are more than two percent greater than the original modeling results. These differences reflect the deviation in price levels, updated information about generic and biosimilar launches, and the percentage of expense the negotiated drugs represent for each year. Part B negotiated prices for initial price applicability year 2028 are not currently available, so we do not quantify the change from our original assumptions. We also had assumed that maximum fair prices for initial price applicability years 2026 and 2027 would also apply to Part B utilization. Final policies for those years contained the maximum fair prices to the Part D benefit. This change from our assumption did not meaningfully affect overall estimates, due to multiple factors including limited observed utilization of most IPAY 2026 and IPAY 2027 drugs in Part B and the timing of certain generic or biosimilar entrants.

Part D drug inflation rebates were higher than originally assumed. Converting the published inflation rebates owed from the applicable period to a calendar year basis, 2023 inflation rebates were over $500 million dollars. This is higher than the $400 million dollar estimate shown in Table 10. This implies that drug prices increased slightly faster than originally assumed, generating higher inflation rebates. As a percentage of gross drug costs, the original estimate represents 0.01 percent, while the actual amount was 0.02 percent.

For Part B, our original estimates assumed that the drug inflation rebates would be negligible. Actual Part B drug inflation rebates due for calendar years 2023 and 2024 were $14 million and $121 million, respectively. These amounts represent approximately 0.01 percent and 0.04 percent of the incurred charges for OM in 2023 and 2024. Since drug inflation rebates are not incurred on MA utilization, this is the most appropriate comparison.

Other, more nuanced elements of the IRA changes also differed from our original expectations. For example, the Manufacturer Discount Program is likely larger than we initially assumed, but the PDE reporting is not yet complete for the discount's first year. Similarly, the impacts of the IRA on Part D DIR are unknown, as Part D plan sponsors have not yet submitted the 2025 DIR reports. These elements may have larger effects on overall Part D expense than the other assumption deviations described previously.

The costs and transfers attributable to the Part D redesign are attributable to the IRA and are not a result of this rule.

We received no comments on the impacts of the Part D redesign proposals. We are finalizing those provisions without modification, as discussed in section II.A. of this final rule.

2. Effects of Part D Redesign: Specialty Tier

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

In the Contract Year 2027 proposed rule, we proposed 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 will 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.

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. This provision does not impose new requirements on Part D sponsors or change existing operational processes.

This provision codifies a conforming change made in response to the redesigned Part D benefit; thus, the impact analysis of the redesigned Part D benefit discussed in section XI.C.1. of this final rule does not relate to this provision. 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))

In the Contract Year 2027 proposed rule, we proposed to codify the methodology for determining the specialty-tier coinsurance/deductible ranges that was established in the Final CY 2025 Part D Redesign Program Instructions. This provision will 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 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.

Because this provision codifies a conforming change made in response to the redesigned Part D benefit, the impact analysis of the redesigned Part D benefit discussed in section XI.C.1. of this final rule does not relate to this provision. In the Contract Year 2022 final rule (86 FR 6078), we codified the specialty-tier maximum allowable cost-sharing methodology and concluded that the specialty-tier provisions, including those permitting 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 finalizing our update to this methodology to align with the redesigned Part D benefit will 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.

We received no comments on the impacts of this proposal and are finalizing this provision without modification.

3. Effects of the Medicare Coverage Gap Discount Program (§§ 423.100, and 423.2300 through 423.2345 (Subpart W))

In the Contract Year 2027 proposed rule, we proposed to codify the sunset of the Coverage Gap Discount Program, which was enacted under the Affordable Care Act and began on January 1, 2011. The Part D benefit redesign under section 11201 of the IRA, which eliminated the coverage gap phase of the Part D benefit, included sunsetting the Coverage Gap Discount Program on 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 benefit redesign, including sunsetting the Coverage Gap Discount Program, are attributable to the IRA, as described in greater detail in section C.1 of this Detailed Economic Analysis, and are not a result of this rule.

We received no comments on the impacts of the proposals related to the Coverage Gap Discount Program, which we are finalizing without modification.

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))

In the Contract Year 2027 proposed rule, we proposed to codify policies implementing the Manufacturer Discount Program, established under section 11201 of the IRA as part of the 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 proposed 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, as described in greater detail in section C.1. of this Detailed Economic Analysis, and are not a result of this rule.

We received no comments on the impacts of the Manufacturer Discount Program proposals. We are finalizing the policies largely as proposed, with limited modifications, which are described in greater detail in section II.C. of this final rule.

5. Effects of Third-Party Marketing Organization (TPMO) Oversight: Revising the Record Retention Requirements for Marketing and Sales Call Recordings

This provision proposed 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, which 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 to 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). As finalized, CMS is reducing the overall retention time from 10 to 6 years. Years 1 through 3 must be audio recordings, and years 4 through 6 can be either audio recordings or transcripts. This will take effect on October 1, 2026, to coincide with the beginning of the 2027 plan year marketing, as defined under §§ 422.2263(a) and 423.2263(a).

To determine the cost of the existing requirement and thus estimate the cost savings, CMS reviewed different types of storage costs. The first type is cloud storage 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 or marketed (or both) 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 with access to call recording technology at a reduced cost or otherwise factor it into agent/broker contractual arrangements. Finally, CMS noted 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 made it more difficult to establish the savings associated with this provision.

In this final rule, CMS is finalizing a requirement that agent and broker marketing and sales audio call recordings to be stored for years 1 through 3 and permits either audio call recordings or transcripts for years 4 through 6. To estimate the cost savings associated with revising the call recording retention requirement, CMS had to estimate both the cost to record and retain audio recordings as well as the cost to transcribe calls and retain the transcriptions. In estimating costs, CMS assumes MA plans and Part D sponsors will retain documentation through the use of transcripts for years 4 through 6.

CMS used the same methodology as in the Contract Year 2027 proposed rule for estimating the costs of call recordings. CMS first estimated the number of licensed and appointed agents to sell Medicare products, including MA plans and PDPs, to be 100,000.[145] CMS acknowledged 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 acknowledged that the typical cost to agents combines both the recording and the storage costs into one fee. With these challenges acknowledged, for the Contract Year 2027 proposed rule, CMS used 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.[146] [147] [148] [149] Further, CMS estimated that approximately 60 percent of the cost is attributed to the recording costs while the other 40 percent is attributed to the cost of storage ($14 is storage [35*0.4]). The Contract Year 2027 proposed rule for a 6-year audio recording retention period estimated 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 estimated that this provision would save an estimated $6.72 million per year ($67.2 [savings per agent per year] * 100,000 [agents]), or $67.2 million over a 10-year period.

To estimate the cost to capture and retain calls via a transcript, CMS reviewed the cost and processes associated with converting calls into transcripts. Converting recorded calls into transcripts range from $0.10 to $0.30 per minute for AI generated transcripts while human generated transcripts beginning at $1.25 per minute.[150] These costs were based on transcriptions being completed after the call, using the original call recording.

While reviewing the costs to transcribe calls, CMS identified other methods of recording and transcribing calls. In the current marketplace, applications are available to simultaneously record and transcribe calls. These applications vary in pricing, with the estimated cost ranging from $109 per year to $300 per year, depending on whether the agent/broker is using a ''standard'' or ''pro version''.[151] Using these updated costs, CMS is revising our final cost estimate for the final regulation.

Using the originally proposed number of agents at 100,000 and an average of the updated cost of $204.5 [109+300)/2], CMS estimates that the final regulation will save $20.5 million per year ($204.5*100,000) or $205 million over the course of 10 years. Based on the previous noted limitations, CMS specifically requested comments on these estimates and welcomed additional data that may help the Agency to further quantify the savings associated with this provision. We requested comments on our assumptions of savings, taking into account the continued requirement for the recording of a beneficiary's enrollment into a plan.

We did not receive comments on the impact of this provision in the Contract Year 2027 proposed rule. Based on CMS's updated information the provision is being finalized with the modifications identified previously.

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 proposed 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 finalized in this rule, we have estimated the impact of the measure removals on the Medicare Trust Fund in this rule. We also proposed 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 finalized changes on MA contracts using the 2025 Star Ratings data. We calculated the net impacts summarized in Table 7 due to these finalized Star Ratings updates by quantifying the difference in the MA organization's final Star Rating with the finalized changes and without the finalized changes. We assume Medicare Trust Fund impacts due to the Star Ratings changes associated with these finalized revisions to the measure set and methodology. Not moving forward with the implementation of the HEI and continuing to include the historical reward factor will be effective for the 2027 Star Ratings and will 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 will be effective also for the 2028 Star Ratings and will impact the 2029 plan payments and 2029 QBPs. The removal of the remaining measures (with the exception of the Diabetes Care—Eye Exam measure which will remain in the Star Ratings, as discussed in section V.B. of this final rule) will be effective for the 2029 Star Ratings and will impact the 2030 plan payments and 2030 QBPs.

All impacts are considered transfers, but we requested 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 final rule impact analysis. 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

[145] *https://www.sparkadvisors.com/resource/where-agents-become-pawns-the-dark-side-of-fmo-contracting-and-what-it-means-for-agents.*

[146] *https://www.claap.io/blog/chorus-pricing.*

[147] *https://www.nextiva.com/x20/lpGVDT11_i?utm_source=getvoip&utm_medium=affiliate&utm_campaign=lpgvdt&utm_term=nextiva%20plans.*

[148] *https://www.zoom.us/pricing/zoom-phone.*

[149] CMS recognizes that some of the tools do not include unlimited, 10-year storage. Storage may be an additional cost.

[150] *https://rev.outgrow.us/rev-pricing-calculator; https://www.scribbl.co/post/cost-for-transcription-services; https://www.gmrtranscription.com/prices#GenTranscription; https://www.dittotranscripts.com/blog/how-much-do-human-transcription-services-cost/#:~:text=How%20Much%20Does%20Human%20Transcription,and%20thus%20incur%20higher%20fees.*

[151] *https://www.withallo.com/blog/best-call-transcription-software-apps.*

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 final rule. We estimated the cumulative impact of the finalized changes to the Star Ratings calculations since there are interactions between the changes. We updated the estimated impacts from the Contract Year 2027 proposed rule because, as discussed in section V.B. of this final rule, we are retaining the Diabetes Care—Eye Exam measure in the Star Ratings. The impacts are shown in Table 12. For the Star Ratings updates, the net impact is estimated to be between $5.02 billion in 2028 and $1.89 billion in 2036, resulting in a 10-year net impact estimate of $18.56 billion, which equates to 0.21 percent of the Medicare payments to private health plans for the years 2027 through 2036.

TABLE 12: 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	1,360	0.18%
2031	1,340	0.16%
2032	1,430	0.16%
2033	1,620	0.17%
2034	1,780	0.17%
2035	1,800	0.16%
2036	1,890	0.16%
Total	**18,560**	**0.21%**

Comment: A couple of commenters requested that CMS update the modeling using data from the 2026 Part C and D Star Ratings, with a commenter noting that this would take into account the three new measures added to the 2026 Star Ratings. These commenters also requested that CMS clarify the measures and weights used in the modeling.

Response: The impact analysis included in the Contract Year 2027 proposed rule was based on modeling that used data from the 2025 Star Ratings but accounted for measure and measure weight changes that occurred in the 2026 Star Ratings. Based on this, CMS does not believe it is necessary to update the modeling using data from the 2026 Star Ratings. The modeling included the three measures added to the 2026 Star Ratings (Improving or Maintaining Physical Health, Improving or Maintaining Menth Health, and Kidney Health Evaluation for Patients with Diabetes) and the weight changes for the patient experience, complaints, and access measures from 4 to 2. In other words, the modeling used the measure set and measure weights from the 2026 Star Ratings. Measure changes for years beyond the 2026 Star Ratings were not included.

Comment: A commenter estimated the impact of the proposed changes and came to substantially different estimates than CMS shared in the Contract Year 2027 proposed rule. This commenter estimated the net impact would be savings of billions of dollars to the Medicare Trust Fund rather than the cost estimated by CMS.

Response: We appreciate this commenter's analysis of the impact of the proposed changes; however, this commenter would not have all necessary data available to estimate the impact of the proposed changes. For example, while contracts have data on their own performance on the reward factor and simulated HEI reward, the commenter would not have data on the HEI or the reward factor for the full set of contracts included in the Star Ratings as CMS has not made those data publicly available.

After consideration of the public comments we received, we are finalizing all of the Star Ratings provisions except the proposal to remove the Diabetes Care—Eye Exam measure (Part C).

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 final rule, we are finalizing a third exception at § 422.514(h)(3) to allow D–SNPs that serve full-benefit dually eligible individuals in a coordination-only D–SNP or HIDE 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 changes will 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 to begin disenrolling those members in 2030 as currently required under § 422.514(h).

We expect that establishing a third exception at § 422.514(h)(3) will 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) will be reduced. We note that we are also finalizing 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 this exception to have an impact on savings estimates in the April 2024 final rule. The methodologies and baseline data used in the estimates presented in Table 10 are consistent with those used in the April 2024 final rule estimates, except the Tables 10 and 11 estimates exclude certain coordination-only D–SNPs and HIDE SNPs that would be exempt under this final rule.

For our third exception at § 422.514(h)(3), as shown in Table 13, 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 13: 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 14 shows the estimated Part D costs of the 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 K8: 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

We did not receive comments on the regulatory impact analysis associated with this proposal and, therefore, are finalizing the regulatory impact analysis without modification. We respond to public comments received on other aspects of our proposal in section IV.C. of this final rule. We are finalizing the amendments to §§ 422.107(d)(1) and 422.514(h) largely as proposed, with some modifications, which are described in detail in section IV.C. of this final rule.

8. Effects of Rescinding the Mid-Year Supplemental Benefits Notice

This provision rescinds the requirement established in the April 2024 final rule (89 FR 30448) that required MA organizations to provide annual mid-year notices to enrollees regarding unused supplemental benefits. The requirement was to take effect on January 1, 2026, and required 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 were 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 will prevent the burden that would have been imposed on MA organizations. Based on updated BLS wage data, this will 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 will 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 $68,747 (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 will 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 estimated this provision will 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 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.

CMS received no comments regarding the impacts of this proposal and is finalizing this provision without modification.

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 final rule codify existing policy where we have evidence, as discussed in the appropriate preamble sections, that the codification of 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 finalized 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.

We did not receive comments on this proposal and are finalizing this provision without modification.

E. Regulatory Review Costs

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this final rule, then we should estimate the cost associated with regulatory review. We received approximately 42,632 comments specific to the provisions in this final rule, 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 final 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 final rule. For each entity that reviews the rule, the estimated cost is therefore $1,324.40 (10 hours × $132.44). Therefore, we estimate that the maximum total cost of reviewing the final rule is $56.4 million ($1,324.40 × 42,632 reviewers). However, we expect 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 $5.6 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 15, 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 15: ACCOUNTING STATEMENT -CLASSIFICATIONS OF ESTIMATED TRANSFERS AND COSTS, CONTRACT YEARS 2026-2036 (MILLIONS)

Category	3% Discount Rate	7% Discount Rate
COSTS		
Annualized monetized costs	-$21.2	-$20.7
TRANSFERS		
Annualized monetized transfers	$1,625.7	$1,541.5
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 final 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,[152] 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 1,071 businesses using this NAICS code, we believe 799 (or 74.6 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, 99.7 percent (424,395 out of 425,715) are considered small.[153]

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.[154] 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 Original 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 Original 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 or lower beneficiary cost sharing or both, 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 firms. 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, 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 7, the proposals described in this rule are expected to result in cost savings amounting to approximately $23.4 million in 2027 and $23.5 million in subsequent years. Most affected entities are expected to

[152] Medicare Advantage/Part D Contract and Enrollment Data, *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data.*

[153] US Census Bureau, 2022 SUSB Annual Data Tables by Establishment Industry, *https://www.census.gov/data/tables/2022/econ/susb/2022-susb-annual.html;* and US Census Bureau, 2022 Nonemployer Statistics Datasets, *https://www.census.gov/programs-surveys/nonemployer-statistics/data/datasets.html?text-list-d6a8ce0de1%3Atab=2022#text-list-d6a8ce0de1.*

[154] U.S. Department of Health and Human Services, Guidance on Proper Consideration of Small Entities in Rulemaking, *https://aspe.hhs.gov/sites/default/files/documents/dd6288d1b8db19ee8a1f37b3ce775003/guidance-proper-consideration-hhs-2003-rulemaking.pdf.*

have cost savings as a result of this rule. For example, we anticipate that the 697 MA organizations will experience a net cost savings. 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 $756,929 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, $2,902 for 2027, and $2,878 per year starting in 2028.

Many of the other entities affected by the provisions of this final rule are similarly expected to see cost savings, though others will see negligible cost increases. The following table outlines costs savings, the estimated number of entities affected, and aggregate costs and cost savings over the next 10 years:

TABLE K9: SUMMARY OF INITIAL AND RECURRING COSTS AND COST SAVINGS BY PROVISION FOR OTHER ENTITIES, WITH 10-YEAR AGGREGATE ESTIMATES (2027–2036)

Provision	Per Entity Impact	# of Entities Affected	Annual Aggregate Impact	10-Year Aggregate Impact (2027–2036)
Removing Account-based Medical Plans from Creditable Coverage Disclosures	-$13/yr	7,049 group health plans	-$90,000/yr (savings)	-$900,000 (savings)
Revising TPMO Call Retention Requirement	Varies	Unspecified number of TPMOs	-$20,500,000/yr (savings)	-$205,000,000 (savings)
Passive Enrollment	$16,479 for 2027, and $15,475 for 2028 and each subsequent year	11 D-SNP contracts	+$201,881/yr (costs)	+$2,018,810 (costs)

We reiterate our belief that this final 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. These cost savings are described in Table 7. Even among the D–SNPs that are expected to incur new net costs through the passive enrollment provision, D–SNPs must agree to receive enrollees through the passive enrollment process. Especially small D–SNPs that cannot incur the additional costs would opt not to participate in passive enrollment. 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.

Comment: A commenter expressed concerns about the assumptions used in the Regulatory Impact Analysis. The commenter noted that the new out-of-pocket maximum and sunsetting of the Medicare Coverage Gap Discount Program may disproportionately burden smaller plans with limited revenue to absorb increased drug costs. The commenter added that the proposed changes will impact plans differently based on size, type, and populations served, noting that certain Star Ratings changes may harm SNPs and small plans serving vulnerable populations in long-term care facilities. The commenter recommended that CMS conduct a granular analysis of how each change affects small and specialty plans, and to tailor regulations to avoid harming plans serving beneficiaries requiring institutional or institutional-equivalent care.

Response: We appreciate the commenter's concerns regarding the potential impact of this rule on small MA organizations and SNPs. However, we consider aspects of the commenter's statement to concern statutory changes and are out of scope, and on the whole we believe that the rule will not have a significant economic impact on most small entities. We reiterate that the vast majority of affected entities, including small plans, are expected to experience net cost savings as a result of this rule. Our analysis of cost estimates and time burdens are specific to each respondent type (*i.e.,* MA organization, D–SNP, Part D sponsor, group health plan, etc.) to ensure that estimated impacts reflect the burden experienced by each type of entity. Many provisions also do not have an impact on small entities as they do not produce costs or cost savings; therefore, we do not include those provisions in this analysis. In addition, MA organizations are expected to include compliance costs in their bids, ensuring small plans have necessary resources, and can address cost changes through adjusting administrative costs, modifying benefit structures, and adjusting profit margins. CMS remains committed to ensuring all Medicare enrollees, including those served by SNPs and small plans, have access to high-quality, affordable coverage, and we will continue to monitor the impact of these provisions.

We are certifying that 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 final rule constitutes our RFA analysis.

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 2026, that threshold is approximately $193 million. This final rule is not anticipated to have an unfunded effect on State, local, or Tribal governments, in the aggregate, or on the private sector of $193 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 final 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 final 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 final rule is expected to be an E.O. 14192 deregulatory action. We estimate that this rule generates $19.2 million in annualized cost savings at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

K. Conclusion

This final rule will result in net annualized cost savings ranging between $21.2 and $20.7 million for calendar years 2026 to 2036, at the 3 percent and 7 percent discount rates, respectively. These savings are primarily attributable to the provision revising aspects of TPMO oversight. This final rule will also result in net annualized monetized transfers ranging between $1.63 billion and $1.54 billion for calendar years 2026 to 2036, at the 3 percent and 7 percent 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 amends 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 (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, 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 paragraph (b)(5)(i) of this section, 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.

* * * * *

(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.

* * * * *

(g) *Elections requiring prior CMS approval*—(1) *CMS approval.* SEPs specified in paragraph (g)(2) of this section 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. Revising paragraph (f)(1)(i)(A);

■ b. Adding paragraph (f)(1)(i)(C);

■ c. Revising paragraphs (f)(1)(iii)(G) and (f)(4)(iii); and

■ d. Adding paragraph (g).

The revisions and additions read as follows:

§ 422.102 Supplemental benefits.

* * * * *

(f) * * *

(1) * * *

(i) * * *

(A) A chronically ill enrollee is an individual enrolled in the MA plan who meets all of the following:

(*1*) Has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee.

(*2*) Has a high risk of hospitalization or other adverse health outcomes.

(*3*) Requires intensive care coordination.

* * * * *

(C) An enrollee who has one or more comorbidities and medically complex chronic conditions alone is not sufficient to demonstrate that an enrollee meets all 3 criteria set forth in paragraph (f)(1)(i)(A) of this section. MA plans must, through health risk assessments, review of claims data, or other similar means, demonstrate that enrollees meet all 3 criteria set forth in paragraph (f)(1)(i)(A) of this section.

* * * * *

(iii) * * *

(G) Cannabis products that are illegal under applicable State or Federal law.

* * * * *

(4) * * *

(iii) Have objective criteria for SSBCI. Specifically:

(A) Have and apply written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI;

(B) Document the written policies specified in paragraph (f)(4)(iii)(A) of this section and the objective criteria on which the written policies are based; and

(C) For each SSBCI, list all the written policies and objective criteria on which the policies are based, as noted in paragraphs (f)(4)(i) and (f)(4)(iii)(A) of this section, on their public-facing website.

* * * * *

(g) *Administration of supplemental benefits*—(1) *General rule.* MA organizations must have processes for delivering supplemental benefits to enrollees that ensure compliance with § 422.100(c)(2) and paragraphs (a) through (f) of this section and appropriate access to all covered items and services, in accordance with § 422.112(a).

(2) *Provision of benefits through debit card.* MA organizations that administer reductions in cost sharing or provide coverage of 100 percent of the cost of a mandatory supplemental benefit through use of a debit card must do all of the following:

(i) Provide debit cards that are electronically linked to plan covered items and services through a real-time identification mechanism to verify eligibility of plan covered benefits at the point of sale.

(ii) Provide instructions for debit card use and customer service support to enrollees.

(iii) Have an alternative process that allows for reimbursement of eligible expenses for plan covered benefits in circumstances where the debit card is unusable at the point of sale, including but not limited to debit card malfunction or when a beneficiary is entitled to obtain covered benefits out-of-network.

(iv) Ensure debit cards are limited to the specific plan year.

■ 7. Section 422.107 is amended by adding paragraph (d)(1)(i) and reserved 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), where the State Medicaid agency does not mandate enrollment in Medicaid managed care for all full-benefit dually eligible individuals, and either the State Medicaid agency contract allows a dual eligible special needs plan established through this paragraph (d)(1) to enroll full-benefit dually eligible individuals or the plan is a highly integrated dual eligible special needs plan, the State Medicaid agency 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]

* * * * *

■ 8. Section 422.111 is amended by—

■ a. Revising paragraph (b)(6); and

■ b. Removing paragraph (l).

The revision reads as follows:

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(6) *Supplemental benefits.* Any mandatory supplemental benefits (including reductions in cost sharing) or optional supplemental benefits, the premium for optional supplemental benefits, and the applicable conditions and limitations associated with receipt or use of supplemental benefits. This includes both of the following:

(i) Disclosure of eligible over-the-counter items.

(ii) If providing supplemental benefits through a debit card, specifying which benefits may be accessed using the debit card.

■ 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) and (d)(6) and (7).

§ 422.152 [Amended]

■ 11. Section 422.152 is amended by removing paragraph (a)(5).

■ 12. Section 422.162 is amended by revising paragraphs (b)(3)(iv)(A)(*2*) and (b)(3)(iv)(B)(*2*) to read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

* * * * *

(b) * * *

(3) * * *

(iv) * * *

(A) * * *

(*2*) For contract consolidations approved on or after January 1, 2022, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score. If a measure score for a consumed or surviving contract is missing due to not having enough data to meet the measure technical specification or the reliability is less than 0.6 for a CAHPS measure, CMS treats this measure score as missing in the calculation of the enrollment-weighted measure score.

(B) * * *

(*2*) For contract consolidations approved on or after January 1, 2022, for all measures except HEDIS, CAHPS, and HOS, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score. For all measures except HEDIS, CAHPS, HOS, and call center measures, if a measure score for a consumed or surviving contract is missing due to not having enough data to meet the measure technical specification, CMS treats this measure score as missing in the calculation of the enrollment-weighted measure score.

* * * * *

■ 13. 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.

* * * * *

■ 14. 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).

The revision reads 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]

■ 15. Section 422.308 is amended in paragraph (c)(1) by removing the word ''gender'' and adding in its place the word ''sex''.

■ 16. 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.

* * * * *

■ 17. 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 paragraph (a)(4)(xvii) of this section.

(c) * * *

(2) * * *

(iv) The contract is being terminated based on paragraph (a)(4)(xvii) of this section.

* * * * *

■ 18. Section 422.514 is amended by adding paragraphs (h)(3)(iii) and (iv) to read as follows:

§ 422.514 Enrollment requirements.

* * * * *

(h) * * *

(3) * * *

(iii) If an MA organization subject to paragraph (h)(1) of this section holds a State Medicaid agency contract with a State that does not mandate enrollment in Medicaid managed care for all full-benefit dually eligible individuals and the State Medicaid agency contract allows, 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 dually eligible individuals who are enrolled in Medicaid fee-for-service. These D–SNPs may not enroll full-benefit dually eligible individuals who are 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.

(iv) 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]

■ 19. Section 422.752 is amended by removing and reserving paragraph (d).

■ 20. 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 may not submit materials for the contract under the organization's Multi-Contract Entity number and third-party marketing organizations may not submit materials under the Multi-Plan number as described in § 422.2262(d)(2)(i).

* * * * *

§ 422.2262 [Amended]

■ 21. Section 422.2262 is amended by removing paragraphs (a)(1)(i) and (ii) and redesignating paragraphs (a)(1)(iii) through (xix) as paragraphs (a)(1)(i) through (xvii), respectively.

■ 22. 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.

* * * * *

■ 23. Section 422.2267 is amended by—

■ a. Revising paragraphs (e)(5)(ii)(B)(1);

■ c. Removing and reserving paragraph (e)(31);

■ d. Revising paragraph (e)(41) introductory text and paragraph (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.

* * * * *

(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.

* * * * *

■ 24. 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) All marketing and sales calls, including the audio portion of calls conducted via web-based technology, must be recorded and retained in their entirety for a minimum period of 6 years. For the first 3 years of the retention period, records must be maintained in audio format. For years 4, 5, and 6, records may be maintained in either audio format or as complete and accurate transcript recordings.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 25. The authority for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 26. 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.

* * * * *

■ 27. 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.

* * * * *

■ 28. 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 paragraph (k)(2) of this section 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).

■ 29. 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 paragraph (g)(2) of this section 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).

* * * * *

■ 30. Section 423.38 is amended by revising paragraphs (c)(2), (c)(8) introductory text, (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.

* * * * *

■ 31. 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 or of any selected drug subsidy under section 1860D–14D 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 § 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.

* * * * *

■ 32. 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—

(i) Covered Part D drugs that are not paid for under the Part D plan as a result of application of any annual deductible or other cost-sharing rules for covered Part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under § 423.104(d)(5)(iii), including any price differential for which the Part D enrollee is responsible under § 423.124(b); or

(ii) 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 in § 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; and

(2) That are paid for—

(i) By the Part D enrollee or on behalf of the Part D enrollee by another person, and the Part D enrollee (or person paying on behalf of the Part D enrollee) is not reimbursed through insurance or otherwise, a group health plan, or other third party payment arrangement, or the person paying on behalf of the Part D enrollee is not paying under insurance or otherwise, a group health plan, or third party payment arrangement;

(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

(iii) Under § 423.782.

(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.

* * * * *

■ 33. Section 423.104 is amended by—

■ a. Revising paragraphs (d)(1) introductory text, (d)(2) heading, (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), and (d)(5)(iv);

■ h. Revising paragraphs (e)(5) introductory text, (e)(5)(i), and (f)(1)(ii)(B)(*3*); and

■ i. 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) *Limit on specialty-tier cost threshold adjustment.* (*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.

Equation 1 to Paragraph (d)(2)(iv)(D)(*3*)(*ii*)

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

(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 (d)(3) 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 (d)(5)(i)(A) 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 (d)(5)(iii) 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 (d)(5)(iii) 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 paragraph (d)(5)(iv)(C) of this section) and a multiplicative update (as defined in paragraph (d)(5)(iv)(D) of this section).

(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 2 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.

■ 34. 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).

* * * * *

■ 35. Section 423.182 is amended by revising paragraphs (b)(3)(ii)(A)(*2*) and (b)(3)(ii)(B)(*2*) to read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

* * * * *

(b) * * *

(3) * * *

(ii) * * *

(A) * * *

(*2*) For contract consolidations approved on or after January 1, 2022, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 423.184(g)(1)(i), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score. If a measure

score for a consumed or surviving contract is missing due to not having enough data to meet the measure technical specification or the reliability is less than 0.6 for a CAHPS measure, CMS treats this measure score as missing in the calculation of the enrollment-weighted measure score.

(B) * * *

(*2*) For contract consolidations approved on or after January 1, 2022, for all measures except CAHPS, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 423.184(g)(1)(i), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score. For all measures except CAHPS and call center measures, if a measure score for a consumed or surviving contract is missing due to not having enough data to meet the measure technical specification, CMS treats this measure score as missing in the calculation of the enrollment-weighted measure score.

* * * * *

■ 36. 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]

■ 37. 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).

The revision reads 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.

* * * * *

■ 38. 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.

* * * * *

■ 39. 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 (b) 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) of this section.

* * * * *

■ 40. 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)'' in alphabetical order.

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) paid by manufacturers under the Manufacturer Discount Program (as defined at § 423.100). 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.

* * * * *

■ 41. 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).

■ 42. Section 423.325 is amended by revising paragraph (a)(3) to read as follows:

§ 423.325 PDE submission timeliness requirements.

(a) * * *

(3) A PDE record for a paid claim transaction associated with a PDE record that was previously rejected by CMS 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 that was rejected is otherwise found to have been submitted in error.

* * * * *

■ 43. Section 423.329 is amended by revising paragraph (c)(1) and adding paragraph (e) to read as follows:

§ 423.329 Determination of payments.

* * * * *

(c) * * *

(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) and negotiated and approved under § 423.272 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).

■ 44. 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.

* * * * *

■ 45. 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 remainder 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.

■ 46. 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)—

* * * * *

■ 47. 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.

* * * * *

■ 48. Section 423.464 is amended by revising paragraph (f)(2)(i)(C) to read as follows:

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

* * * * *

(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.

* * * * *

■ 49. 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.

■ 50. 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 revisions and 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 for the Coverage Gap Discount Program and the requirements in subpart AA of part for the Manufacturer Discount Program.

* * * * *

(d) * * *

(1) * * *

(vi) Enable CMS to review original format documentation or information utilized from all written, electronic, and verbal communications between the plan sponsor and 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 sufficient documentation to support Part D coverage 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 plan sponsor and 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) of this section. This includes:

(A) Date and time the request for a coverage determination or point-of-sale claim adjudication was received and, when available, the identity of the individual or entity who submitted the request.

(B) Name and title, as applicable if additional outreach is made, of the individual the Part D plan contacted to obtain the information needed to complete 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 for a coverage determination or point-of-sale claim adjudication when used to determine Part D coverage for 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.

* * * * *

■ 51. 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

■ e. Adding paragraph (d).

The revisions and 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).

■ 52. Section 423.882 is amended by revising the definition of ''Allowable retiree costs'' and ''Gross covered retiree pan-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) paid by manufacturers under the Manufacturer Discount Program (as defined by § 423.100).

* * * * *

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).

* * * * *

§ 423.884 [Amended]

■ 53. 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) introductory text, (d)(1)(i) and (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.''

■ 54. 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.

■ 55. Section 423.1002 is amended by revising the definition of ''Affected party'' to read 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.

* * * * *

■ 56. 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 may not submit materials for the contract under the organization's Multi-Contract Entity number and third-party marketing organizations may not submit materials under the Multi-Plan number as described in § 423.2262(d)(2)(i).

* * * * *

§ 423.2262 [Amended]

■ 57. Section 423.2262 is amended by removing paragraphs (a)(1)(i) and (ii) and redesignating paragraphs (a)(1)(iii) through (xviii) as paragraphs (a)(1)(i) through (xvi), respectively.

■ 58. 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.

* * * * *

■ 59. 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.

* * * * *

(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.

* * * * *

■ 60. 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) All marketing and sales calls, including the audio portion of calls conducted via web-based technology, must be recorded and retained in their entirety for a minimum period of 6 years. For the first 3 years of the retention period, records must be maintained in audio format. For years 4, 5, and 6, records may be maintained in either audio format or as complete and accurate transcript recordings.

■ 61. Revise and republish § 423.2300 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.

(6) Resolution of beneficiary disputes involving coverage gap discounts.

(7) 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.

■ 62. Section 423.2305 is amended by—

■ a. Revising and republishing the introductory text and the definition of ''Applicable discount'';

■ c. 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''; and ''National Drug Code'';

■ d. Revising and republishing the definition of ''Negotiated price''; and

■ e. Removing the definition of ''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—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;

(i) Includes all price concessions (as defined in § 423.100) from network pharmacies or other network providers; and

(ii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices;

(2) Is reduced by those discounts, direct or indirect subsidies, rebates, non-pharmacy price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale; and

(3) Excludes any dispensing fee or vaccine administration fee for the applicable drug.

(4) In connection with applicable drugs dispensed by an out-of-network provider in accordance with the applicable beneficiary's Part D plan out-of-network policies, the negotiated price means the plan allowance as set forth in § 423.124, less any dispensing fee or vaccine administration fee.

§ 423.2310 [Amended]

■ 63. 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''.

■ 64. 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]

■ 65. 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]

■ 66. 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]

■ 67. 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]

■ 68. 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''.

■ 69. Section 423.2345 is amended by—

■ a. Revising the section heading;

■ 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), 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), all Coverage Gap Discount Program Agreements under this subpart are terminated as of January 1, 2025.

■ 70. 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.

* * * * *

■ 71. 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).

■ 71. 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

* * * * *

■ 72. 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.

■ 73. 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.

* * * * *

■ 74. 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.

* * * * *

■ 75. 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''; and

■ 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.

■ 76. Add subpart AA to read as follows:

Subpart AA—Medicare Part D Manufacturer Discount Program

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)(3)(i)(A) of this section that map to NDCs associated with single source drugs or biological products;

(C) Identify all mapped HCPCS codes identified in paragraph (a)(3)(i)(B) of this section 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 (a)(3)(i)(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 (a)(3)(i)(D) of this section 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) *Part D total expenditures for a specific drug for 2021 and small manufacturer phase-in eligibility.* 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.

(2) [Reserved]

(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 must include supporting documentation.

(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 this part.

§ 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 do all of the following:

(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) of this section 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) of this section 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) of this section.

(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 under this paragraph (c)(1)(v)(A)(*2*) 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) of this section 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 (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 (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) *Transfer of labeler codes.* 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 calendar 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 at a location specified by the TPA and, with the exception of work papers, audit data cannot be removed from such specified location.

(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 subpart T of this part, the civil money penalty is due, as applicable, once the administrative process 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 subpart T of this part, 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 this part.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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