DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 460

[CMS–4208–F]

RIN 0938–AV40

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

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

ACTION: Final rule.

SUMMARY: This final rule revises the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), Medicare cost plan, and Programs of All-Inclusive Care for the Elderly (PACE) regulations to implement changes related to prescription drug coverage, the Medicare Prescription Payment Plan, dual eligible special needs plans (D–SNPs), Part C and D Star Ratings, and other programmatic areas, including the Medicare Drug Price Negotiation Program. This final rule also codifies existing sub-regulatory guidance in the Part C and Part D programs.

DATES:

Effective date: These regulations are effective June 3, 2025.

Applicability dates: The provisions in this rule are applicable to coverage beginning January 1, 2026, except as otherwise noted. The updates to marketing and communication provisions at §§ 422.2267(e)(30) and 423.2267(e)(32) for integrated member ID cards are applicable for all contract year (CY) 2027 marketing and communications beginning October 1, 2026. The requirements related to eligibility and election, targeted outreach, and general outreach regarding participation in the Medicare Prescription Payment Plan for 2026 at §§ 423.2267(e)(45) through (51), 423.2265(b)(16), and 423.137(d), (e), and (m) are applicable beginning October 1, 2025. The health risk assessment (HRA) provision that we are finalizing at § 422.101(f)(1)(v) is applicable beginning October 1, 2026, for HRAs conducted for effective dates of enrollment on or after January 1, 2027. The addition of the updated Part C Breast Cancer Screening measure as described in section III.E. of the final rule is applicable for 2029 Star Ratings beginning January 1, 2027.

FOR FURTHER INFORMATION CONTACT:

Lucia Patrone, (410) 786–8621—General Questions.

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

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

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

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

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

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

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

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

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose

The primary purpose of this final rule is to amend the regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE). This final rule includes a number of new policies that will improve these programs for contract year 2026, as well as codify existing Part C and Part D sub-regulatory guidance.

In this final rule, CMS codifies certain Part D requirements from the Inflation Reduction Act of 2022 (IRA). Specifically, this rule codifies the IRA's vaccine and insulin cost-sharing requirements and codifies the program instruction for the Medicare Prescription Payment Plan program. Additionally, CMS is finalizing two IRA-related provisions that are needed to help ensure that selected drugs with maximum fair prices (MFPs) in effect under the Negotiation Program are available to beneficiaries at the point of dispensing and that the MFPs are effectuated for dispensing entities timely.

B. Summary of the Major Provisions

1. Vaccine Cost-Sharing Changes

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

2. Insulin Cost-Sharing Changes

We are finalizing as proposed this provision to implement section 11406 of the IRA, which amends section 1860D–2 of the Act to require that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to covered insulin products, and the Part D cost-sharing amount for a one-month supply of each covered insulin product must not exceed the statutorily defined ''applicable copayment amount'' for all enrollees. The applicable copayment amount for 2023, 2024, and 2025 is $35. For 2026 and each subsequent year, in accordance with the statute, we are finalizing that, with respect to a covered insulin product covered under a prescription drug plan (PDP) or a Medicare Advantage prescription drug (MA–PD) plan prior to an enrollee reaching the annual out-of-pocket threshold, the ''covered insulin product applicable cost-sharing amount'' is the lesser of—

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

3. Medicare Prescription Payment Plan

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

Limited Income Newly Eligible Transition (LI NET) program at § 423.2536. We also proposed to codify the requirements we established in the Final CY 2025 Part D Redesign Program Instructions for the treatment for Medical Loss Ratio (MLR) purposes of Medicare Prescription Payment Plan unsettled balances for 2026 and subsequent years.

We are finalizing all requirements for 2026 and future years as proposed with a few exceptions:

- Modified the timing and content requirements for the renewal notice at § 423.137(d)(10)(iv).
- Modified the requirements for the telephonic notice of election approval at § 423.137(d)(10)(ii).
- Modified the requirements for voluntary termination effective date at § 423.137(f)(2)(i)(A)(*1*).
- Modified timing requirements for the involuntary termination notice at § 423.137(f)(2)(ii)(D)(*1*).
- Modified § 423.137(i)(2) to state that Part D plan sponsors should require long-term care pharmacies to provide the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to the Part D enrollee (or their authorized representative) at the time of the pharmacy's typical enrollee cost-sharing billing process.
- Modified § 423.137(m)(1) to exempt dual eligible special needs plans (D–SNPs) from certain general outreach and education requirements.
- Modified § 423.137(j)(7) to remove the requirements for Part D sponsors to ensure that pharmacies are prepared to provide information regarding out-of-pocket (OOP) costs for the Medicare Prescription Payment Plan to a participant at the point of sale (POS).

4. Improving Experiences for Dually Eligible Enrollees

Dually eligible individuals face fragmentation in many parts of the health care system, including their experiences as enrollees of Medicare and Medicaid managed care plans. One way in which we seek to address such fragmentation is 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. We are finalizing new Federal requirements for D–SNPs that are applicable integrated plans to: (1) have integrated member identification (ID) cards that serve as the ID cards for both the Medicare and Medicaid plans in which an enrollee is enrolled; and (2) conduct an integrated health risk assessment (HRA) for Medicare and Medicaid, rather than separate HRAs for each program. We are also finalizing provisions to codify timeframes for special needs plans to conduct HRAs and individualized care plans (ICPs) and prioritize the involvement of the enrollee or the enrollee's representative, as applicable, in the development of the ICPs.

5. Timely Submission Requirements for Prescription Drug Event (PDE) Records

We are finalizing as proposed PDE submission timeframes similar to those timeframes described in the October 2011 guidance on the timely submission of PDE records and refer to those timeframes as the General PDE Submission Timeliness Requirements. CMS is codifying PDE submission timeframes that initial PDE records are due within 30 calendar days following the date the claim is received by the Part D sponsor (or its contracted first tier, downstream, or related entity). Adjustment and deletion PDE records are due within 90 calendar days following discovery of the issue requiring a change to the PDE. Resolution of rejected PDE records are due within 90 calendar days following the receipt of rejected record status from CMS. In addition, we are finalizing as proposed regulatory changes at § 423.325(b) to establish a distinct PDE submission timeliness requirement for selected drugs, in which CMS requires that a Part D sponsor must submit initial PDE records for selected drugs (as described at section 1192(c) of the Act) within 7 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim.

6. Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements

We are finalizing as proposed our proposal to amend § 423.505 by adding paragraph (q), requiring that Part D sponsors' network participation agreements with contracting pharmacies, including any contracts with any first tier, downstream, and related entities require such pharmacies to be enrolled in the Medicare Drug Price Negotiation Program's (''Negotiation Program'') Medicare Transaction Facilitator Data Module (''MTF DM'') and that such pharmacies certify the accuracy and completeness of their enrollment information in the MTF DM. We believe the inclusion of the requirement for Part D sponsors' network pharmacies to be enrolled in the MTF DM that will be added to Part D sponsors' network contracts with pharmacies will facilitate continued beneficiary access to selected drugs that are covered Part D drugs, promote access to negotiated MFPs under the Negotiation Program for both beneficiaries and dispensing entities, and help ensure accurate Part D claims information and payment.

7. Clarifying MA Organization Determinations To Enhance Enrollee Protections in Inpatient Settings

We are finalizing our proposal to clarify that the definition of ''organization determination'' includes MA plan decisions made concurrent to the enrollee's receipt of services. We are also finalizing our proposals to codify existing guidance that requires plans give a provider notice of a coverage decision, in addition to the enrollee, whenever the provider submits a request on behalf of an enrollee, as well as our proposal to modify existing regulations to clarify that an enrollee's liability to pay for services cannot be determined until an MA organization has made a claims payment determination. Lastly, we are finalizing our proposal to restrict plans' ability to use information gathered after the inpatient admission has taken place when reviewing the appropriateness of the admission itself.

8. Risk Adjustment Data Updates

We are finalizing a series of provisions related to risk adjustment data updates. First, we are finalizing a technical change to the definition of Hierarchical Condition Categories (HCCs) to remove the reference to a specific version of the ICD, while maintaining a reference to the ICD in general, to keep the HCC definition in § 422.2 current as newer versions of the ICD become available and are adopted by the Secretary, as well as substituting the terms ''disease codes'' with ''diagnosis codes'' and ''disease groupings'' with ''diagnosis groupings'' to be consistent with ICD terminology. Additionally, we are codifying the longstanding practice of requiring the collection and mandatory submission of risk adjustment data by PACE organizations (at § 460.180(b)) and Cost plans (at § 417.486(a)).

C. Summary of Costs and Benefits

TABLE 1—SUMMARY OF COSTS AND BENEFITS

Provision	Description	Financial impact
1. Vaccine Cost-Sharing Changes.	We are codifying section 11401 of the IRA to require that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to, and there is no cost sharing for an adult vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) covered under Part D.	We do not expect these regulatory changes to have an impact on the Medicare Trust Funds.
2. Insulin Cost-Sharing Changes.	We are codifying section 11406 of the IRA to require that the Medicare Part D deductible shall not apply to covered insulin products, and the Part D cost-sharing amount for a one-month supply of each covered insulin product must not exceed the ''covered insulin product applicable cost-sharing amount.''	We estimate that this provision will increase Federal transfers from the Medicare Supplementary Medical Insurance Trust Fund by approximately $1.2 billion from 2026–2035.
3. Medicare Prescription Payment Plan.	We proposed to codify, with limited modifications, agency guidance implementing section 11202 of the IRA, which establishes the Medicare Prescription Payment Plan and requires Part D sponsors to provide all Part D enrollees the option to pay their out-of-pocket (OOP) prescription drug costs in monthly amounts over the course of the plan year, instead of paying OOP costs at the point of sale (POS). We are finalizing all requirements for 2026 and future years as proposed with a few exceptions: • Modified the timing and content requirements for the renewal notice at § 423.137(d)(10). • Modified the requirements for the telephonic notice of election approval at § 423.137(d)(10)(ii). • Modified the requirements for voluntary termination effective date at § 423.137(f)(2)(i)(A)(*1*). • Modified timing requirements for the involuntary termination notice at § 423.137(f)(2)(ii)(D)(*1*). • Modified § 423.137(i)(2) to state that Part D plan sponsors should require long-term care pharmacies to provide the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to the Part D enrollee (or their authorized representative) at the time of the pharmacy's typical enrollee cost-sharing billing process. • Modified § 423.137(m)(1) to exempt dual eligible special needs plans (D–SNPs) from certain general outreach and education requirements. • Modified § 423.137(j)(7) to remove the requirements for Part D sponsors to ensure that pharmacies are prepared to provide information regarding OOP costs for the Medicare Prescription Payment Plan to a participant at the POS.	We do not expect these regulatory changes to have an impact on the Medicare Trust Funds.
4. Improving Experiences for Dually Eligible Enrollees.	We are finalizing new Federal requirements for D–SNPs that are applicable integrated plans (AIPs) to—(1) have integrated member ID cards that serve as the ID cards for both the Medicare and Medicaid plans in which an enrollee is enrolled; and (2) conduct an integrated HRA for Medicare and Medicaid, rather than separate HRAs for each program. We are also finalizing provisions to codify timeframes for special needs plans to conduct HRAs and ICPs and prioritize the involvement of the enrollee or the enrollee's representative, as applicable, in the development of the ICPs.	The integrated HRA provisions may cause a small number of AIPs to incur some upfront costs to make administrative updates. We do not expect the provisions regarding integrated member ID cards and ICPs to have any financial impact.
5. Timely Submission Requirements for Prescription Drug Event (PDE) Records.	We are codifying at § 423.325 PDE submission timeliness requirements. Specifically, CMS is codifying timeframes at § 423.325(a) to require that—(1) initial PDE records be submitted within 30 calendar days following the date the claim is received by the Part D sponsor (or its contracted first tier, downstream, or related entity); (2) adjustment and deletion PDE records are due within 90 calendar days following discovery of the issue requiring a change to the PDE; and (3) resolution of rejected PDE records are due within 90 calendar days following the receipt of rejected record status from CMS. In addition, we are finalizing regulatory changes at § 423.325(b) to establish a distinct PDE submission timeliness requirement for selected drugs, in which CMS requires that a Part D sponsor must submit initial PDE records for selected drugs (as described at section 1192(c) of the Act) within 7 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim.	We do not expect these regulatory changes to have an impact on the Medicare Trust Funds.
6. Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements.	We are codifying at § 423.505(q) a requirement on Part D sponsors (or first tier, downstream, or related entities, such as PBMs, acting on the sponsors' behalf) to include in their network pharmacy agreements a provision that requires such pharmacies to be enrolled in the MTF DM (or any successor to the MTF DM) and to certify to CMS that the enrollment information provided by such pharmacies in the MTF DM is accurate, complete, and up to date.	We do not expect these regulatory changes to have an impact on the Medicare Trust Funds.
7. Clarifying MA Organization Determinations to Enhance Enrollee Protections in Inpatient Settings.	We are finalizing changes to clarify the definition of organization determination, codify requirements related to delivery of notices to providers, clarify that an enrollee's liability to pay for services cannot be determined until an MA organization has made a claims payment determination, and restrict plans' ability to use information gathered after the inpatient admission has taken place when reviewing the appropriateness of the admission itself.	We anticipate that these changes could decrease the number of inpatient downgrades which could, in turn, create a non-quantified cost to MA organizations that could be passed on to the Medicare Hospital Insurance Trust Fund.
8. Risk Adjustment Updates ...	We are finalizing a technical change to the definition of Hierarchical Condition Categories (HCCs) to remove the reference to a specific version of the ICD, while maintaining a reference to the ICD in general. Additionally, we are codifying the longstanding practice of requiring the collection and mandatory submission of risk adjustment data by PACE organizations (at § 460.180(b)) and Cost plans (at § 417.486(a)).	We do not expect these regulatory changes to have an impact on the Medicare Trust Funds.

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

The proposed rule titled ''Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' appeared in the December 10, 2024 **Federal Register** (89 FR 99340) (hereinafter referred to as the ''Contract Year 2026 proposed rule'').

In response to the Contract Year 2026 proposed rule, we received approximately 31,227 timely pieces of correspondence containing multiple comments on the proposed rule. We note that some of the public comments were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed in this final 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 are finalizing several of the provisions from the proposed rule, some with minor clarifications based on comments received. In this final rule, we are not summarizing or responding to comments received with respect to the provisions of the proposed rule that we are not addressing or finalizing at this time. Rather, as appropriate, and if applicable, we will address those comments at a later time in a subsequent rulemaking document.

With respect to the section of the proposed rule entitled ''Formulary Inclusion and Placement of Generics and Biosimilars,'' CMS continues to encourage Part D sponsors to prioritize formulary placement for generics and biosimilars through favorable tier placement relative to branded and reference products. As we noted in the proposed rule, CMS currently conducts an extensive formulary review process to ensure Part D sponsors provide an adequate formulary consistent with § 423.120(b)(2). In addition, as also noted in the proposed rule, we have been monitoring beneficiary access to generics and biosimilars, utilization of multi-source brand drugs when generics are available, and situations where the brand drug is situated more favorably in comparison to the generic with regard to tiering and UM, and we will continue to do so. While we are not adding the additional step in our formulary review process described in the proposed rule, the policy reminders and clarifications with respect to Part D plan formularies providing broad access to generics and biosimilars as part of a cost-effective drug utilization program still apply. CMS may consider codifying additional requirements regarding formularies in future rulemaking if necessary.

CMS will continue to review regulations and policies in the Medicare program and make necessary and appropriate changes to ensure consistency with the Executive Order 14192, ''Unleashing Prosperity Through Deregulation.. Such regulations and policies currently under review include but are not limited to—

- Health Equity Index Reward for the Parts C and D Star Ratings;
- Annual health equity analysis of utilization management policies and procedures;
- Requirements for MA plans to provide culturally and linguistically appropriate services; and
- Quality improvement and health risk assessments (HRAs) focused on equity and social determinants of health (SDOH).

We also do not intend to finalize the following provisions from the proposed rule: Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures, Part D Coverage of Anti-Obesity Medications (AOMs) and Application to the Medicaid Program, and Ensuring Equitable Access to Medicare Advantage Services—Guardrails for Artificial Intelligence (AI). CMS, however, does want to acknowledge the broad interest in regulation of AI 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 finalizing 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 IRA Provisions for the Medicare Prescription Drug Benefit Program

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

1. Background

Section 11401 of the Inflation Reduction Act of 2022 (IRA) amended section 1860D–2 of the Act by adding new paragraph (8) to subsection (b) and new paragraph (5) to subsection (c) and making other conforming amendments to require that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to, and there is no cost sharing for, an adult vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) covered under Part D. Section 11401(e) of the IRA directed the Secretary to implement section 11401 of the IRA for 2023, 2024, and 2025 by program instruction or other forms of program guidance. In accordance with the law, CMS issued memoranda via the Health Plan Management System (HPMS) that outlined requirements for Part D sponsors regarding the implementation of section 11401.

On September 26, 2022, CMS released an HPMS memorandum titled ''Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin.'' [1] In this memorandum, we provided guidance that for any new ACIP-recommended adult vaccine that becomes available during a plan year, Part D sponsors must apply the $0 cost-sharing requirements in section 1860D–2(b)(8) of the Act to applicable claims with dates of service after ACIP's issued recommendation.

On April 4, 2023, CMS issued an HPMS memorandum titled ''Final Contract Year (CY) 2024 Part D Bidding Instructions'' which explained that, in order for a vaccine to be considered ACIP-recommended for adult use, it must be both adopted by the Director of the Centers for Disease Control and Prevention (CDC) and published in the CDC's Morbidity and Mortality Weekly Report (MMWR).[2]

On July 24, 2023, CMS issued a revision to the April 4, 2023 memorandum, which clarified that the effective date of the $0 cost-sharing requirement for an ACIP-recommended

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

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

adult vaccine must be aligned with the date on which the CDC Director adopts the respective ACIP vaccine recommendation, as posted on the CDC's website, not the date on which the recommendation is published in the MMWR.[3]

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

We received the following comments on this section of the proposed rule, and our responses follow:

Comment: Many commenters supported CMS' proposal to codify the statutory $0 cost-sharing requirement for ACIP-recommended adult vaccines that was added to section 1860D–2 of the Act by section 11401 of the Inflation Reduction Act.

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

2. Definition of ACIP-Recommended Adult Vaccine

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

Consistent with the September 26, 2022 HPMS memorandum, we proposed to define an ''ACIP-recommended adult vaccine'' as a vaccine licensed by the FDA for use in adults and administered in accordance with ACIP recommendations. In alignment with the September 26, 2022 HPMS memorandum, we interpreted the term ''recommendation'' to refer to a recommendation under any one of ACIP's categories of recommendations, including routine, catch-up, risk-based, and shared clinical decision-making immunization recommendations.

Some vaccines that are not on the ACIP Adult Immunization Schedule for routine immunization are included on the ACIP Vaccine Recommendations and Guidelines web page.[4] This web page describes ACIP recommendations for vaccines that are used in limited populations and under limited circumstances. For example, ACIP recommends certain vaccinations for travelers prior to visiting certain countries. Therefore, consistent with the September 26, 2022 HPMS memorandum, as long as the vaccine is an FDA-licensed vaccine that is recommended by ACIP for use by adults, such vaccine would meet our proposed definition of an ACIP-recommended adult vaccine, when provided in accordance with ACIP recommendations.

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

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

We received the following comments on this section of the proposed rule, and our responses follow:

Comment: A few commenters requested that we release a HPMS memorandum that includes a list of ACIP-recommended adult vaccines and the dates on which these vaccines should be covered with no cost sharing.

Response: The most updated information regarding ACIP-recommended adult vaccines and the effective date of ACIP recommendations is available on the Centers for Disease Control and Prevention's (CDC's) website at: *https://www.cdc.gov/acip-recs/hcp/vaccine-specific/*. Given that the CDC's website is the best source for this information, we decline to accept the commenters' recommendation to issue separate guidance.

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

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

We also proposed at § 423.120(g)(3) that enrollees who submit direct member reimbursement (DMR) requests for ACIP-recommended adult vaccines accessed at either out-of-network pharmacies or providers (in accordance with § 423.124(a) and (c)), or at in-network pharmacies or providers, that a Part D sponsor determines are coverable under their benefit must not be subject to cost sharing. While Part D sponsors generally may charge the enrollee for the difference between the cash price and plan allowance for DMRs for covered Part D drugs accessed from both out-of-network and in-network pharmacies, neither § 423.124(b) nor Chapter 14 of the Prescription Drug Benefit Manual directly addresses covered Part D drugs that have statutorily limited cost sharing.[5]

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

[4] *https://www.cdc.gov/acip-recs/hcp/vaccine-specific/index.html.*

[5] Section 423.124(b) currently states that a Part D sponsor that provides its Part D enrollees with coverage other than defined standard coverage may require its Part D enrollees accessing covered Part D drugs at out-of-network pharmacies to assume financial responsibility for any differential between the out-of-network pharmacy's (or provider's) usual and customary price and the Part D sponsor's plan allowance. Section 50.4.3 of Chapter 14 of the Medicare Prescription Drug Benefit Manual (*https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/chapter-14-coordination-of-benefits-v09-17-2018.pdf*) provides detailed guidance on how Part D sponsors must process DMR requests that are submitted by enrollees who paid cash at an out-of-network (or an in-network) pharmacy (or provider)

Because there can be no cost sharing for ACIP-recommended adult vaccines accessed at either out-of-network pharmacies or providers (in accordance with § 423.124(a) and (c)), or at in-network pharmacies or providers, that a Part D sponsor determines are coverable under their benefit, the Part D sponsor must reimburse the enrollee for the full cash price paid to the pharmacy or provider for an ACIP-recommended adult vaccine.

The total gross covered drug cost (TGCDC) is usually reported differently on PDEs depending on whether the drug was accessed at an out-of-network or in-network pharmacy or provider. Specifically, Part D sponsors report the cash price that the enrollee paid to the pharmacy or provider as the TGCDC for out-of-network DMRs but only report the negotiated price as the TGCDC for in-network DMRs. However, we clarified in the proposed rule that with respect to ACIP-recommended adult vaccines, as an exception to the Chapter 14 guidance, the sponsor should report the cash price paid to the pharmacy or provider as the TGCDC on the PDE for both out-of-network and in-network DMRs. Regardless, there is no true out-of-pocket (TrOOP) cost accumulation for these claims because the beneficiary has no cost sharing for ACIP-recommended adult vaccines under the basic Part D benefit.

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

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

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

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

We received the following comments on this section of the proposed rule, and our responses follow:

Comment: Several commenters provided feedback related to the implementation of utilization management strategies for vaccines. A few of these commenters opposed the use of utilization management strategies to determine whether an enrollee meets the age or clinical requirements recommended by ACIP for a particular vaccine. These commenters stated that utilization management can limit or delay beneficiaries' access to vaccines. A commenter urged CMS to ensure that all commercially available Part D vaccines are included on Part D formularies and that utilization management for vaccines is used appropriately. Another commenter urged CMS to issue guidance to ensure Part D plans are providing coverage and access to ACIP-recommended vaccines and are not imposing restrictive utilization management strategies. Finally, other commenters requested that CMS ensure Part D sponsors are not implementing utilization management strategies that prevent a provider or pharmacy from stocking or administering vaccines.

Response: We appreciate these commenters sharing their concerns related to utilization management strategies for vaccines. As described in Chapter 6, Section 30.2.7 of the Prescription Drug Benefit Manual, CMS reviews all Part D sponsors' formularies to ensure they contain all commercially available Part D vaccines and to ensure that Part D sponsors are only using utilization management tools to—

- Assess the necessity of vaccines that are less commonly administered in the Medicare population, such as anthrax and yellow fever vaccines;
- Facilitate use of vaccines in line with ACIP recommendations; and
- Evaluate potential reimbursement of those vaccines that could be covered under Part B when directly related to the treatment of an injury or direct exposure to a disease or condition (for example, tetanus).

In order to ensure a vaccine meets the definition of an ''ACIP-recommended adult vaccine'' and is therefore subject to the cost-sharing requirements outlined in this rule, a Part D sponsor may implement utilization management strategies to determine if the vaccine is being administered in accordance with ACIP recommendations, which is consistent with the Chapter 6 guidance outlined previously.

Given that our existing guidance in Chapter 6 of the Prescription Drug Benefit Manual clearly outlines the situations in which Part D sponsors may implement utilization management for vaccines, we decline to issue additional guidance on this topic.

Comment: Several commenters expressed concern about Part D sponsors restricting coverage for specific vaccine products and having a ''preferred'' brand of a particular

and where the pharmacy (or provider) did not submit the claim to the Part D plan.

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

vaccine. Commenters stated that these restrictions have been implemented using utilization management strategies (for example, step therapy), $0 reimbursement to pharmacies for less preferred vaccine products, and National Drug Code (NDC) blocks. Commenters emphasized the negative impact these strategies may have on beneficiary access to vaccines. For example, the commenters asserted that a beneficiary may present to a pharmacy to receive a vaccine and, if the vaccine product in stock is not the ''preferred'' brand on the beneficiary's Part D plan's formulary, the beneficiary would need to return to the pharmacy once the ''preferred'' brand is in stock or find another pharmacy with the ''preferred'' brand currently in stock. Commenters also stated how difficult and costly it would be to keep every brand of a vaccine in stock to avoid these situations. A commenter noted that this would be particularly costly in primary care settings where providers are not paid until after a vaccine is administered, and they cannot receive reimbursement for unused vaccines. All commenters requested that CMS not allow these strategies to be implemented.

Response: We appreciate the concerns these commenters shared about the potential negative impacts of Part D sponsors restricting coverage for certain brands of a vaccine. We reiterate our rules outlined in Chapter 6, Section 30.2.7, of the Prescription Drug Benefit Manual which state that Part D sponsors' formularies must contain all commercially available Part D vaccines and, as discussed earlier in this preamble, the only allowable uses of utilization management for vaccines are to assess the necessity of vaccines that are less commonly administered in the Medicare population, facilitate the use of vaccines in line with ACIP recommendations, and evaluate potential reimbursement of vaccines that could be covered under Part B. Given that these are the only situations in which utilization management can be used for vaccines, Part D sponsors may not implement utilization management, including step therapy and NDC blocks, to prefer one brand of a vaccine over another.

Comment: A few commenters expressed concerns about beneficiaries receiving Part D vaccines in primary care settings. The commenters stated that because these settings are not considered in-network, beneficiaries must pay for the vaccine and wait to be reimbursed, which can disincentivize them from receiving recommended vaccines. The commenters emphasized that being considered out-of-network can negatively affect primary care providers' relationships with their patients as they navigate vaccine coverage requirements for each patient and must often refer patients to network pharmacies to receive recommended vaccines. A commenter stated that having to refer patients to network pharmacies for vaccine administration can lead to confusion and increased vaccine hesitancy and may disproportionately affect patients who may have difficulty obtaining transportation to an in-network pharmacy. They also noted that individuals without Part D coverage are not able to receive ACIP-recommended adult vaccines with no cost sharing.

Another commenter requested that we describe our expectations for applying utilization management strategies when vaccines are administered at an out-of-network pharmacy, such as a primary care setting, as Part D sponsors do not have direct relationships with providers in these settings. The commenter stated that there can be operational barriers to imposing utilization management in these settings and requested guidance on how to implement utilization management when vaccines are administered by providers, such as physicians, in out-of-network settings.

Response: We appreciate the commenters sharing their concerns about Part D enrollees receiving ACIP-recommended vaccines out-of-network. Part D sponsor networks are generally defined as pharmacy networks; therefore, if an enrollee receives a vaccine at a physician's office, this is most often out-of-network. As noted in the preamble to the final rule titled ''Medicare Program; Medicare Prescription Drug Benefit'' which appeared in the **Federal Register** on January 28, 2005 (70 FR 4194), a Part D enrollee receiving a vaccine in a physician's office constitutes a situation in which out-of-network access would be permitted because a beneficiary could not reasonably be expected to obtain that vaccine at a network pharmacy. We refer the commenters to our current regulations and guidance regarding claims for vaccines administered out-of-network. Specifically, § 423.124(a)(2) establishes that Part D sponsors must ensure that Part D enrollees have adequate access to vaccines and other covered Part D drugs appropriately dispensed and administered by a physician in a physician's office. In Chapter 5, Section 60.2, of the Prescription Drug Benefit Manual, we note that it may be challenging for enrollees to pay upfront and be reimbursed by their Part D plan after receiving a vaccine in their physician's office.

We encourage the commenters to review the possible approaches detailed in Section 60.2.2 of the Prescription Drug Benefit Manual to improve access to Part D vaccines administered and dispensed by a physician without requiring upfront beneficiary payment and subsequent reimbursement by Part D sponsors. The two possible approaches are: (1) a model vaccine notice for physicians (paper claim enhancement) where Part D sponsors provide all enrollees with a vaccine-specific notice that enrollees can bring to their physician with the information necessary for a physician to receive authorization of coverage for a particular vaccine and bill for the vaccine; and (2) web-assisted electronic physician billing where a physician uses a commercially-developed web-based system to electronically request out-of-network reimbursement from Part D sponsors on behalf of enrollees. Both approaches allow providers in primary care settings to administer ACIP-recommended vaccines to Part D enrollees without requiring an upfront payment.

Regarding utilization management for vaccines administered in out-of-network settings, we would expect that any utilization management requirements imposed on vaccines would need to be satisfied regardless of whether the vaccine is being administered at a network or out-of-network setting. However, we believe Part D sponsors are best situated to determine how to operationalize the implementation of utilization management requirements for out-of-network claims. As discussed earlier in this preamble, the only allowable uses of utilization management for vaccines are to assess the necessity of vaccines that are less commonly administered in the Medicare population, facilitate the use of vaccines in line with ACIP recommendations, and evaluate potential reimbursement of vaccines that could be covered under Part B. We also note that, consistent with Chapter 6, Section 10.14.3, of the Prescription Drug Benefit Manual, in the absence of any information showing previous immunization (that is, claims data), the Part D sponsor should make payment available for a vaccine and its administration consistent with ACIP recommendations. Therefore, if a Part D sponsor determines an ACIP-recommended adult vaccine is coverable under their benefit, the enrollee must not be subject to cost sharing regardless of whether they received the vaccine in-network or out-

of-network. Alternatively, if a Part D sponsor determines a vaccine does not meet the definition of an ''ACIP-recommended adult vaccine,'' the $0 cost-sharing requirement would not apply.

Comment: A commenter requested clarification on managing coverage determinations in instances where a Part D sponsor requires a prior authorization (PA) for a vaccine. The commenter stated that because many vaccines are administered in pharmacies under standing orders, there is not a physician writing an individual prescription for each enrollee receiving a vaccine. Therefore, there is no physician who can provide information in support of a PA or appeal. The commenter noted that pharmacies are typically not involved in coverage determinations and questioned whether a pharmacist is permitted to request a PA or appeal and provide information in support of a PA or appeal.

Response: As described in § 423.566(c), the only individuals who can request a standard or expedited coverage determination are the enrollee; the enrollee's representative, on behalf of the enrollee; or the prescribing physician or other prescriber, on behalf of the enrollee. However, as stated in Section 40.12.3 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, Part D sponsors are permitted, but not required, to treat the presentation of a prescription at the pharmacy as a coverage determination. Therefore, a Part D sponsor can treat a transaction in which a pharmacist explains to an enrollee that a drug is subject to prior authorization as a request for a coverage determination. A pharmacist may then communicate with the Part D sponsor and may be able to override the point-of-sale prior authorization requirement and allow the claim to process. As stated in Chapter 6, Section 30.2.2.1, of the Prescription Drug Benefit Manual, Part D sponsors may decide that it is reasonable to accept information from pharmacists in situations where point-of-sale edits are applied. In these cases, if a network pharmacy is able to provide the necessary information at the point-of-sale, it negates the need for additional administrative review through the coverage determination process and reduces delay in access to Part D drugs, including vaccines. However, we note that a pharmacist's involvement would occur at the initial coverage decision level, consistent with Section 40.9 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, and not the appeal level.

Comment: A commenter requested guidance on how to manage situations in which PA requests are submitted for vaccines. The commenter described a situation in which the Part D sponsor determines that a vaccine is not being administered in accordance with ACIP's recommendations and the enrollee is charged the applicable cost sharing. The commenter questioned whether this would be considered a fully favorable, partially unfavorable, or fully unfavorable decision. If this is a partially or fully unfavorable decision, the commenter questioned whether this decision should be classified as a denial due to a lack of medical necessity. The commenter also requested guidance for how plans should process requests in situations where a request is submitted to the plan for a vaccine to be covered at $0 cost sharing, but the plan determines the vaccine is not being administered in accordance with ACIP recommendations. The commenter noted that CMS did not propose allowing enrollees to request cost-sharing exceptions when a vaccine is not being administered in accordance with ACIP recommendations. Specifically, the commenter questioned whether these requests should be dismissed or denied.

Response: If a request is submitted to a Part D plan asking for a vaccine to be covered at $0 cost sharing, we would expect either: (1) a fully favorable decision if the vaccine is covered at $0; (2) a partially favorable decision if the vaccine is covered but subject to cost sharing; or (3) an adverse decision if the vaccine is not covered. If a request is submitted to a Part D plan asking for a vaccine to be covered, but the request does not specify a preferred cost-sharing amount, we would expect either: (1) a fully favorable decision if the vaccine is covered but subject to cost sharing; or (2) an adverse decision if the vaccine is not covered. In cases where a partially favorable or adverse decision is made, an enrollee must be provided proper notice and appeal rights, consistent with § 423.568(g). We note that it would not be appropriate to dismiss a request in any of these scenarios. A partially favorable or adverse decision would be considered a denial.

Comment: A commenter encouraged CMS to educate pharmacists about direct member reimbursement (DMR) requests so they can inform their patients that reimbursement is available for vaccines received out-of-network.

Response: We thank the commenter for their suggestion. Part D plans currently provide information to their enrollees regarding how to request reimbursement when they use an out-of-network pharmacy or provider in Chapter 5 of the Evidence of Coverage (EOC) document which is provided to all Part D enrollees.

Comment: A commenter questioned whether direct member reimbursement (DMR) requests for ACIP-recommended adult vaccines can only be submitted by beneficiaries or also by providers, including physicians and pharmacies. The commenter noted that they have seen provider-submitted claims that charge more than the negotiated rates for vaccines. If requests cannot be submitted by providers, the commenter recommended that CMS issue separate guidance for provider-submitted claims to ensure there is clarity on how these requests should be managed. They also recommend that CMS limit reimbursement for these claims to contracted rates. If requests can be submitted by providers, the commenter recommended that CMS monitor claims for ACIP-recommended vaccines as the $0 cost-sharing requirement for these vaccines may increase both the plan and CMS' liability. The commenter also stated that because there is no limit on the price of ACIP-recommended vaccines, it is possible that pharmacies and providers may charge higher cost sharing at the point-of-sale and, instead of processing claims online, they would have the beneficiary submit the claim to their Part D plan in order to receive a higher payment. Another commenter questioned how, when DMR requests are submitted, reimbursement to providers for the vaccine product and administration fees should be addressed. The commenter noted that vaccinating providers continue to face challenges with receiving adequate reimbursement for providing vaccines.

Response: We thank the commenter for sharing their questions and recommendations regarding DMR requests. We note that our reference to DMR requests in the proposed and final rules is specific to beneficiary-submitted requests where a beneficiary is requesting reimbursement for an ACIP-recommended adult vaccine for which they incurred out-of-pocket costs. With respect to DMR requests submitted by beneficiaries for prescriptions obtained from in-network pharmacies, § 423.120(c)(3) specifies that a Part D sponsor must require its network pharmacies to submit claims to the Part D sponsor or its intermediary whenever the card described in paragraph (c)(1) of this section is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its

intermediary. Network pharmacies that decline to process network claims online and instead recommend that beneficiaries submit paper claims would be in violation of this requirement. We continue to expect DMR requests for prescriptions obtained from network pharmacies to be limited and submitted only for reasons, such as the claims processing systems being temporarily unavailable for the pharmacy or the Part D sponsor or its intermediary when the enrollee obtains their prescription. Any post-reimbursement reconciliation between the network pharmacy and plan sponsor would be a contractual matter between the parties.

With respect to provider-submitted claims for vaccines, which we do not consider DMR requests, CMS does not prohibit Part D sponsors from establishing arrangements with out-of-network (OON) providers or pharmacies to facilitate OON access in accordance with the requirements specified in § 423.124. As described earlier in this preamble, Chapter 5, Section 60.2, of the Prescription Drug Benefit Manual provides options that Part D sponsors and OON providers may use to facilitate access to vaccines given that vaccines are often provided in physician offices. While we encourage such arrangements for vaccine access, CMS guidance makes it clear that it is not a requirement and that such facilitated approaches to OON access for vaccines would need to be agreed upon between the Part D sponsor and provider. Therefore, it is up to Part D sponsors to establish their own policies on whether to accept OON claims directly from providers or pharmacies, and, if they do, to establish an agreed upon reimbursement amount with the OON provider or pharmacy that could include a prohibition on balance billing the enrollee.

Our guidance for provider-submitted claims for vaccines is provided in Chapter 5 of the Prescription Drug Benefit Manual, as discussed previously.

4. Effective Date of ACIP Recommendations

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

In the proposed rule, we noted that it is highly unlikely that an ACIP recommendation will be posted without the date on which it was adopted by the CDC Director; however, in the event that a recommendation is posted without an effective date, we noted that CMS would consult with the CDC to obtain the date the recommendation was adopted by the CDC Director and provide guidance.

In the proposed rule, we noted that the ''effective date of the ACIP recommendation'' and the date on which it is published on the CDC's website may not always be the same date (if, for example, the website posting occurs after the date specified as the date the CDC Director adopted the recommendation). Nevertheless, we proposed that the ''effective date of the ACIP recommendation'' would determine when the cost-sharing requirements apply. Consequently, if an enrollee paid cost sharing for an ACIP-recommended adult vaccine after the ''effective date of the ACIP recommendation'' (for example, the enrollee received the vaccine after the ''effective date of the ACIP recommendation,'' but prior to the recommendation being posted on the CDC website), once the recommendation has been posted to the CDC website, the Part D sponsor would need to reimburse the enrollee for any cost sharing they paid for the vaccine.

In instances where ACIP expands a previous recommendation, narrows a previous recommendation, or removes a previous recommendation, the proposed ''effective date of the ACIP recommendation'' would be the date the CDC Director adopted the changed recommendation once the recommendation is posted on the CDC's website. We noted in the proposed rule that a change to an ACIP recommendation alone does not affect a vaccine's status as a Part D drug. Specifically, a Part D drug is defined at § 423.100, in relevant part, as including a vaccine, if used for a medically accepted indication, as defined in section 1860D–2(e)(4) of the Act. Since an ACIP recommendation does not affect what is considered a medically accepted indication, as defined under section 1860D–2(e)(4) of the Act, for a particular vaccine, an ACIP recommendation alone does not affect a vaccine's status as a Part D drug. However, if the FDA labeling changes to align with a narrowed ACIP recommendation, this may change what is considered a medically accepted indication and may change what indications are coverable under Part D for a particular vaccine. In other words, if an ACIP recommendation is narrowed or removed, the vaccine may still be coverable under Part D, but an enrollee may be subject to cost sharing for the vaccine if it is not administered in accordance with the revised ACIP recommendation.

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

Additionally, we discussed in the proposed rule that when an ACIP recommendation is narrowed and a Part D sponsor does not currently have a PA requirement in place for that vaccine, the plan may submit a negative formulary change request to add a PA requirement for that vaccine that aligns with the newly narrowed recommendation, consistent with § 423.120(e)(1). Once the request is approved, Part D sponsors may implement the PA requirement and, if the plan determines that the vaccine is not being used for an ACIP-recommended use, may charge the enrollee the applicable cost sharing. Part D sponsors are permitted, but not required, to make retroactive determinations for claims that were processed with $0 cost sharing after the ''effective date of the ACIP recommendation'' and before the date on which the PA requirement went into effect.

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

Because the cost-sharing limits for vaccines outlined in our proposed rule, and finalized in this final rule, have been in place since 2023 through program instruction authority and we have annually reviewed cost sharing in

plan benefit package submissions, we believe the impacts of our proposed codification of these requirements should have minimal impact on Part D sponsors and beneficiaries.

We received the following comments on this section of the proposed rule, and our responses follow.

Comment: A few commenters requested that we change the definition of the ''effective date of the ACIP recommendation.'' A commenter recommended we use the date the recommendation is published in the CDC's MMWR. Another commenter recommended we use the day after the last day of the ACIP meeting at which the recommendation was approved. Another commenter expressed concern about situations in which the CDC Director does not adopt an ACIP recommendation.

Response: We thank the commenters for their suggestions, but we decline to change our definition of the ''effective date of the ACIP recommendation.'' As we explained in the proposed rule, in the April 4, 2023 HPMS memorandum titled ''Final Contract Year (CY) 2024 Part D Bidding Instructions,'' we stated that the effective date for an ACIP recommendation is the date on which it is adopted by the CDC Director and published in the MMWR. However, on July 24, 2023, based on updated instruction from the CDC, we issued a revision to the memorandum and clarified that the effective date is the date on which the CDC Director adopts the ACIP recommendation, as posted on the CDC's website, not the date on which the recommendation is published in the MMWR. We noted that if the date of publication in the MMWR was used, it is likely there would be a delay in beneficiaries accessing new ACIP-recommended vaccines at $0 cost sharing because of the delay in publication. For example, on October 24, 2024, the CDC Director adopted recommendations to update the dosing interval and schedule for a meningococcal serogroup B vaccine (MenB–4C), but the recommendation was not published in the MMWR until December 12, 2024.[7] [8]

In the July 24, 2023 memorandum, we also stated that if the CDC Director's adoption of an ACIP recommendation is posted as official on the CDC website but an adoption date is not specified, the effective date would be the day after the last day of the ACIP meeting at which the recommendation was approved. However, we did not include this requirement in the proposed rule. We understand from the CDC that there may be situations in which the CDC Director amends or rejects a recommendation after the ACIP meeting concludes. Therefore, if the day after the last day of the ACIP meeting date was used as the ''effective date of the ACIP recommendation,'' it is possible that a vaccine could be inappropriately considered an ACIP-recommended adult vaccine for a short period of time.

Our proposed definition of ''effective date of the ACIP recommendation'' aligns with the CDC's current process for publishing ACIP recommendations that have been adopted by the CDC Director. Based on guidance from the CDC, it is highly unlikely that an ACIP recommendation will be posted without the date on which it was adopted by the CDC Director. In the unlikely event this does occur, CMS will consult with the CDC to obtain the date the recommendation was adopted by the CDC Director and provide guidance.

Comment: A commenter questioned CMS's expectations when an existing ACIP recommendation is narrowed. The commenter requested clarification regarding whether Part D sponsors are required to add a PA requirement with respect to the vaccine and to submit a negative formulary change request to CMS when an ACIP recommendation is narrowed. The commenter stated that if CMS requires plans to submit a negative formulary change request to add a PA requirement in response to a narrowed ACIP recommendation, this would result in delays in implementing the narrowed ACIP recommendation. Finally, the commenter recommended that if a plan does add a PA requirement for a vaccine, CMS should allow the plan to implement the PA requirement immediately without submitting and waiting for approval of a negative formulary change request.

Response: As stated in the proposed rule, Part D sponsors are not required to implement PA requirements for vaccines to determine if they are being used in accordance with ACIP recommendations. We clarify that Part D sponsors are not required to add a PA requirement when an ACIP recommendation is narrowed. However, if a Part D sponsor chooses to add a PA requirement to determine if the vaccine is being used in accordance with the narrowed ACIP recommendation, the sponsor must comply with the applicable negative formulary change requirements at § 423.120(e) and applicable notice requirements at § 423.120(f).

In the proposed rule, we stated that unless the Part D sponsor is otherwise notified, the negative change request will be considered approved after 30 days, as specified in § 423.120(e)(3)(i). However, we clarify that, depending on the nature of the narrowed ACIP recommendation, the negative formulary change could be considered either a maintenance change or a non-maintenance change as defined at § 423.100. If the change is a maintenance change, the requirements in § 423.120(e)(3)(i) will apply, meaning that the request is deemed approved 30 days after submission unless CMS notifies the Part D sponsor otherwise. If the change is a non-maintenance change, the requirements in § 423.120(e)(3)(ii) will apply, meaning that the change must not be implemented until the Part D sponsor receives a notice of approval from CMS.

Regardless of whether a negative formulary change is considered a maintenance or non-maintenance change, Part D sponsors are not permitted to immediately implement the PA requirement and must wait until the negative formulary change request is approved. Once the PA requirement is approved, the Part D sponsor may implement the PA requirement and may make retroactive determinations for claims that were processed with $0 cost sharing after the ''effective date of the ACIP recommendation'' and before the date on which the PA requirement went into effect.

Comment: A commenter expressed concern about potential delays in implementing $0 cost sharing when a new ACIP recommendation is posted to the CDC website by the CDC without an effective date. The commenter was concerned about waiting for CMS to work with CDC to obtain the effective date and issue guidance in instances where the CDC did not specify the date on which the recommendation was adopted by the CDC Director. The commenter requested that CMS allow a grace period for Part D sponsors to implement all cost-sharing changes after an ACIP recommendation is posted online, regardless of whether a date is specified or not, as it takes some time to implement cost-sharing changes.

Response: We appreciate the commenter's suggestion but note that, based on guidance from the CDC, we expect that it is highly unlikely that an ACIP recommendation will be posted without the date on which it was adopted by the CDC Director. We also decline to make a change to our proposed requirements to allow Part D sponsors to have a grace period to implement cost-sharing changes after an

[7] *https://www.cdc.gov/acip/vaccine-recommendations/.*

[8] *https://www.cdc.gov/mmwr/volumes/73/wr/mm7349a3.htm?s_cid=mm7349a3_w.*

ACIP recommendation is posted. To ensure beneficiaries can immediately benefit from a new ACIP recommendation, the ''effective date of the ACIP recommendation'' is the date on which cost-sharing requirements apply. If a Part D sponsor is not able to effectuate $0 cost sharing for an ACIP recommended adult vaccine as of the ''effective date of the ACIP recommendation'' and an enrollee pays cost sharing for the ACIP-recommended adult vaccine after the ''effective date of the ACIP recommendation,'' the Part D sponsor will need to reimburse the beneficiary for any cost sharing paid for the vaccine.

After considering the public comments we received, and for the reasons set forth in the proposed rule and in our responses to comments, we are finalizing the changes to §§ 423.100 and 423.120 as proposed.

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

1. Background

Section 11406 of the Inflation Reduction Act of 2022 (IRA) amended section 1860D–2 of the Act by adding new paragraph (9) to subsection (b) and new paragraph (6) to subsection (c) and making other conforming amendments to require that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to covered insulin products, and the Part D cost-sharing amount for a 1-month supply of each covered insulin product must not exceed the statutorily defined ''applicable copayment amount'' for all enrollees. For 2023, 2024, and 2025, the applicable copayment amount is $35. For 2026 and each subsequent year, the applicable copayment amount is the lesser of: (1) $35; (2) an amount equal to 25 percent of the maximum fair price (MFP) established for the covered insulin product in accordance with Part E of title XI of the Act; or (3) an amount equal to 25 percent of the negotiated price of the covered insulin product under the PDP or MA–PD plan. Section 11406(d) of the IRA directed the Secretary to implement section 11406 of the IRA for 2023, 2024, and 2025 by program instruction or other forms of program guidance. In accordance with the law, CMS issued several memoranda related to cost sharing for covered insulin products via the Health Plan Management System (HPMS) that outlined expectations for Part D sponsors regarding the implementation of section 11406. On September 26, 2022, CMS released an HPMS memorandum titled ''Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin,'' in which we provided program instructions for the implementation of the requirements in section 11406.[9] On April 4, 2023, we released additional guidance in the ''Final Contract Year (CY) 2024 Part D Bidding Instructions'' in which we provided instructions for Part D sponsors as they prepared to submit bids for CY 2024.[10] Lastly, on April 1, 2024, we released ''Final CY 2025 Part D Redesign Program Instructions.'' [11]

We proposed to codify the cost-sharing requirements for covered insulin products under Part D for 2026 and each subsequent plan year.

We received the following comments on this section of the proposed rule, and our responses follow:

Comment: We received many comments that were supportive of our proposal to codify the statutory cost-sharing requirements for covered insulin products that were added to section 1860D–2 of the Act by section 11406 of the IRA.

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

Comment: A commenter requested that CMS publish technical prescription drug event (PDE) reporting guidance for covered insulin product claims.

Response: We thank the commenter for their recommendation. We have released PDE reporting instructions for the implementation of provisions of the IRA for contract years 2023, 2024, and 2025. Our most recent guidance, entitled ''Prescription Drug Event Record Reporting Instructions for the Implementation of the Inflation Reduction Act for Contract Year 2025'' was published on April 15, 2024 and can be found here: *https://www.cms.gov/files/document/pderecordreportinginstructionsfortheimplementationoftheiraforcontractyear2025508g.pdf*. We anticipate that additional guidance will be released for contract year 2026.

2. Definition of Covered Insulin Product

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

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

While our proposed definition of ''covered insulin product'' includes products that are a combination of more than one type of insulin or both insulin and non-insulin drug or biological products, the definition would be limited to those products that are FDA-licensed biological products. Consequently, because a compounded drug product, as described in § 423.120(d), is not FDA-licensed, it would not meet the definition of ''covered insulin product.'' As such, a compounded drug product would not be subject to the requirements for a ''covered insulin product'' under our proposed definition at § 423.100.

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

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

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

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

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

We did not receive any comments on this section of the proposed rule and are finalizing the definition of ''covered insulin product'' at § 423.100 as proposed.

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

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

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

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

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

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

For example, the August 15, 2024 publication ''Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026'' establishes the maximum fair price for the covered insulin product Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill as $119 for a 30-day supply in CY 2026.[12] If, in this example, a plan's negotiated price, as defined in § 423.100, is $95, then an amount equal to 25 percent of the maximum fair price is $29.75 and an amount equal to 25 percent of the negotiated price is $23.75. Therefore, the covered insulin product applicable cost-sharing amount would be $23.75, as it is the lesser of $35, $29.75, and $23.75.

We received the following comments on this section of the proposed rule, and our responses follow:

Comment: Several commenters requested clarification regarding the applicable cost-sharing amount for covered insulin products that are selected drugs under the Medicare Drug Price Negotiation Program, as established by sections 11001 and 11002 of the IRA and added to sections 1191 through 1198 of the Act. As described in section 1860D–2 of the Act, and our proposed definition of ''covered insulin product applicable cost-sharing amount'' at § 423.100, this amount is the lesser of $35, an amount equal to 25 percent of the maximum fair price (MFP), or an amount equal to 25 percent of the negotiated price. Some of these commenters expressed concern regarding the existing guidance for managing situations in which the applicable cost-sharing amount is determined to be equal to 25 percent of the MFP established for the covered insulin product in accordance with Part E of title XI of the Act. A few commenters noted that the MFP only includes the ingredient cost of a covered insulin product and does not include taxes and dispensing fees and requested guidance on how plan sponsors should treat these costs. A commenter, referring to dispensing fees but not sales tax, noted that if reimbursement for covered insulin product claims does not include reimbursement for the ingredient cost of the insulin product and a dispensing fee, below cost or inadequate reimbursement may harm pharmacies and limit beneficiary access to insulin. Other commenters, referring to both sales tax and dispensing fees, requested that these costs be included as part of the applicable copayment amount when it is equal to 25 percent of the MFP, which they note would be consistent with how cost sharing is calculated when 25 percent of the negotiated price is the applicable cost-sharing amount.

Response: We thank the commenters for their comments. The MFP established for a covered insulin product in accordance with Part E of title XI of the Act only includes the ingredient cost of the insulin product. As such, the amount paid by an enrollee for a 1-month supply of a covered insulin product cannot exceed 25 percent of the MFP, if this amount is lower than $35 or 25 percent of the negotiated price. Therefore, Part D plans are responsible for covering the cost of the dispensing fee and any applicable sales tax. If the applicable covered insulin product applicable cost-sharing amount is determined to be 25 percent of the negotiated price, we note that, consistent with the definition of negotiated price § 423.100, this price includes all price concessions from network pharmacies or other network providers as well as dispensing fees. If the applicable covered insulin product applicable cost-sharing amount is determined to be $35, the amount paid by an enrollee cannot exceed $35.

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

Comment: A commenter recommended that CMS consider allowing the establishment of a copayment amount for insulin products that provides flexibility for Part D plan sponsors. Specifically, the commenter recommended that CMS permit plans to set a copayment that is equal to no more than 25 percent of the MFP or the negotiated price, while also allowing for a $35 copay when it is less than 25 percent of the MFP or the negotiated price. The commenter asserted that this approach would provide flexibility for Part D sponsors, ensure enrollees are subject to predictable cost sharing, and encourage pharmaceutical manufacturers to maintain or lower prices of covered insulin products.

Response: We appreciate the commenter's suggestion. In accordance with the statute, plans are permitted to set a copayment that is less than or equal to $35 so long as that copayment amount is no more than 25 percent of the MFP or 25 percent of the negotiated price. However, it is not clear if the commenter is asking whether the copayment can be greater than $35 as long as it is equal to no more than 25 percent of the MFP or the negotiated price. While a plan may establish a copayment that is equal to or less than $35, we clarify that the copayment cannot exceed $35 even if such copayment would otherwise be equal to no more than 25 percent of the MFP or the negotiated price. While we recognize the importance of allowing Part D sponsors to have some flexibility in how they structure their benefits, the covered insulin product applicable cost-sharing amount that we are codifying in this rule is statutorily defined in section 1860D–2(b)(9)(D) of the Act as the lesser of $35, an amount equal to 25 percent of the MFP, and an amount equal to 25 percent of the negotiated price. As noted in the proposed rule, Part D sponsors have the flexibility to meet this cost-sharing requirement by establishing a copayment amount that is equal to or lower than $35 for a 1-month supply, establishing a coinsurance percentage that is equal to or lower than 25 percent of the product's MFP or negotiated price, or establishing both a copayment amount equal to or lower than $35 and a coinsurance percentage equal to or lower than 25 percent of the product's MFP or negotiated price.

We clarify that if a Part D sponsor places a covered insulin product on a formulary tier with a copayment or coinsurance that is lower than the statutory maximum cost-sharing amount (that is, the lesser of $35, 25 percent of the negotiate price, or 25 percent of the MFP), the Part D sponsor will need to use the copayment or coinsurance amount specified for the tier when determining the enrollee's cost-sharing amount. For example, if a covered insulin product is placed on a formulary tier with a copayment amount of $20, the enrollee's cost-sharing amount would be the lesser of $20, 25 percent of the negotiated price, or 25 percent of the MFP, if the insulin product is a selected drug. Similarly, if a covered insulin product is placed on a formulary tier with a coinsurance percentage of 20 percent, the enrollee's cost-sharing amount would be the lesser of the 20 percent coinsurance or $35.

We also clarify that if a Part D sponsor places a covered insulin product on a formulary tier with a copayment or coinsurance that is greater than the statutory maximum cost-sharing amount, the Part D sponsor will still need to use the defined covered insulin product applicable cost-sharing amount to ensure that the enrollee's cost sharing does not exceed such amount. For example, if a covered insulin product is placed on a formulary tier with a copayment amount of $50, the enrollee's cost-sharing amount cannot exceed the covered insulin product applicable cost-sharing amount, which is defined as the lesser of $35, 25 percent of the negotiated price, or 25 percent of the MFP. Similarly, if a covered insulin product is placed on a formulary tier with a coinsurance percentage of 30 percent, the enrollee's cost-sharing amount cannot exceed the covered insulin product applicable cost-sharing amount, which is defined as the lesser of $35, 25 percent of the negotiated price, or 25 percent of the MFP.

Comment: A commenter requested that CMS adjust how it describes the applicable cost-sharing amount for covered insulin products. The commenter stated that the current guidance stating that cost sharing is equal to or lower than $35 or 25 percent of the MFP or the negotiated price is unclear. The commenter recommended rewording this requirement to state that cost sharing cannot exceed the maximum cost sharing of the lower of $35 per month, 25 percent of the MFP, or the negotiated price.

Response: We thank the commenter for their suggestion. However, we decline to adopt this change as we believe the current language describing the covered insulin product applicable cost-sharing amount is sufficiently clear.

4. Cost Sharing for Covered Insulin Products

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

a. Duration of Supply

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

With respect to extended-day supplies (that is, greater than a 1-month supply) of covered insulin products, we proposed that cost sharing must not exceed the cumulative ''covered insulin product applicable cost-sharing amount'' that would apply if the same days' supply was dispensed in the fewest number of 1-month supply increments necessary. For example, if a covered insulin product is dispensed for greater than a 1-month supply, but less than a 2-month supply, the lesser of $70 or 25 percent of MFP or negotiated price, whichever applies, would remain the maximum cost-sharing amount. Similarly, the lesser of $105 or 25 percent of the MFP or negotiated price,

whichever applies, would apply for a covered insulin product that is dispensed for greater than a 2-month supply up to a 3-month supply. If the ''covered insulin product applicable cost-sharing amount'' is a coinsurance, the coinsurance percentage would be applied to the negotiated price regardless of the days' supply dispensed.

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

b. Out-of-Network Claims

In the September 26, 2022 HPMS memorandum, we provided guidance on managing out-of-network claims. Consistent with this guidance, we proposed that enrollees who submit direct member reimbursement (DMR) requests for covered insulin products accessed at either out-of-network pharmacies or providers (in accordance with § 423.124(a) and (c)), or at in-network pharmacies or providers, must not pay more than the ''covered insulin product applicable cost-sharing amount.'' While Part D sponsors generally may charge the enrollee for the difference between the cash price and plan allowance for DMRs for covered Part D drugs accessed from both out-of-network and in-network pharmacies, neither § 423.124(b) nor Chapter 14 of the Prescription Drug Benefit Manual directly addresses covered Part D drugs that have statutorily limited cost sharing.[13] Therefore, for covered insulin products accessed at either out-of-network pharmacies or providers (in accordance with § 423.124(a) and (c)), or at in-network pharmacies or providers, we proposed at § 423.120(h)(4) that the Part D sponsor must reimburse the enrollee for the full cash price paid to the pharmacy or provider for a covered insulin product minus the ''covered insulin product applicable cost-sharing amount.''

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

c. Tier Placement & Utilization Management

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

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

We received the following comments on this section of the proposed rule, and our responses follow:

Comment: A few commenters requested that we monitor out-of-network claims for covered insulin products, stating that they believe there are limited circumstances in which a beneficiary would need to obtain a covered insulin product from an out-of-network pharmacy, especially considering the existing requirements for pharmacy networks and the availability of mail order prescriptions. The commenters recommended that CMS analyze utilization data and determine if out-of-network fills for covered insulin products are routinely being used without a particular need. The commenters asserted that routine use of out-of-network fills may interfere with Part D plans' care coordination and recommend that limits be placed on access to covered insulin products at out-of-network pharmacies.

Response: We agree with the commenters that out-of-network access should not routinely be used to access covered insulin products. We reiterate our existing requirements at § 423.124, under which a Part D sponsor must ensure that enrollees have access to covered Part D drugs at out-of-network pharmacies only if they cannot reasonably be expected to obtain such drugs at a network pharmacy and do not access covered Part D drugs at an out-of-network pharmacy on a routine basis.

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

Moreover, § 423.124(c) requires Part D sponsors to establish reasonable rules to appropriately limit out-of-network access to covered Part D drugs.

Comment: A commenter requested clarification on whether direct member reimbursement (DMR) requests for covered insulin products can only be submitted by beneficiaries or whether DMR requests can also be submitted by providers. The commenter recommended that CMS monitor claims for covered insulin products, as the codification of CMS's cost-sharing requirements for insulin products could increase both the plan and CMS's liability. The commenter also stated that because there is no limit on the price of covered insulin products that are not selected drugs under the Medicare Drug Price Negotiation Program, it is possible that pharmacies may decline to process network claims online and instead recommend that beneficiaries submit paper claims directly to their Part D plan in an attempt to charge higher prices at the point-of-sale and receive higher payments.

Response: We thank the commenter for sharing their questions and recommendations regarding DMR requests. We note that our reference to DMR requests in the proposed and final rules is specific to beneficiary-submitted requests where a beneficiary is requesting reimbursement for a covered insulin product for which they incurred out-of-pocket costs. With respect to DMR requests submitted by beneficiaries for prescriptions obtained from in-network pharmacies, § 423.120(c)(3) specifies that a Part D sponsor must require its network pharmacies to submit claims to the Part D sponsor or its intermediary whenever the card described in § 423.120(c)(1) is presented or on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary. Network pharmacies that decline to process network claims online and instead recommend that beneficiaries submit paper claims would be in violation of this requirement. We continue to expect DMR requests for prescriptions obtained from network pharmacies to be limited and submitted only for reasons such as the claims processing systems being temporarily unavailable for the pharmacy or the Part D sponsor or its intermediary when the enrollee obtains their prescription. Any post-reimbursement reconciliation between the network pharmacy and plan sponsor would be a contractual matter between the parties.

Comment: A commenter opposed a cumulative covered insulin product applicable cost-sharing amount. The commenter stated that cost sharing is determined on a claim-by-claim basis and interpreted the language in the proposed rule to require that Part D sponsors track cost sharing for extended-day supply claims and ensure that the cost sharing does not exceed one of the cost-sharing thresholds cumulatively.

Response: We clarify that the reference to ''the cumulative 'covered insulin product applicable cost-sharing amount' '' in the proposed rule was not intended to require assessment across multiple covered insulin product claims. The covered insulin product's applicable cost-sharing amount is assessed on a claim-by-claim basis. For extended-day supplies, the applicable cost-sharing amount is determined based on the days' supply for the individual claim. For example, if a covered insulin product is dispensed with a days' supply greater than 1 month, but less than 2 months, the lesser of $70, 25 percent of the MFP, or 25 percent of the negotiated price would be the applicable cost-sharing amount. In other words, the Part D sponsor only needs to look at the days' supply for an individual claim to determine the applicable cost-sharing amount for a covered insulin product.

Comment: A commenter stated that monthly prescriptions for insulin can create challenges for patients. The commenter requested that CMS allow quarterly prescriptions for insulin.

Response: We do not prohibit prescriptions for covered insulin products from being written and dispensed for greater than 1-month supplies. In the proposed rule, we provided guidance on how to apply cost sharing for extended-day supplies of covered insulin products. We also proposed to codify at § 423.120(h)(3) that Part D sponsors must ensure that any enrollee cost sharing for each prescription fill greater than a 1-month supply does not exceed the cumulative ''covered insulin product applicable cost-sharing amount,'' that would apply if the same days' supply was dispensed in the fewest number of 1-month supply increments necessary.

After considering the public comments we received, and for the reasons set forth in the proposed rule and in our responses to comments, we are finalizing the changes to §§ 423.100 and 423.120 as proposed.

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

1. Background

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

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

As described in more detail in the proposed rule, section 11202(c) of the IRA directs the Secretary to implement the Medicare Prescription Payment Plan for 2025 by program instruction or other forms of program guidance. In accordance with the law, CMS released the Medicare Prescription Payment Plan: Final Part One Guidance on Select Topics, Implementation of Section 1860D–2 of the Social Security Act for 2025, and Response to Relevant Comments (''final part one guidance'') and Medicare Prescription Payment Plan: Final Part Two Guidance on Select Topics, Implementation of Section 1860D–2 of the Social Security Act for 2025, and Response to Relevant Comments (''final part two guidance''), establishing critical operational, technical, and communication requirements for the Medicare Prescription Payment Plan for 2025. CMS does not have authority to implement the Medicare Prescription Payment Plan through program instruction authority beyond 2025. As such, we pursued rulemaking to codify the requirements of the program for 2026 and subsequent years.

With only a few exceptions, we proposed to codify, without modification, the requirements established in the final part one guidance and the final part two

guidance at § 423.137 for 2026 and subsequent years.

CMS's approach in codifying the requirements established in the final part one guidance and final part two guidance is to limit changes to the requirements already set forth and allow stakeholders to gain experience with the program, minimize additional burden for Part D plan sponsors, and minimize disruption for Medicare Prescription Payment Plan participants. Instances where we proposed to make modifications to the requirements previously finalized for 2025 include—

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

We also proposed new requirements for the following three additional topics:

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

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

Finally, section 1103 of Title I, Subpart B of the Health Care and Education Reconciliation Act (Pub. L. 111–152) amended section 1857(e) of the Act to add a medical loss ratio (MLR) requirement to Medicare Part C (MA program). An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. Because section 1860D–12(b)(3)(D) of the Act adopts by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Medicare Part D program. Consistent with the inclusion of plan losses in the administrative expense portion of the Part D bid and the treatment of Medicare Prescription Payment Plan unsettled balances as administrative costs under section 1860D–2(b)(2)(E)(v)(VI) of the Act, in the proposed rule, we proposed to modify §§ 422.2420(b)(4)(i)(D) and 423.2420(b)(4)(i)(D) to codify the exclusion of such balances from the MLR numerator, a policy which CMS initially established in the final part two guidance for 2025.

Comment: Many commenters expressed support for the Medicare Prescription Payment Plan program. Commenters stated that the program addresses the burden of high OOP costs early in the year and can improve access to medications and avoid financial hardship, particularly for those on fixed incomes or managing multiple chronic conditions. Commenters also expressed support for CMS's proposal to, with only a few exceptions, codify, without modification, the requirements established in the final part one guidance and final part two guidance. A commenter expressed that the guidance was developed after extensive stakeholder input, and the commenter believes it reflects an appropriate balance between bureaucratic processes and a positive consumer experience.

Response: CMS thanks the commenters for their support.

Comment: Some commenters expressed opposition to CMS's proposal to codify the Medicare Prescription Payment Plan guidance in regulation. A commenter requested that CMS delay implementation of the program for at least one year to allow for additional stakeholder input, pilot testing, and refinement of the program's design. Some commenters requested that CMS defer codification of the program, except for statutorily required items, until Part D plan sponsors have had more time and experience with the Medicare Prescription Payment Plan.

Response: CMS thanks the commenters for their feedback. As noted in the proposed rule, CMS does not have authority to implement the Medicare Prescription Payment Plan through program instruction authority beyond 2025. As section 1860D–2(b)(2)(E)(i) of the Act requires that Part D plan sponsors offer the Medicare Prescription Payment Plan for all plan years beginning on or after January 1, 2025, CMS also does not have the authority to delay the implementation of the Medicare Prescription Payment Plan. Although CMS is required to pursue rulemaking to codify the program at this time, CMS has pursued an approach of, with only a few exceptions, codifying the requirements established in the final part one guidance and final part two guidance at § 423.137 for 2026 and subsequent years without modification in order to allow stakeholders to gain experience with the program, minimize additional burden for Part D plan sponsors, and minimize disruption for Medicare Prescription Payment Plan participants. Codifying only certain requirements would cause considerable confusion and disruption in the administration of the Medicare Prescription Payment Plan.

CMS remains committed to engaging with shareholders through interview series, individual meetings, and other fora, and incorporating feedback into future rulemaking, as applicable, as Part D plan sponsors gain more experience with the program.

Comment: Some commenters expressed opposition to CMS making any modifications to the Medicare Prescription Payment Plan program for 2026 and subsequent years, even certain limited modifications. Commenters expressed that Part D plan sponsors will need time to continue assessing and implementing the required changes and that, given the extensive changes to the Part D program taking effect in 2025, finalizing additional, significant requirements on Part D plan sponsors for 2026 and 2027 is premature. A commenter recommended that CMS not impose new requirements for 2026 unless the requirements provide Part D plan sponsors more flexibility and are optional rather than mandatory.

Response: CMS thanks the commenters for their feedback. CMS agrees that limiting changes to the requirements in place for 2025 will allow stakeholders to gain experience with the program, minimize additional burden for Part D plan sponsors, and minimize disruption for Medicare Prescription Payment Plan participants. Accordingly, CMS is not finalizing any requirements for real-time election or for Part D plans to provide pharmacies with easily accessible information on a Part D enrollee's costs incurred under the program. CMS believes that the limited modifications to the Medicare Prescription Payment Plan codified in this final rule will improve the efficiency of the program and minimize disruptions for program participants. CMS has addressed specific comments related to real-time election and automatic renewal in section II.C.2.(c). of this final rule and comments related to providing pharmacies with easily

accessible information on a Part D enrollee's costs in section II.C.2.(i). of this final rule. CMS remains committed to engaging with stakeholders and incorporating feedback into future rulemaking, as applicable, as stakeholders gain more experience with the program.

Comment: A commenter expressed concern that the complexity of the Medicare Prescription Payment Plan program could cause beneficiary confusion. The commenter expressed concern that beneficiaries who fail to opt in correctly or inadvertently miss payments may experience disruptions in their access to essential medications, placing their health at significant risk. The commenter further stated that beneficiaries who struggle to meet their monthly installment obligations due to unforeseen financial hardships could face increased stress and uncertainty, potentially exacerbating existing health disparities.

Response: CMS appreciates the commenter's feedback. CMS understands that the Medicare Prescription Payment Plan program is complex and believes that ongoing robust efforts to educate beneficiaries about the program by CMS, plan sponsors, and other interested parties will be important to ensuring that beneficiaries are appropriately informed about the program. In 2024, CMS developed educational materials and tools to help beneficiaries assess whether the program is right for them and raise awareness of other financial assistance programs, such as the Low-Income Subsidy (LIS) Program, and encouraged Part D plan sponsors and other interested parties to use the language and examples in the CMS-developed materials to craft their own educational materials.

2. Proposed Provisions

a. Basis, Scope, and General Rule

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

In the proposed rule, CMS stated that the provision applies to all Part D plan sponsors, including both stand-alone PDPs and MA–PD plans, as well as Employer Group Waiver Plans (EGWPs), cost plans, and demonstration plans. CMS further stated that for the reasons articulated in the final part two guidance, we do not expect plans that exclusively charge $0 cost sharing for covered Part D drugs to offer enrollees the option to pay their OOP costs through monthly payments over the course of the plan year or otherwise comply with the Medicare Prescription Payment Plan requirements set forth in the proposed rule and in the proposed new regulation at § 423.137.

In the proposed rule, we proposed to codify at § 423.137(a) the requirements we established in the final part one guidance and final part two guidance to apply to plan year 2026 and subsequent years and, in the case of a plan operating on a non-calendar year basis, for the portion of the plan year starting on January 1, 2026. As explained in more detail in the proposed rule at 89 FR 99356, we intend to not expect plans operating on a non-calendar year basis to comply with the Medicare Prescription Payment Plan requirements set forth in this final rule and in the new regulations finalized at § 423.137 to the extent that those requirements differ from those established in the final part one guidance and final part two guidance during any portion of the non-calendar plan year that starts in 2025 and continues into 2026.

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

As described in the proposed rule at 89 FR 99356 and section II.C.2.(b) of this final rule, the formula for calculating the maximum monthly cap differs for the first month of participation in the program versus the remaining months of the year. The cap for the first month for which the Part D enrollee has opted into the Medicare Prescription Payment Plan incorporates an enrollee's True Out-of-Pocket costs (TrOOP) prior to election into the program.[14] However, the subsequent month calculation is determined by calculating the sum of any remaining OOP costs owed by the participant from a previous month that have not yet been billed and any additional OOP costs for the Medicare Prescription Payment Plan in the subsequent month. As such, for the subsequent month calculation of the Part D cost sharing incurred by the Part D enrollee, the term ''OOP costs for the Medicare Prescription Payment Plan'' includes those Part D cost sharing amounts that the enrollee is responsible for paying after accounting for amounts paid by third-party payers.

Specifically, the OOP costs for the Medicare Prescription Payment Plan do not include the covered plan pay amount or other TrOOP-eligible amount(s), such as any amount paid by potential third-party payers, such as State Pharmaceutical Assistance Programs or charities. Additionally, within the definition of OOP costs for the Medicare Prescription Payment Plan, we proposed to define ''remaining OOP costs owed by the participant'' to be the sum of OOP costs for the Medicare Prescription Payment Plan that have not yet been billed to the program participant. For example, as described in more detail in section II.C.2.(b). of this final rule, if a Medicare Prescription Payment Plan participant incurs $2,000 in January and is billed $166.67, the remaining OOP costs owed by the participant are $2,000 − $166.67 = $1,833.33.

Finally, pursuant to our authority under section 1860D–14(e)(5)(B) of the Act to waive such requirements of title XI and title XVIII of the Act as may be necessary to carry out the purposes of the LI NET program, we proposed to codify a waiver for the LI NET program with respect to the requirements of the Medicare Prescription Payment Plan for plan year 2026 and subsequent years. (Because the LI NET sponsor is a Part D sponsor and the LI NET contract is a PDP contract, many existing provisions in Part 423 apply to LI NET. Certain requirements were waived by the statute (such as dissemination of information and formulary requirements) and some requirements were waived through rulemaking (such as medication therapy management and quality improvement

[14] TrOOP is spending on covered Part D drugs by the beneficiary or on their behalf by certain third parties. TrOOP costs determine when a beneficiary becomes an applicable beneficiary for the Manufacturer Discount Program, reaches the annual OOP threshold, and subsequently enters the catastrophic coverage phase.

activities).) Specifically, we proposed to revise § 423.2536 to include the proposed Medicare Prescription Payment Plan requirements at § 423.137 discussed in this section to the list of Part D requirements waived for the LI NET program. We would do this by redesignating paragraphs (c) through (k) as paragraphs (d) through (l) and adding the new proposed waiver at paragraph (c). In addition, we proposed to add the materials proposed at §§ 423.2265(b)(16) and 423.2267(e)(45) through (51) (that is, information about the Medicare Prescription Payment Plan on sponsor websites and forms and notices related to the program) to the list of communication requirements waived for the LI NET program. We proposed to do this by revising newly redesignated § 423.2536(i)(1) and (4).

Comment: A commenter expressed support for CMS's policy of not expecting plans that exclusively charge $0 cost sharing for covered Part D drugs to offer enrollees the option to pay their OOP costs through monthly payments over the course of the plan year or otherwise comply with the Medicare Prescription Payment Plan requirements set forth in the proposed rule. The commenter requested that CMS also apply that policy to dual eligible special needs plans (D–SNPs) that offer nominal cost-sharing. The commenter anticipates that termination of the MA Value-Based Insurance Design (VBID) model will reduce the number of D–SNPs that can offer $0 copays for Part D drugs and expressed concern that an LIS enrollee in a plan with Part D cost sharing could experience higher cost-sharing in later months under the Medicare Prescription Payment Plan if their cost sharing in the early months of a year is shifted to the later months.

Response: CMS thanks the commenter for their support and feedback. CMS does not expect Part D plans that exclusively charge $0 cost sharing for covered Part D drugs to all plan enrollees to offer the Medicare Prescription Payment Plan because there is no practical application for the Medicare Prescription Payment Plan in Part D plans that do not charge cost sharing. While CMS recognizes that Part D enrollees with low cost sharing may be less likely to benefit from the Medicare Prescription Payment Plan, under section 1860D–2(b)(2)(E)(i) of the Act, Part D plan sponsors must provide the option to participate in the Medicare Prescription Payment Plan to all Part D enrollees, including subsidy eligible individuals as defined in paragraph (3)(A) of section 1860D–14(a) of the Act. Because the statute explicitly requires that the Medicare Prescription Payment Plan be offered to subsidy-eligible individuals and because such beneficiaries could determine that they would benefit from the Medicare Prescription Payment Plan under certain circumstances, D–SNPs that offer nominal cost sharing are required to offer the Medicare Prescription Payment Plan to their enrollees.

Comment: A commenter expressed support for CMS's proposal to add the Medicare Prescription Payment Plan to the list of Part D requirements waived for the LI NET program. Another commenter expressed support for the definitions proposed for the Medicare Prescription Payment Plan program and stated that they add additional clarity about the subset of costs eligible for the program.

Response: CMS thanks the commenters for their support.

Comment: A commenter requested that CMS waive Medicare Prescription Payment Plan requirements for EGWPs, as the commenter believes the program will add significant administrative costs without providing meaningful benefits to EGWP enrollees.

Response: CMS appreciates the commenter's feedback but declines to waive the requirement to offer the Medicare Prescription Payment Plan for EGWPs. Section 1860D–22(b) of the Act and 42 CFR 423.458(c) permit CMS to waive or modify any requirement that hinders the design of, offering of, or enrollment in an EGWP. Under section 1860D–2(b)(2)(E)(i) of the Act, all Part D plan sponsors must provide the option to participate in the Medicare Prescription Payment Plan to all Part D enrollees. Regardless of whether EGWP enrollees are less likely to benefit from the Medicare Prescription Payment Plan than enrollees in other types of plans, waiving the requirements of the Medicare Prescription Payment Plan would mean that some EGWP beneficiaries who would be likely to benefit would not be able to take advantage of the program. CMS believes that waiving requirements for EGWPs is not aligned with the statutory requirement that all Part D enrollees must be provided with the option to participate in the program.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing all proposed provisions at §§ 423.137(a) and (b) and 423.2536 without modification.

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

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

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

Additionally, incurred costs for the Medicare Prescription Payment Plan (as used in the statutory definition of the first month's maximum cap calculation) means the incurred costs, with the meaning set forth at section 1860D–2(b)(4)(C) of the Act and described in section 30 of the Final CY 2025 Part D Redesign Program Instructions (Final 2025 Program Instructions), that were incurred prior to effectuation of an election into the Medicare Prescription Payment Plan, including all TrOOP-eligible costs.[15] If election into the program occurs mid-month, this would include Part D costs incurred within the calendar month of election but prior to election.

Under section 1860D–2(b)(2)(E)(iv)(II) of the Act, for each subsequent month for which the Part D enrollee has opted into the program, the maximum monthly cap is determined by calculating the sum of any remaining OOP costs owed by the participant from a previous month that have not yet been billed and any additional OOP costs for

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

the Medicare Prescription Payment Plan in the subsequent month, divided by the number of months remaining in the plan year. The number of months remaining includes the month for which the cap is being calculated. This calculation repeats for each month in which the participant remains in the Medicare Prescription Payment Plan. The resulting maximum monthly cap will change if additional OOP costs for the Medicare Prescription Payment Plan are incurred.

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

The proposed rule discussed the specifics of the first and subsequent month calculation for the maximum monthly cap on cost-sharing payments.

Comment: A commenter expressed support for finalizing the program calculations.

Response: CMS thanks the commenter for their support.

Comment: A commenter expressed concern that the program calculations are not intuitive and may be confusing for program participants.

Response: CMS appreciates the commenter's feedback. However, section 1860D–2(b)(2)(E)(iv) of the Act specifies how the maximum monthly caps on OOP cost sharing payments are to be calculated, and CMS does not have the authority to change the statutory formula for the maximum monthly cap.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing all proposed provisions at § 423.137(c) without modification.

c. Eligibility and Election

Under section 1860D–2(b)(2)(E)(i) of the Act, Part D plan sponsors must provide the option to opt into the Medicare Prescription Payment Plan to all Part D enrollees, including enrollees who are eligible for LIS. Consistent with the statute, in the proposed rule, we proposed to codify the requirement that Part D sponsors must offer the program to all Part D enrollees, including those who are LIS eligible, at § 423.137(d).

In addition, under section 1860D–2(b)(2)(E)(v)(III)(aa) of the Act, Part D plan sponsors may not restrict the application of the Medicare Prescription Payment Plan benefit to specific covered Part D drugs. We proposed to codify this requirement for 2026 and subsequent years at § 423.137(d)(5).

Section 1860D–2(b)(2)(E)(v)(II) of the Act also states that a Part D enrollee may opt into the Medicare Prescription Payment Plan prior to the beginning of the plan year or in any month during the plan year. In the proposed rule, we proposed the following requirements for 2026 and subsequent years:

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

We also proposed requirements for election into the program. We proposed that the Part D enrollee, or their authorized legal representative, must complete an election request, provide the required information to the Part D plan sponsor, and be approved by the Part D plan sponsor to opt into the Medicare Prescription Payment Plan. As discussed in more detail in the proposed rule, we also proposed to require Part D plan sponsors to have specific election mechanisms available to Part D enrollees who wish to opt into the Medicare Prescription Payment Plan.

We further proposed that Part D plan sponsors must consider Medicare Prescription Payment Plan election requests regardless of the election mechanism or format provided it includes certain information necessary to be complete, as described in the proposed rule.

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

We also outlined proposed requirements for receipt of election requests and incomplete election requests. We further proposed requirements for Part D plan sponsors to process retroactive election requests in cases where an enrollee cannot have immediate election into the program and believes that any delay in filling a prescription due to the 24-hour timeframe required to process a program election request may seriously jeopardize their life, health, or ability to regain maximum function and so must pay OOP to the pharmacy.

Section 1860D–2(b)(2)(E)(v)(II) of the Act requires Part D plan sponsors to offer the Medicare Prescription Payment Plan to all Part D enrollees in any month during the year. At § 423.137(d)(8), for 2026 and subsequent years, we proposed to codify requirements for mid-year plan switches, consistent with the requirements included in the final part one guidance for 2025. The proposed rule outlined new requirements related to participation in the program from year to year, a topic CMS did not address in the final part one guidance or final part two guidance because the IRA limited CMS's program instruction authority to a single year of the program (that is, contract year (CY) 2025). We proposed requiring Part D plan sponsors to send a notice alerting the Part D enrollee that their participation in the program will continue into the next year unless they indicate that they would like to opt out for the upcoming year. This notice would be required to be sent out to program participants by the end of the annual coordinated election period (no later than December 7) and must include the Part D plan sponsor's program terms and conditions for the upcoming year.

We also addressed other program election communications and notice requirements for Part D plan sponsors, including timing, content, and supplemental information requirements for the election request form, notice of election approval, and notice of denial.

CMS issued model materials that Part D enrollees can use to fulfill the election request and election approval requirements through the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model

Documents (CMS–10882; OMB 0938–1475) ICR package. As established in § 423.2267(c), model materials and content are required materials and content created by CMS as an example of how to convey beneficiary information. If Part D plan sponsors choose to not use a CMS-developed model version of a particular required material or content, they must still accurately convey the vital information in the required material or content to the beneficiary.

Comment: A few commenters expressed support for finalizing the effectuation timeframes for election requests, including the 24-hour effectuation requirement for election requests made during the plan year. A commenter requested that plans be able to make exceptions to the 24-hour requirement, such as for effectuating election requests received via paper form and requested that CMS exercise enforcement discretion for effectuation timeframes. Other commenters requested the effectuation timeframe for election requests made during the plan year be extended to 72 hours.

Response: CMS thanks the commenters for their feedback. To ensure a seamless election process for Part D enrollees and ensure they have timely access to the program and their Part D prescriptions, CMS is finalizing the requirement for Part D plan sponsors to process election requests received during the plan year within 24 hours. Through this requirement, CMS reiterates the importance of ensuring that Part D enrollees, once they request to participate, are able to access the benefits of the program as timely as possible. This is particularly important for those who may wait to pick up a prescription until their program participation is effectuated. Additionally, CMS emphasizes that Part D plan sponsors can encourage those who are likely to benefit from the program to opt in prior to the plan year or during the plan year prior to going to a pharmacy through strong education and outreach efforts.

In response to comments regarding operational challenges effectuating election requests received via the paper form, CMS acknowledges these concerns but reiterates the importance of ensuring that Part D enrollees gain timely access to the program and their prescriptions, regardless of the means of election request.

Comment: Many commenters expressed support for real-time election, stating that it would reduce burden on enrollees, prevent drug dispensing delays, and reduce prescription abandonment. Many of these commenters acknowledged that plan-facilitated real-time election may need to be implemented as a temporary measure but expressed a strong preference for a pharmacy-facilitated real-time election process once it is technologically feasible.

However, many commenters opposed requirements for real-time election, especially in the early years of the program. These commenters pointed to technological and operational challenges with real-time election (both plan-facilitated and pharmacy-facilitated) and requested additional years of program experience before considering a real-time election requirement. In addition, some commenters expressed concerns that real-time election processing could impose additional pharmacy burden (due to potential workflow disruption or provision of program education to enrollees).

Response: CMS thanks the commenters for their feedback CMS agrees that prompt access to the program is important and supports actions by Part D plan sponsors to prevent drug dispensing delays and reduce prescription abandonment. However, CMS also acknowledges that there are technological barriers to industry-wide implementation of real-time election for 2026. As noted in the proposed rule, our research indicates that there is no mechanism at the POS for program election information to be documented in a manner that complies with election requirements; technological updates would be needed to support POS election. These updates would require significant lead time and coordination with industry standards committees that have existing processes and timelines outside of CMS's purview.

While real-time election (facilitated by Part D plan sponsors outside of the POS) need not involve changes to the current NCPDP Telecommunication Standard, CMS recognizes that additional information technology systems modifications may be necessary for sponsor-facilitated election updates to interface in real-time with the pharmacy benefit manager (PBM) and pharmacy systems. Finally, CMS is cognizant of potential additional burden pharmacies may face under a real-time election option. As such, CMS is not requiring Part D plan sponsors to effectuate election requests received via phone or web in real-time for 2026. CMS continues to encourage Part D plan sponsors to process election requests within timeframes shorter than 24 hours or in real-time if they are able.

Additionally, CMS reiterates the importance of targeted outreach prior to the plan year to identify enrollees likely to benefit from the program in advance of any POS notifications, which will streamline the program election process. This requirement, alongside the 24-hour effectuation timeframe during the plan year and the required process to retroactively apply the program to those meeting criteria for an urgent situation, will reduce the likelihood of dispensing delays and prescription abandonment. CMS will continue to evaluate program operations and election processes and consider future modifications to effectuation requirements.

Comment: Many commenters expressed support for the proposed automatic election renewal process, stating that automatic renewal would reduce the burden on Medicare Prescription Payment Plan participants. Some commenters opposed the automatic renewal requirements, instead suggesting that automatic renewal be optional for plans to implement in the early years of the program. Some of these commenters also suggested that plans be able to exempt some participants from automatic renewal, such as those with unpaid cost sharing amounts or those who appear not likely to benefit in the upcoming year. A commenter suggested that CMS issue criteria to help plans identify a targeted subset of participants for renewal. Another commenter requested that participants in long-term care settings be exempt from automatic renewal.

Response: CMS thanks the commenters for their feedback. We agree that automatic renewal eases burden for both participants and plan sponsors. While there may be some participants who did not meet program thresholds for ''likely to benefit'' in the current year or who appear not likely to benefit in the upcoming year, we believe that consistent standards for participation renewal for all participants promotes the cleanest implementation of the program, especially in the early years of the Medicare Prescription Payment Plan.

Comment: Multiple commenters suggested that CMS revise the automatic renewal requirements to extend to participants switching plans within the same parent organization or Part D plan sponsor. A commenter requested that CMS clarify how automatic renewal would work with CMS-approved crosswalks.

Response: CMS thanks the commenters for their questions. The automatic renewal requirements are generally intended to align with existing

Part D program enrollment requirements. As such, if a Part D enrollee would be required to complete a new enrollment request for the upcoming plan year (such as when an enrollee chooses to switch between plan benefit packages (PBPs) within the same contract), that enrollee would also need to re-elect into the Medicare Prescription Payment Plan. Generally, in situations in which the Part D enrollee is not required to complete a new Part D enrollment request for the upcoming year (such as when someone remains in the same PBP or when their PBP is part of a consolidated renewal plan), then the enrollee's participation in the Medicare Prescription Payment Plan would also automatically carry over for the upcoming year.

Comment: A commenter requested that CMS clarify when the requirement for automatic renewal would start (that is, at the end of 2025 for CY 2026 or at the end of 2026 for CY 2027).

Response: Automatic renewal requirements will take effect for the CY 2026 plan year. As such, Part D plan sponsors will be required to automatically renew Medicare Prescription Payment Plan participation for enrollees who are participating in the program in 2025.

Comment: A couple of commenters requested that CMS update technical guidance for the submission of beneficiary-level data elements into the MARx Medicare Advantage Prescription Drug (MARx) system upon finalization of the rule to reflect the automatic renewal policy.

Response: CMS thanks the commenters for their recommendations. Any potential modifications to the technical guidance for CY 2026 will be published in Fall 2025.

Comment: Many commenters supported the requirement for a separate renewal notice, including the requirements to include the Part D plan sponsor's program terms and conditions for the upcoming year and a reminder that the participant may opt out of the program at any time, including for the upcoming plan year. Commenters requested the opportunity to review and provide feedback for the renewal notice through an Information Collection Request (ICR) process. Some commenters suggested alternative mechanisms to notify participants about automatic renewal, such as adding language to existing annual plan documents (such as the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC), the program notice of election approval, or the program monthly bill). A commenter also suggested that if a separate notice is required, it should be distributed after the annual coordinated election period to avoid confusion during times of increased plan switching.

Response: CMS thanks the commenters for their feedback. CMS believes that a separate notice is important to clearly communicate to Medicare Prescription Payment Plan participants that their program participation will continue in the upcoming plan year. The model notice will be incorporated into the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents ICR package (CMS–10882; OMB 0938–1475) and will be made available to the public for review and comment under the standard non-rule Paperwork Reduction Act (PRA) process which includes the publication of 60- and 30-day **Federal Register** notices and the posting of the collection of information documents on our PRA website. CMS will also consider adding educational language related to automatic renewal of participation to other Part D materials, such as the ANOC.

Finally, CMS appreciates the suggestion to delay the timing of the required renewal notice until after the annual coordinated election period to account for participants who may switch plans for the upcoming year and thus not be eligible for automatic renewal. CMS agrees that this will reduce beneficiary confusion and promote a more efficient automatic renewal process. At § 423.137(d)(10)(iv)(A), CMS has modified the timing requirement for the renewal notice in this final rule, such that the renewal notice must be sent after the end of the annual coordinated election period but prior to the beginning of the plan year.

Comment: A commenter requested that CMS clarify whether, given the automatic renewal process, plans would be required to send the program fact sheet, paper election request, and ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to Part D enrollees currently participating in the program.

Response: CMS appreciates the opportunity to clarify. Part D plan sponsors are required to send only the renewal notice to Part D enrollees who are currently participating in the Medicare Prescription Payment Plan and will be automatically renewed for the upcoming year. Part D plan sponsors are not required to perform ''likely to benefit'' analyses for current program participants, nor to send the ''Medicare Prescription Payment Plan Likely to Benefit Notice.'' We also note that although a Part D sponsor may choose to send the Medicare Prescription Payment Plan mailing described at § 423.137(m)(1) to all of its Part D enrollees or only to a Part D enrollee who is receiving a new membership ID card, we encourage Part D sponsors to not send the paper enrollment form to current Medicare Prescription Payment Plan participants to reduce potential beneficiary confusion.

Comment: A commenter requested that CMS remove requirements for telephonic delivery of the notice of election approval during the plan year. The commenter stated that the process adds to plan burden and is often confusing for beneficiaries, who have already received a confirmation number when they completed the telephone or electronic election process.

Response: CMS thanks the commenter for their feedback. CMS agrees that when a Part D plan sponsor is able to fully complete the election request process in the course of a telephonic or electronic interaction and at that same time provides the enrollee with the effective date of their program effectuation (which must be within 24 hours of receipt) and satisfies other notice of election approval requirements as outlined at § 423.137(d)(10)(ii), then a second telephonic notification of election acceptance is redundant. CMS is modifying the criteria at § 423.137(d)(10)(ii)(A)(*3*) to reflect that exception. In these cases, the Part D plan sponsor must still deliver the written notice within 3 calendar days.

Comment: A few commenters expressed support for the requirements for Part D plan sponsors to include information on the availability of the LIS program and other financial assistance programs in the election-related materials; a few commenters also requested that information about financial assistance programs be added to either the election request form or the educational materials required with the election request form. A few commenters suggested modifications to the requirements for the election request form, including adding language stating that enrollees with low, stable drug costs are not likely to benefit from the program and adding a field to differentiate election requests for the current year versus the upcoming plan year. A commenter requested that the period for opting into the Medicare Prescription Payment Plan for the upcoming plan year be delayed until December 10 (after the end of the annual coordinated election period) to allow for plan switching to be completed before processing elections.

Response: CMS thanks the commenters for their feedback and notes that the CMS-developed Medicare Prescription Payment Plan fact sheet contains information on programs, like the LIS program (also known as Extra Help), that can lower costs for enrollees.[16]

As stated in this final rule, Part D plan sponsors are required to furnish additional educational information on the Medicare Prescription Payment Plan with the election request form and the notice of acceptance; Part D plan sponsors are encouraged to use the CMS-developed educational fact sheet to satisfy requirements to provide supplemental information on the program. The fact sheet includes language to help enrollees decide if they are likely to benefit from participating in the program. With regard to the requested field to differentiate the intended year of the election request, CMS will consider any changes to the existing model materials through the standard non-rule PRA process. Under section 1860D–2(b)(2)(E)(v)(II) of the Act, a Part D enrollee may opt into the Medicare Prescription Payment Plan prior to the beginning of the plan year or in any month during the plan year. CMS believes that requiring Part D plan sponsors to allow Part D enrollees to opt into the Medicare Prescription Payment Plan prior to the plan year, including during the annual coordinated election period for the subsequent year, simplifies the election process for Part D enrollees.

Comment: A commenter expressed support for continuing to require telephone and electronic election options. Some commenters suggested that program election be integrated into Medicare Plan Finder.

Response: CMS thanks the commenters for their support and suggestions. CMS notes that enhancements were made to Medicare Plan Finder starting with CY 2025 to display a cost preview based on a consumer's specific drug list, a set of consumer-selected MA or Part D plans, and consumer-selected pharmacies, including both retail locations and mail order options. However, CMS reiterates that participation in the Medicare Prescription Payment Plan is an arrangement between the Part D plan sponsor and the Part D enrollee, and, as such, Part D plan sponsors are ultimately responsible for managing the election process.

Comment: A few commenters expressed support for CMS's requirement that in case of retroactive election, the Part D plan sponsor is responsible for reimbursing the participant, not the pharmacy. A commenter requested that the timeframe for processing retroactive election requests be extended from 24 hours to 72 hours.

Response: CMS thanks the commenters for their support and feedback. CMS is finalizing requirements for retroactive election requests as proposed. With respect to retroactive election requests, CMS reiterates the importance of ensuring that Part D enrollees, once they request to participate, are able to access the benefits of the program as timely as possible. CMS believes that this applies equally to a retroactive election request as to a non-retroactive request. Accordingly, we are finalizing this requirement as proposed.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, at § 423.137(d)(9), for 2026 and subsequent years, we are finalizing the proposed requirements related to participation renewal, with a modification to the timing of the required notice and required contents. The notice must be sent after the end of the annual coordinated election period but prior to the end of the plan year; Part D plan sponsors must include their program terms and conditions for the upcoming plan year as part of the renewal notice or as a separate attachment. We are also finalizing as proposed those requirements for 2026 and subsequent years at § 423.137(d)(10)(ii), with one modification. In response to comments received, we are modifying the criteria for when an initial telephone notice of election approval is not required. If a Part D plan sponsor is processing an election request over the phone or electronically and at that same time provides the enrollee with the effective date of their program effectuation (which must be within 24 hours of receipt) and other notice of election requirements as outlined at § 423.137(d)(10)(ii), then a second telephonic notification of election acceptance is not required. In these cases, the Part D plan sponsor must still deliver the written notice within 3 calendar days. We are finalizing all other provisions as § 423.137(d) as proposed.

d. Part D Enrollee Targeted Outreach

Consistent with our authority under section 11202 of the IRA and under section 1860D–12(b)(3)(D) of the Act, in the proposed rule, we proposed to codify the targeted outreach framework and thresholds established in the final part one guidance and final part two guidance at § 423.137(e). The statute establishes that some Part D enrollees will incur OOP costs that make them likely to benefit from election into the Medicare Prescription Payment Plan. While this program is open to all Part D enrollees, Part D enrollees incurring high OOP costs earlier in the plan year are generally more likely to benefit. Section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act requires that Part D plan sponsors have a mechanism in place to notify a pharmacy when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the enrollee may benefit from participating in the program. CMS recognizes, however, that notification of Part D enrollees likely to benefit from the Medicare Prescription Payment Plan prior to reaching the pharmacy POS will be a critical component to program success. Therefore, in the 2025 guidance, CMS proposed requirements for Part D plan sponsors to undertake targeted outreach, both prior to and during the plan year, directly to Part D enrollees likely to benefit from the program.

While the statute requires a likely to benefit notification, it does not outline the specific criteria or define the profile of someone who is likely to benefit under the program. As discussed in further detail in the proposed rule, CMS developed a standardized, quantitative framework for assessing ''likely to benefit,'' which was used to inform targeted outreach requirements both prior to and during the plan year.

For 2026 and subsequent years, we proposed to codify at paragraph (e)(1)(i)(A) of § 423.137 that a Part D enrollee is likely to benefit from participating in the program if the enrollee incurs $600 or more in OOP costs for a single prescription. Additionally, at paragraph (e)(2), we proposed to codify that Part D plan sponsors must notify a pharmacy when a Part D enrollee incurs OOP costs for a single prescription that equals or exceeds the $600 POS threshold.

As discussed in the proposed rule, for 2025, CMS required Part D plan sponsors to review their Part D claims history from the first three quarters of the year and conduct outreach to Part D enrollees who incurred at least $2,000 in OOP costs for covered drugs through September of 2024. Part D plan sponsors may develop supplemental strategies for identification of Part D enrollees likely to benefit prior to the plan year. In the proposed rule, for 2026 and subsequent years, we proposed to codify, at

[16] The Medicare Prescription Payment Plan fact sheet can be accessed at *medicare.gov/publications.*

paragraph (e)(1)(i)(B), this likely to benefit criteria and, at paragraph (e)(3)(i), the related requirements for Part D plan sponsor direct outreach to identified likely to benefit prior to the plan year. In addition to these criteria, in the final part two guidance, CMS established a requirement for 2025 for Part D plan sponsors to put in place reasonable guidelines for ongoing identification of Part D enrollees likely to benefit during the plan year. We proposed to codify this requirement for ongoing identification and notification of enrollees for 2026 and subsequent years at paragraph (e)(3)(ii).

Based on the required analysis to fulfill requirements at paragraph (e)(3) and any additional analysis Part D plan sponsors conduct to identify enrollees who may be likely to benefit from this program, we proposed to codify at paragraph (e)(4) that the Part D plan sponsor must send the standardized ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to identified enrollees. We proposed to add this notice as a required standardized communication material for Part D plan sponsors at § 423.2267(e)(47). Prior to the plan year, the notification must occur no later than the end of the annual coordinated election period (open enrollment), which is December 7 of each year. We proposed that this outreach may be done via mail or electronically (based on the Part D enrollee's preferred and authorized communication methods) and must include a Medicare Prescription Payment Plan election request form. The outreach must also include additional information about the Medicare Prescription Payment Plan, which may be fulfilled by including the CMS-developed fact sheet.

In the proposed rule, we proposed to codify at paragraph (e)(4)(i)(A) of § 423.137 that if Part D plan sponsors develop and use alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR part 423, subpart V, and in the Medicare Communications and Marketing Guidelines (MCMG). Additionally, the initial notice may be provided via telephone, so long as the standardized ''Medicare Prescription Payment Plan Likely to Benefit Notice'' and additional information are sent within 3 calendar days of the telephone notification.

As discussed in the proposed rule, Part D plan sponsors should be aware that potential changes to a Part D enrollee's clinical condition, medication status, or cost sharing (for example, discontinuation of therapy or addition of supplemental payers) could affect the likelihood that a Part D enrollee may benefit from the Medicare Prescription Payment Plan and should counsel enrollees about their participation in the program accordingly. There are scenarios in which a Part D enrollee is less likely to benefit, and therefore, should not be notified that they are likely to benefit from the program. In the proposed rule, we proposed to codify at paragraph (e)(5) the targeted outreach exclusions.

As noted in the proposed rule, we plan to revisit these targeted outreach requirements in future rulemaking, as CMS gains program experience and can evaluate program data and operations. In general, we expect to maintain the same overall framework for targeted outreach. In the proposed rule, we outlined an approach where CMS would assess the targeted outreach requirements for the POS notification threshold and prior to plan year criteria on an annual basis and make modifications, if needed, based on review and analysis of Medicare Prescription Payment Plan data and other Medicare data. Although CMS is not codifying an approach to modifying targeted outreach criteria for future years of the program, we solicited public comments on the approach and will use feedback from interested parties to support future policy development.

Comment: Several commenters expressed support for CMS's intent to evaluate its targeted outreach framework and the likely to benefit thresholds for future years based on program experience. Specifically, a few commenters recommended that CMS use 2025 as an evaluation year to assess the Medicare Prescription Payment Plan's current operations, including the criteria for providing the ''Medicare Prescription Payment Plan Likely to Benefit Notice.'' Several commenters expressed support for CMS's proposal to maintain the current framework for targeted outreach to enrollees that are likely to benefit, including those who reached the $2,000 threshold by September of the previous plan year. A commenter stated that the proposal should help to minimize pharmacies' administrative burdens.

Response: CMS appreciates the commenters' support and feedback. As outlined in the proposed rule, CMS plans to revisit these requirements in future rulemaking, after gaining program experience and evaluating program data and operations.

Comment: A few commenters recommended that CMS reevaluate the identification criteria for likely to benefit to exclude LIS members, dually eligible individuals, or fully integrated dual eligible special needs plan (FIDE SNP) and highly integrated dual eligible special needs plan (HIDE SNP) members who already have limited cost-sharing responsibilities. A commenter recommended CMS narrow the scope of the program and relieve administrative burden on Part D plan sponsors by setting a higher threshold. The commenter stated that as currently implemented, any member with any amount of cost-sharing may elect into the program. Another commenter recommended CMS adopt a lower threshold for determining which patients will likely benefit from participation in the program. The commenter stated that the pharmacy POS notification threshold is too high and should take into account the total cost of all prescriptions a patient collects at the pharmacy that day and their OOP costs to date.

Response: CMS thanks the commenters for their feedback. Under section 1860D–2(b)(2)(E)(i) of the Act, Part D plan sponsors must provide the option to opt into the Medicare Prescription Payment Plan to all Part D enrollees, including enrollees who are eligible for LIS. As discussed in the proposed rule, individuals with low, stable drug costs (such as LIS enrollees) are not likely to benefit from the program. Therefore, Part D plan sponsors are encouraged to provide support tailored to beneficiaries' unique situations and clearly communicate to enrollees when it appears that they are less likely to benefit from the program (for example, enrollees with low-to-moderate recurring OOP drug costs). Additionally, as discussed in the proposed rule, CMS has established requirements for Part D plan sponsors to provide information on the LIS program as part of their Medicare Prescription Payment Plan materials, including in the billing statement, notice of election approval, and on their websites. For the pharmacy POS notification, CMS chose a single prescription drug cost POS threshold of $600 because this approach strikes the best balance between identifying Part D enrollees with a very high likelihood (~98 percent) of benefiting from the Medicare Prescription Payment Plan, while reducing the risk of identifying Part D enrollees for whom the program may not be as helpful.[17]

[17] In the final part one guidance, CMS summarized key findings from an analysis of POS

Comment: A few commenters recommended that CMS assess the efficacy of the targeted outreach criteria by investigating and publishing data on OOP costs of those enrollees who are likely to benefit and who elect into the program and of those enrollees who were notified that they were likely to benefit but did not elect into the program.

Response: CMS appreciates the commenters' suggestions. As stated in the proposed rule, CMS requires Part D plan sponsors to report information related to the Medicare Prescription Payment Plan on prescription drug event (PDE) records and through reporting requirements at the beneficiary level through the MARx system and contract-PBP levels through the Health Plan Management System (HPMS). CMS will use these data to assess any potential revisions to the POS notification threshold in future years and will consider opportunities for publicly sharing the data.

Comment: A commenter recommended that CMS conduct broader outreach to beneficiaries beyond the targeted outreach notification requirements. The commenter stated that broad outreach is important for many patients who may not fall into the likely to benefit parameters but could still see significant positive impacts from the program.

Response: CMS thanks the commenter for their feedback. CMS agrees that educating beneficiaries about the program is important for its success. In advance of the implementation of the program on January 1, 2025, CMS developed new educational resources and updated existing Part D materials, such as the ANOC, EOC, and Explanation of Benefits (EOB), to inform Part D enrollees about the program. CMS's education and outreach efforts discussed in the proposed rule and this final rule are not comprehensive of the various activities CMS is undertaking to educate Part D enrollees and other stakeholders about the program. Supporting broad awareness of the Medicare Prescription Payment Plan is, however, a shared responsibility between CMS and Part D sponsors. To ensure all prospective and current Part D enrollees are aware of the program, CMS has also established general Part D plan sponsor outreach and education requirements, which are discussed in further detail in the proposed rule and this final rule. After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed provisions at § 423.137(e) without modification.

e. Termination of Election, Reinstatement, and Preclusion

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

We proposed standards for termination of election, reinstatement, and preclusion consistent with the statutory requirements. CMS established procedures for voluntary termination of election, under which Part D plan sponsors are required to have a process to allow a participant who has opted into the Medicare Prescription Payment Plan to opt out during the plan year. For 2025, we required Part D plan sponsors to process the participant's voluntary termination request and send the individual a notification confirming the termination within 10 calendar days of receipt of the request but did not specify the effective date of termination. For 2026 and subsequent years, we proposed to maintain the requirement for Part D plan sponsors to send the notice of voluntary termination within 10 calendar days of receipt but require that the effective date of termination must be within 24 hours of receipt of the voluntary termination request. We solicited public comment on this proposal.

When a participant opts out of the Medicare Prescription Payment Plan, a Part D plan sponsor must provide the individual with a notice of voluntary termination after the individual notifies the Part D plan sponsor that they intend to opt out under the Part D plan sponsor's established process. At § 423.137(f)(2)(i)(A)(*2*)(*ii*) of the proposed rule, we outlined required contents for the notice of voluntary termination. As discussed in the proposed rule, a Part D plan sponsor must offer the enrollee terminating their program participation the option to repay the full outstanding amount in a lump sum but is prohibited from requiring full immediate repayment from a participant. For 2026 and subsequent years, we proposed to codify the voluntary termination process and notice requirements at § 423.137(f)(2)(i) and to add the voluntary termination notice as a required material and content for Part D plan sponsors at § 423.2267(e)(50).

We also proposed standards for involuntary termination, including requirements for the provision of a grace period of at least two months when an individual has failed to pay the billed amount by the payment due date and requirements for reinstatement. If an individual fails to pay the billed amount within 15 calendar days of the payment due date, the Part D plan sponsor must send the individual an initial notice of failure to pay. The required contents of the notice of failure to pay are detailed in the proposed rule and at § 423.137(f)(2)(ii)(C)(*2*)(*i*). If the individual fails to pay the amount due by the end of the grace period, the Part D plan sponsor must send the individual an involuntary termination notice explaining that the individual has been terminated from the Medicare Prescription Payment Plan. We proposed that the involuntary termination notice must be sent within 3 business days following the last day of the end of the grace period and must include the contents detailed in the proposed rule and at § 423.137(f)(2)(ii)(D)(*2*). For 2026 and subsequent years, we proposed to codify these notice requirement standards at § 423.137(f)(2)(ii) and to add the notice of failure to pay and notice of involuntary termination as required model materials and content for Part D plan sponsors at § 423.2267(e)(48) and (49). For the grace period, we proposed to make certain modifications to the timing requirements for the grace period and initial notice of nonpayment established in the final part one guidance. Specifically, for 2025, we required that the grace period must begin on the first day of the month for which the balance is unpaid or the first day of the month following the date on which the payment is requested, whichever is later. For 2026 and subsequent years, we proposed to change the date on which the grace period must begin to the first day of the month following the date on which the initial notice is sent. As discussed in the proposed rule, we believe this would simplify the timing requirements for the notice of nonpayment and the required grace period. We solicited comment on the proposed change.

We proposed that if a participant fails to pay their monthly billed amount with fewer than two full calendar months remaining in the calendar year, the grace period must carry over into the next calendar year. If the program

thresholds ranging from $400 to $1,000. The proportion of identified enrollees who would benefit from the program ranged from 90 percent to greater than 99 percent.

participant is within their grace period from the prior year, the Part D plan sponsor must allow the participant to opt into the program for the next year, but if the participant fails to pay the amount due from the prior year during the required grace period, the Part D plan sponsor may terminate the individual's participation in the program in the new year.

A participant must be allowed to pay the overdue balance in full during the grace period to remain in the program. Additionally, Part D plan sponsors must reinstate an individual who has been terminated from the Medicare Prescription Payment Plan within a reasonable timeframe if the individual demonstrates good cause for failure to pay the program billed amount within the grace period and pays all overdue amounts billed. As discussed in the proposed rule, CMS proposed to adopt the same meaning of ''good cause'' outlined in section 60.2.4 of the Medicare Prescription Drug Benefit Manual, Chapter 3—Eligibility, Enrollment and Disenrollment that applies to reinstatements when an enrollee fails to pay their Part D premiums. A Part D plan sponsor may reinstate an individual who has been terminated from the Medicare Prescription Payment Plan and pays all overdue amounts billed in full, at the sponsor's discretion and within a reasonable timeframe, even if the individual does not demonstrate good cause. For 2026 and subsequent years, we proposed to codify these grace period and reinstatement requirements at § 423.137(f)(3).

In the proposed rule, we clarified that, consistent with the statute, a Part D plan sponsor may only preclude an individual from participating in the Medicare Prescription Payment Plan in a subsequent year if the individual owes an overdue balance to that plan sponsor. If an individual enrolls in a Part D plan offered by a different Part D plan sponsor than the Part D plan sponsor to which the individual owes an overdue balance, that individual cannot be precluded from opting into the Medicare Prescription Payment Plan in a subsequent year by that different Part D plan sponsor. We also stated that preclusion may extend beyond the immediate subsequent plan year if a Part D enrollee remains in a plan offered by the same Part D plan sponsor and continues to owe an overdue balance. For 2026 and subsequent years, we proposed to codify requirements related to preclusion of election in a subsequent plan year at § 423.137(f)(4).

We proposed to prohibit Part D enrollment penalties for failure to pay a Medicare Prescription Payment Plan amount billed. Additionally, we outlined that a Part D plan sponsor is prohibited from disenrolling a Part D enrollee from a Part D plan or declining future enrollment into a Part D plan for failure to pay any amount billed under the Medicare Prescription Payment Plan. We also proposed that if a participant in the Medicare Prescription Payment Plan is disenrolled voluntarily or involuntarily from their Part D plan under the provisions at 42 CFR 423.44(b), the participant is also terminated from the Medicare Prescription Payment Plan in that plan. For 2026 and subsequent years, we proposed to codify these requirements at § 423.137(f)(5) and (6).

Comment: Several commenters expressed support for CMS's proposal to clearly identify the grace period start date and simplify the grace period timing requirements by changing the start of the grace period to the first day of the month following the issuance of the initial failure to pay notice. A commenter stated that the change will provide a better member experience and simplify plan sponsor operations and management of the program. However, a few commenters expressed opposition to the proposal, noting that it will extend the grace period by up to a month from the initial claim in some cases. The commenters expressed concern that this will allow for potential program abuse by extending the time to accumulate unpaid claims before Part D plan sponsors can end beneficiaries' participation in the program. Another commenter stated that the grace period should begin on the due date of missed payment because this is a date that is known by all parties.

A commenter expressed opposition to the proposed grace period length and recommended CMS shorten the minimum grace period to reduce potential risk for non-payments.

Response: CMS thanks commenters for their feedback. CMS will continue to engage stakeholders on issues related to implementation and program integrity. While CMS appreciates the recommendation to have the grace period begin on the due date of the missed payment, we do not agree with the suggestion. Requiring the grace period to begin on the first day of the month following the date on which the initial notice is sent simplifies the program requirements, reducing the burden on Part D plan sponsors.

Comment: A few commenters recommended that CMS add information about retroactive LIS eligibility to the notice of voluntary termination, notice of failure to pay, involuntary termination notice, and billing statement in order to provide timely information about accessing LIS assistance. A commenter recommended that the involuntary and voluntary termination notices for the program include reminders to beneficiaries to continue to pay monthly Part D premiums to maintain drug coverage.

Response: CMS thanks commenters for their feedback. As discussed in the proposed rule, CMS has established requirements for Part D plan sponsors to provide information on the LIS program as part of their Medicare Prescription Payment Plan materials. Part D plan sponsors are required to include general information about the LIS program, including how LIS enrollment for eligible individuals is likely to be more advantageous than participation in the Medicare Prescription Payment Plan, on their websites. In addition, the notice of election approval must include an overview of other Medicare programs that can help lower costs, including the LIS Program (also known as Extra Help), the Medicare Savings Program, the State Pharmaceutical Assistance Program, and the Manufacturer's Pharmaceutical Assistance Program, and how to learn more about these programs. Additionally, CMS notes that the involuntary termination and voluntary termination notices are both required to include a statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan.

Comment: Several commenters expressed concern about the proposed requirement that voluntary terminations take effect within 24 hours. They recommended that CMS extend the timeframe for the effective date of termination to 3 business days or 72 hours from the time the plan sponsor receives the voluntary termination request to accommodate the need for greater flexibility in processing times in some cases, including weekends and holidays. A commenter stated that changing the requirement to 3 business days would provide plan sponsors with adequate time to process the request within the allotted time, provide uniformity across the industry for the program, and simplify data submission processes. A few commenters expressed support for the 24-hour timeframe for the effective date of termination. A commenter stated that CMS has not specified the termination events that fall within the 24-hour requirement. The commenter recommended that CMS provide guidance on the effective program termination date for all plan disenrollment events.

Response: CMS thanks commenters for their feedback. While the 24-hour requirement aligns with the required timeframe for processing election requests during the plan year, CMS agrees that extending the timeframe reduces burden on Part D plan sponsors while still ensuring a timely response to opt out requests during the plan year. Consequently, we are modifying our proposal of 24 hours and finalizing the requirement as 3 calendar days. We are not adopting the recommendation of 3 business days as suggested by a few commenters in order to simplify program requirements by making all timeframe requirements in calendar days. All scenarios in which the Part D enrollee requests to voluntarily terminate their participation in the program must be processed within the 3-calendar day window. CMS is not providing guidance on the effective date for Part D plan sponsors to process involuntary terminations at this time but continues to welcome stakeholder feedback on the issue.

Comment: A commenter stated that patients and pharmacies are concerned that a plan would attempt to collect the unpaid balance at the pharmacy counter after the required 2-month grace period. The commenter recommended that CMS make it easy for beneficiaries and pharmacists to file a complaint with CMS if they suspect incorrect cost-sharing calculations and wrongful termination from the program. Another commenter expressed support for proposals to protect enrollees from improper termination.

Response: CMS appreciates the commenters' feedback and recognizes concerns about protecting beneficiaries from wrongful termination. As described in the proposed rule, Part D sponsors must use their existing coverage determination, appeals, and grievance procedures for the Medicare Prescription Payment Plan to ensure that Part D enrollees have the ability to contest copay amounts and any adverse decisions related to participation in the Medicare Prescription Payment Plan. Additionally, CMS tracks plan grievances and beneficiary complaints entered in the Medicare Complaints Tracking Module (CTM) to assess compliance with all Medicare Prescription Payment Plan requirements and ensure program integrity.

Comment: A commenter recommended that the calculation in the first paragraph of the model notice of failure to pay be aligned with the changes in the final rule and provide the updated model as soon as possible.

Response: CMS thanks the commenter for their suggestion. CMS issued model materials that Part D enrollees can use to fulfill the failure to pay, involuntary termination, and voluntary termination notice requirements through the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS–10882; OMB 0938–1475) ICR package. We will make any necessary changes to align the existing model materials with this final rule through the standard non-rule PRA process, which includes the publication of 60- and 30-day **Federal Register** notices.

Comment: A commenter stated that in section 80.3 of the final part one guidance, CMS states that ''preclusion is only permitted in plans that are offered by the same parent organization.'' The commenter recommended that CMS aligns the language in the proposed rule with the final part one guidance by replacing ''Part D sponsor'' with ''parent organization'' to provide additional clarity and to ensure preclusion is applied consistently by Part D plan sponsors. Another commenter stated that the proposal for § 423.137(f)(4) may be partially unenforceable. The commenter observed that section 1860D–2(b)(2)(E)(v)(IV) of the Act states that ''if an enrollee fails to pay the amount billed for a month as required under this subparagraph [. . .] the PDP sponsor or MA organization may preclude the enrollee from making an election pursuant to clause (i) in a subsequent plan year.'' The commenter argued that, based on their interpretation of the statute, enrollees with the same Part D plan sponsor can be denied participation even after they pay off the outstanding Medicare Prescription Payment Plan balance.

Response: With respect to the comment regarding the use of ''Part D sponsor'' versus ''parent organization'' as it pertains to preclusion, we acknowledge that the final part one guidance referred to ''parent organization'' and replacing ''Part D sponsor'' with ''parent organization'' in the final rule would be consistent with the final part one guidance. However, we believe that using ''Part D sponsor'' instead of ''parent organization'' is more consistent with the statutory language in section 1860D–2(b)(2)(E)(v)(IV)(bb) of the Act without substantively changing the standards for preclusion in election stated in the final part one guidance. Therefore, we are finalizing the reference to ''Part D sponsor'' in the final rule. With respect to the comment regarding the meaning of failure to pay the amount billed, we disagree that section 1860D–2(b)(2)(E)(v)(IV) of the Act permits a Part D plan sponsor to preclude an enrollee from participating in the Medicare Prescription Payment Plan even after they pay off an outstanding Medicare Prescription Payment Plan balance. We do not believe that this interpretation, which would permit a Part D sponsor to forever preclude an enrollee from the program even after they pay any outstanding balance, is consistent with the statute. We consider the best reading of the statute to be that an individual who pays a Medicare Prescription Payment Plan balance is no longer considered to have failed to pay an amount billed, even if the balance was overdue at the time of payment. As such, preclusion would not apply to such an individual.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing all proposed provisions at § 423.137(f) without modification except for the proposals at § 423.137(f)(2)(i)(A)(*1*) and (f)(2)(ii)(D)(*1*) which we are finalizing with modifications.

f. Participant Billing Rights

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

As discussed in the proposed rule, we proposed to codify the requirements established for calendar year 2025 in the final part one guidance for 2026 and subsequent years at § 423.137(g) with an exception. In the final part one guidance, we stated that the plan must work with the participant to determine if they should either refund the difference directly to the Part D enrollee or apply the overpayment to the remaining OOP costs owed by the participant. In the proposed rule, we proposed to require a plan follow its normal processes for adjustments and issuing refunds. We believe this modification will simplify operational processes on the part of Part D plan sponsors without negatively impacting Medicare Prescription Payment Plan participants.

In addition, in the proposed rule, we proposed to modify the approach when Part D claims adjustments result in increased amounts owed by the participant; instead of stating that Part D plan sponsors ''should'' include the additional costs in the revised calculations of remaining OOP costs owed by the participant, we proposed that Part D plan sponsors ''must''

include the increased amount in this manner. This is consistent with the requirement established in the final part one guidance and included in section II.C.2.b. of the proposed rule, which states that once a participant incurs an OOP Part D drug cost, all their OOP costs for all covered Part D drugs will be billed on a monthly basis as long as the participant remains in the program, as well as the uniform benefits requirements at § 423.104(b)(2).

Comment: Multiple commenters expressed support for CMS's proposal to codify the Medicare Prescription Payment Plan billing requirements with certain modifications.

Response: CMS thanks the commenters for their support.

Comment: Several commenters opposed CMS's proposal to require that Medicare Prescription Payment Plan bills be sent separately from monthly billing statements for Part D premiums. Commenters expressed concern that requiring separate bills could cause beneficiary confusion and lead to nonpayment of Medicare Prescription Payment Plan balances, PDP or MA premiums, or both. Commenters requested that CMS allow Part D plan sponsors the flexibility to send either two separate billing statements for monthly premiums owed and amounts owed under the Medicare Prescription Payment Plan, or a single monthly bill that clearly shows monthly premium amounts owed, any cost sharing amounts owed for the prior month under the Medicare Prescription Payment Plan, and the total amount owed to the plan for the month.

Response: CMS appreciates the feedback from commenters on the program's monthly billing statement. The separate monthly program bill is to ensure that program participants do not confuse their payments for incurred OOP costs with their premium or other bills sent from the plan. CMS believes that there is a greater risk of beneficiary confusion from a combined bill rather than separate bills for the Medicare Prescription Payment Plan and Part D premiums. As such, CMS is finalizing this requirement as proposed. CMS intends to continue to engage with stakeholders and incorporate feedback into future rulemaking, as applicable, as Part D plan sponsors gain more experience with the current requirements.

Comment: A commenter expressed opposition to our proposal to require that Part D plan sponsors allow Medicare Prescription Payment Plan participants with unpaid past due balances under a previous plan and who switch plans to elect into the Medicare Prescription Payment Plan under a new plan offered by a different plan sponsor. The commenter expressed concern that carrying a past due invoice from a former plan and joining the program in a new plan may cause beneficiary confusion. The commenter also requested that CMS develop stronger incentives to prevent enrollees from switching plans solely to avoid paying their outstanding cost-sharing bills.

Response: CMS appreciates the commenter's concern but declines to allow Part D plan sponsors to preclude Medicare Prescription Payment Plan participants with unpaid past due balances under a previous plan and who switch plans from electing into the Medicare Prescription Payment Plan. We believe the plain text of the statute limits preclusion of election to only that Part D plan sponsor to which a participant has failed to pay an amount billed. Section 1860D–2(b)(2)(E)(v)(IV)(bb) of the Act requires that, if an enrollee fails to pay the amount billed for a month as required under the Medicare Prescription Payment Plan, ''the PDP sponsor or MA organization may preclude the enrollee from making an election'' to participate in the Medicare Prescription Payment Plan in a subsequent plan year. The statute's use of the definite article ''the'' when referring to the PDP sponsor or MA organization that may preclude an enrollee limits the ability to preclude an enrollee's election to only *the* PDP sponsor or MA organization that is owed the overdue balance and that terminated the enrollee's election pursuant to section 1860D–2(b)(2)(E)(v)(IV)(aa) of the Act.

Comment: A commenter requested that CMS consider allowing Part D plan sponsors to require a single final Medicare Prescription Payment Plan payment upon an enrollee's termination from the Medicare Prescription Payment Plan, rather than providing the option of continued monthly billing after termination, particularly if the enrollee has completely left the PDP or MA–PD plan.

Response: CMS appreciates commenters' feedback regarding billing after a participant is terminated from the Medicare Prescription Payment Plan. CMS included the prohibition of a Part D sponsor from requiring full immediate repayment from a participant who has been terminated from the Medicare Prescription Payment Plan to ensure that individuals are offered maximum flexibility in paying their outstanding balances after termination from the program (either voluntary or involuntary). CMS notes that Part D plan sponsors must offer an individual the option of paying off the outstanding balance as a lump sum amount and anticipates that some individuals may choose that option.

Comment: Several commenters expressed support for CMS's proposal to revise the requirements related to payment adjustments to require that a Part D plan sponsor follow its normal processes for adjustments and issuing refunds and to require that Part D plan sponsors ''must'' include additional costs in the revised remaining OOP costs owed by the participant when Part D claims adjustments result in increased amounts owed by the participant. Commenters expressed that these revisions support program efficiency and transparency. A commenter opposed CMS's proposal to require plan sponsors to include additional costs resulting from Part D claims adjustments in the revised remaining OOP costs owed by a participant and stated that the commenter would prefer for Part D plan sponsors to retain flexibility in the application of these costs until there is at least one year of program experience.

Response: CMS thanks the commenters for their feedback. While CMS appreciates the concerns raised about retaining flexibility in the application of these costs, CMS believes that its revised approach simplifies the requirements for Part D plan sponsors and ensures a uniform experience for Medicare Prescription Payment Plan participants across plans.

Comment: A commenter expressed support for the proposed list of information to be included in the participant billing statement and anticipated that billing statements should not vary significantly from one Part D plan sponsor to another given the specific information required.

Response: CMS thanks the commenter for their support.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed provisions at § 423.137(g) without modification.

g. Participant Disputes

As discussed in the proposed rule at 89 FR 99368, in the proposed rule, CMS proposed to codify at § 423.137(h) requirements for Part D plan sponsors to apply their existing Part D coverage determination, appeal, and grievance procedures to the Medicare Prescription Payment Plan, consistent with the requirements established in the final part one guidance.

In the proposed rule, we stated that Part D plan sponsors must apply their

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

No comments were received on this proposal. In this final rule, we finalize these requirements as proposed for 2026 and subsequent years.

h. Pharmacy POS Notification Process

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

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

The proposed rule also outlined POS requirements for the distribution of the ''Medicare Prescription Payment Plan Likely to Benefit Notice,'' including different processes based on pharmacy setting type. In pharmacy settings in which there is direct contact with enrollees (for example, community pharmacies where enrollees present in person to pick up prescriptions), the proposed rule set forth that the Part D plan sponsor must ensure that a hard copy of the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' is provided to enrollees identified as likely to benefit (or the person acting on their behalf) at the time the prescription is picked up. The proposed rule also set forth that if the pharmacy is in contact with a Part D enrollee identified as likely to benefit and the enrollee declines to complete the prescription purchase, the Part D plan sponsor must ensure that the pharmacy provides the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to the Part D enrollee. Finally, the proposed rule noted that some pharmacy types may not have direct contact with Part D enrollees and/or may lack a practical means for providing the physical standardized ''Medicare Prescription Payment Plan Likely to Benefit Notice'' directly to the Part D enrollee and proposed standards for those settings.

The proposed rule discussed the unique situation of long-term care pharmacies in the preamble and noted that because these pharmacies typically do not have a POS encounter with the enrollee, when the POS notification is received by a long-term care pharmacy, the Part D plan sponsor should not require that the long-term care pharmacy provide the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' prior to dispensing the medication. Instead, the Part D plan sponsor should require the long-term care pharmacy to provide the notice to the Part D enrollee (or their authorized representative) at the time of its typical enrollee cost-sharing billing process.

The proposed rule also discussed special approaches to the POS notification requirements for Indian Health Service (IHS), Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies, which provide no-cost prescription drugs to eligible IHS enrollees. When IHS-eligible Part D enrollees fill a prescription at an I/T/U pharmacy, their covered Part D prescription drug cost sharing, as defined by their plan's benefit structure, is not collected at the POS. As such, if a high-cost prescription drug claim for a Part D enrollee is submitted to a Part D sponsor from an I/T/U pharmacy, the Part D sponsor is not required to return the pharmacy notification indicating the enrollee is likely to benefit from the program. Part D sponsors should also ensure that their customer service representatives are aware of this situation regarding I/T/U pharmacies when receiving inquiries from Part D enrollees regarding program election.

In the proposed rule, we also proposed that for other pharmacy types without in-person encounters (such as mail order pharmacies), Part D sponsors must require the pharmacy to notify the Part D enrollee via a telephone call or their preferred contact method. We noted that this proposed requirement should not, however, be interpreted as a requirement to delay dispensing the medication. Pharmacies are encouraged to utilize existing touchpoints with Part D enrollees, such as outreach to review medication instructions or collect a method of payment, to convey the content of the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' prior to processing payment for the prescription that triggered the notice. Finally, in the proposed rule, we noted that, given the statutory requirement for notification of enrollees likely to benefit at the pharmacy POS, Part D plan sponsors must ensure that their pharmacy network contracts include a provision requiring pharmacies to provide this notification to Part D enrollees.

Comment: A commenter expressed support for the POS notification requirement. Another commenter requested that the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' only be required to be distributed at the POS for initial prescription fills and transfers. A commenter opposed the requirement to provide a hard copy of the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to enrollees identified as likely to benefit and instead requested that pharmacies be allowed to provide the likely to benefit notice via other mechanisms, such as via text messaging, QR codes, patient portal, or

other electronic methods, and make a hard copy available upon request.

Response: CMS thanks the commenters for their feedback. As described in the proposed rule, in pharmacy settings with direct contact with Part D enrollees, the Part D plan sponsor must ensure that a hard copy of the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' is provided to enrollees identified as likely to benefit (or the person acting on their behalf) at the time the prescription is picked up for every prescription that meets the likely-to-benefit notification threshold. For pharmacy types without in-person encounters (such as mail order pharmacies), Part D plan sponsors must require the pharmacy to notify the Part D enrollee via a telephone call or their preferred contact method. These notification strategies are a minimum requirement; pharmacies are encouraged to leverage additional notification strategies (such as those mentioned by the commenters previously).

Comment: A few commenters expressed support for the requirement to use NCPDP code values for communicating with pharmacies. A few commenters requested additional pharmacy education and training, including resources related to the NCPDP-approved message codes used to notify the pharmacy.

Response: CMS thanks the commenters for their feedback. We are finalizing the requirement that the Part D plan sponsor must use standard NCPDP code values for notifying the pharmacy that an enrollee has been identified as likely to benefit at § 423.137(i)(1). CMS will continue to work with Part D plan sponsors to ensure they provide educational materials to pharmacies, providers, and other interested parties.

Comment: A commenter expressed concern that Part D plan sponsors or PBMs will undertake pharmacy audits related to Medicare Prescription Payment Plan pharmacy processes and distribution of the ''Medicare Prescription Payment Plan Likely to Benefit Notice,'' while another commenter stated that Part D plan sponsors are limited in the ways they can compel a pharmacy to distribute the notice. A commenter expressed support for CMS's statement that additional tracking or documentation by the pharmacy or on behalf of the pharmacy by the Part D plan sponsor that the notice has been delivered to the identified enrollee is not required.

Response: CMS thanks the commenters for their feedback. Under section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act, Part D plan sponsors must have a mechanism to notify a pharmacy when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the Part D enrollee may benefit from participating in the program. Furthermore, section 1860D–2(b)(2)(E)(v)(III)(ee) of the Act requires Part D plan sponsors to ensure that a pharmacy, after receiving such notification from the Part D plan sponsor, informs the Part D enrollee that they are likely to benefit from the Medicare Prescription Payment Plan. Given this statutory requirement, we are finalizing at § 423.137(i)(3) that Part D plan sponsors must ensure that their pharmacy network contracts include a provision requiring pharmacies to provide this notification to Part D enrollees. This provision is sufficient to meet the requirements for Part D plan sponsors to ensure that a pharmacy, after receiving such a notification from the Part D plan sponsor, informs the Part D enrollee that they are likely to benefit from the Medicare Prescription Payment Plan. Additional tracking or documentation by the pharmacy or on behalf of the pharmacy by the Part D plan sponsor that the notice has been delivered to the identified enrollee is not required.

Comment: A commenter noted that pharmacists are a trusted source of healthcare information for enrollees and suggested that CMS offer targeted information about the program via the pharmacy. Another commenter expressed support for the CMS's statement that the requirement to provide the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' in no way obligates the pharmacy to provide additional Medicare Prescription Payment Plan counseling or consultation to the Part D enrollee.

Response: CMS thanks the commenters for their feedback. We agree pharmacists play a key role in cost-of-care conversations with their patients, and we encourage Part D plan sponsors to include information about the Medicare Prescription Payment Plan in their communications with network pharmacies. CMS notes, however, that the requirement to provide the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' in no way obligates the pharmacy to provide additional Medicare Prescription Payment Plan counseling or consultation to the Part D enrollee.

In addition, pharmacies are encouraged, but not required, to provide educational material related to the Medicare Prescription Payment Plan, such as the CMS-developed fact sheet, at the time they provide an enrollee with the notice.

Comment: Some commenters expressed concern that language in the preamble noting operational differences for long-term care pharmacies and potential different approaches to distributing the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' were not codified in regulatory text; these commenters requested revisions to the regulatory language. A commenter also suggested that CMS modify the regulatory language in certain provisions related to the POS notification process to reflect long-term care pharmacy processes (that is, that the notification may take place as part of typical enrollee cost-sharing billing, not at the POS).

Response: We appreciate the commenters' feedback. In this final rule, we have modified the regulatory text at § 423.137(i) to include language related to distribution of the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' by long-term care pharmacies at the time of their typical enrollee cost-sharing billing process. We believe that this modification is sufficient to address the unique circumstances of the long-term care pharmacy notification, and we decline to modify the use of ''point of sale notification'' in other locations in the regulatory text. As noted in the proposed rule, we encourage Part D plan sponsors to assess the particular circumstances of their network long-term care pharmacies when establishing timing requirements for pharmacy distribution of the notice.

Comment: A commenter expressed concern about the potential administrative burden specialty pharmacies may experience as the program is implemented and support for flexibilities in program requirements for non-retail pharmacies. The commenter recommended CMS collect feedback from specialty and non-specialty pharmacies and patients about their experience with the first year of implementation before making additional changes to the Medicare Prescription Payment Plan.

Response: CMS appreciates the commenter's support and recommendations and recognizes that pharmacies play an important role in operationalizing the Medicare Prescription Payment Plan. CMS will continue to engage external stakeholders on program implementation.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed provisions at § 423.137(i) with the following modifications. The NCPDP Telecommunication Standard

uses specific code values for various fields. As such, to better align with NCPDP and industry terminology, we are modifying the language at § 423.137(i) from ''standard codes'' to ''standard code values.'' Based on commenters' feedback, we have added language to the regulatory text at § 423.137(i)(2)(iii) to state that the Part D plan sponsor should require the long-term care pharmacy to provide the notice to the Part D enrollee (or their authorized representative) at the time of its typical enrollee cost-sharing billing process. As such, the provision that was previously at § 423.137(i)(2)(iii) is now codified at § 423.137(i)(2)(iv).

i. Pharmacy Claims Processing

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

Consistent with our authority under section 11202 of the IRA and under section 1860D–12(b)(3)(D) of the Act, in the proposed rule, we stated that to ensure a uniform, consistent claims adjudication process and to leverage existing Part D processes to minimize operational burdens, we require that Part D sponsors and pharmacies to use standard electronic claims processing methodology including a distinct Bank Identification Number (BIN) and/or Processor Control Number (PCN) for applicable Medicare Prescription Payment Plan transactions.

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

We also proposed that Part D plan sponsors must ensure that there is no impact to PDE cost/payment field reporting as a result of this claims processing methodology. PDE submissions must reflect participant and plan liability amounts as if the Medicare Prescription Payment Plan did not apply.

Additionally, we proposed that the claims processing methodology should have no impact to prescriber or participant real-time benefit tools, meaning participant liability amounts must be represented as if the Medicare Prescription Payment Plan did not apply.

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

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

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

Additionally, as noted in section II.C.2.h. of this final rule, I/T/U pharmacies provide no-cost prescription drugs to eligible IHS enrollees. When IHS-eligible Part D enrollees fill a prescription at an I/T/U pharmacy, their covered Part D prescription drug cost sharing, as defined by their plan's benefit structure, is not collected at the POS. In the proposed rule, we stated that if an IHS-eligible Part D enrollee is also participating in the Medicare Prescription Payment Plan, the Part D plan sponsor must ensure that the I/T/U pharmacy does not bill the Part D plan's Medicare Prescription Payment Plan BIN/PCN. Instead, the Part D plan sponsor must ensure that the I/T/U pharmacy processes the claim as if the IHS-eligible enrollee were not participating in the Medicare Prescription Payment Plan. If a Part D sponsor receives a claim from an I/T/U pharmacy that was submitted to the Medicare Prescription Payment Plan-specific BIN/PCN, the Part D sponsor must reject the claim. To help prevent this situation from occurring, Part D sponsors must also put in place processes to prevent Medicare Prescription Payment Plan BIN/PCNs from being returned on paid claim responses to I/T/U pharmacies. These requirements apply only with respect to I/T/U pharmacies that dispense prescriptions at no cost to the IHS enrollee. The Part D sponsor must

ensure other network pharmacies providing services to Part D enrollees process claims in accordance with the Medicare Prescription Payment Plan requirements.

Finally, in the proposed rule, we noted concerns about the potential lack of participant visibility into their OOP costs for the Medicare Prescription Payment Plan at the POS and sought comments about how to provide additional support for OOP cost transparency for Medicare Prescription Payment Plan participants, including suggested processes for how Part D plan sponsors can provide this information to pharmacies in a manner that conforms with existing standards.

Comment: In response to the request for comment on opportunities to increase OOP cost transparency, most commenters agreed that enrollees participating in the Medicare Prescription Payment Plan would benefit from knowing at the POS the OOP cost of a claim which will be included in their future Medicare Prescription Payment Plan billing statement. However, most commenters noted that the normal cost sharing amount is already provided in the paid claim billing response provided to the pharmacy. A commenter sought clarification on whether CMS was asking Part D plan sponsors to provide the cost share on the claim being processed or the accumulated OOP amount on the Medicare Prescription Payment Plan coordination of benefits (COB) response to the pharmacy.

Some commenters stated that the OOP cost information is readily available to pharmacies within their dispensing systems and could be verbally conveyed upon request, but they also noted the complexities involved with providing written information to the enrollee at the POS. Written documentation would involve additional programming costs to transcribe the OOP amounts from the paid claim transaction onto a paper document. Further, a few commenters also questioned what enrollee-facing document would be used to convey the information to the participant. A commenter stated that the prescription receipt did not include sufficient space to print the patient pay amount and patient safety messaging.

In addition to the technical complexities involved to produce a written document, a commenter stated that it is unclear what the term ''at the POS'' refers to in various pharmacy settings and that CMS would need to consider how the proposal would apply in different pharmacy settings to ensure that cost transparency effectively reaches those who need it most. To support OOP cost transparency, a commenter noted that they have created tools to help enrollees assess their costs within the program; they suggested incorporating similar support tools within Medicare Plan Finder. Finally, several commenters suggested that before implementing any changes in pharmacy operational processes, CMS should gather at least a full year's data to assess the current system's effectiveness and identify potential gaps, before introducing discussion about new requirements. Commenters suggested that any new requirements be delayed until 2027 or 2028.

Response: CMS thanks commenters for their feedback. By way of clarification and in response to a commenter, we can confirm that the OOP cost that would be provided by the Part D plan sponsor to the pharmacy is the OOP cost the patient would have incurred if the Medicare Prescription Payment Plan COB transaction had not been submitted for the specific Part D claim, rather than the accumulated OOP to date for the patient (which would be complicated to report). We are seeking to ensure that the beneficiary is aware of the OOP cost of a claim which will be included in a future Medicare Prescription Payment Plan billing statement. We agree that accumulations are a dynamic dollar amount that can best be explained by the Part D plan sponsor rather than the pharmacy.

CMS thanks commenters for supporting price transparency at the POS for participants in the Medicare Prescription Payment Plan. As a result of the comments received, we continue to encourage pharmacies to leverage standard industry transaction set data to provide OOP costs to participants verbally upon request. CMS will consider additional requirements in the future.

Comment: A few commenters noted issues with the BIN/PCN electronic claims processing methodology for Medicare Prescription Payment Plan transactions in the early months of program operations. A commenter requested that CMS monitor for issues with the current process before making any changes. Finally, a commenter suggested that CMS provide additional education and support for pharmacists related to Medicare Prescription Payment Plan claims processing.

Response: CMS appreciates the comments. We are actively monitoring program operations, including feedback on pharmacy processes. We understand that the Medicare Prescription Payment Plan is a new program and that its operational complexities may result in additional issues being identified in the early months of implementation. In general, we encourage Part D plan sponsors to promptly resolve any errors with pharmacy claims processing for Medicare Prescription Payment Plan participants and work with the impacted participants to reconcile any payment inaccuracies. In addition, CMS will continue to work with Part D plan sponsors to ensure they provide pharmacies with the information needed to effectively operationalize this program.

Comment: A commenter stated that the BIN/PCN electronic claims processing methodology for the Medicare Prescription Payment Plan was not outlined in the IRA and by requiring that method, CMS is exceeding its statutory authority. Another commenter noted that requiring the BIN/PCN claims processing methodology places additional burden on pharmacies; they requested that CMS instead require a pre-funded card system for processing Medicare Prescription Payment Plan claims.

Response: As discussed in the proposed rule, in addition to the agency's authorities with respect to the Medicare Prescription Payment Plan under section 11202 of the IRA, CMS has authority under section 1860D–12(b)(3)(D) of the Act to impose additional contractual terms and conditions on Part D plan sponsors that are necessary and appropriate. The BIN/PCN claims processing methodology ensures a single, uniform method of adjudicating and managing the patient liability for the Medicare Prescription Payment Plan at the POS; it also leverages existing Part D processes to minimize operational burdens. As such, this requirement is necessary and appropriate for implementation of the Medicare Prescription Payment Plan. In addition, in response to the part one guidance and part two guidance for the Medicare Prescription Payment Plan, issued in 2023 and 2024, CMS heard broad support for this policy from stakeholders, including the importance of a single, uniform method that allows implementation of the program across large and small pharmacies.

As noted in the final part one guidance, the proposals for use of a pre-funded card to operationalize the Medicare Prescription Payment Plan raises concerns related to the level of Part D plan sponsor oversight; timeliness of issuing payment cards; and participants needing to present a physical card at the POS, which could be forgotten, lost, or stolen, potentially causing delays in obtaining prescription drugs, elevated risk of fraud, additional costs to the Part D program and

potential card processing fees for pharmacies. CMS is also aware that not all organizations have the financial capabilities established to enable a pre-funded payment card system.

Comment: A commenter expressed support for CMS's statement that Part D plan sponsors are not required to provide that pharmacies reverse and reprocess claims under the Medicare Prescription Payment Plan that have already been paid for by the Part D enrollee.

Response: CMS thanks the commenter for their support.

Comment: A commenter objected to CMS not proposing specific requirements for Part D plan sponsors related to the use of the Medicare Prescription Payment Plan BIN/PCN with long-term care pharmacies, stating that Part D plans should be required to use the program BIN/PCN for all participants, including those served by long-term care pharmacies, so that the long-term care pharmacy knows the claim is subject to the Medicare Prescription Payment Plan. The commenter expressed concern that exempting Part D plan sponsors from the BIN/PCN would not allow long-term care pharmacies to know that a claim is exempt from cost sharing requirements and would reduce the effectiveness of the Medicare Prescription Payment Plan.

Response: CMS thanks the commenter for their feedback. In most circumstances, we expect Part D plan sponsors to provide the Medicare Prescription Payment Plan BIN/PCN for participating enrollees to all pharmacies, including long-term care pharmacies. The intent of CMS not proposing specific requirements for Part D plan sponsors related to the use of the Medicare Prescription Payment Plan BIN/PCN with long-term care pharmacies is to allow flexibilities for certain situations where long-term care pharmacies do not collect Part D cost sharing from the enrollee but instead bill the long-term care facility for the final patient OOP responsibility. In these scenarios, billing a participant's Part D plan's Medicare Prescription Payment Plan BIN/PCN for the OOP cost that would have been paid by the long-term care facility would result in an additional financial burden for that participant. Therefore, CMS encourages Part D plan sponsors to consider a participant's particular circumstances when developing Medicare Prescription Payment Plan billing practices and to work with the participant, their authorized representative, and the long-term care pharmacy to understand the best billing approach for that participant. As a reminder, like any other participant in the Medicare Prescription Payment Plan, an enrollee residing in a long-term care facility may voluntarily opt out of the Medicare Prescription Payment Plan during the plan year if the program no longer benefits them.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed provisions at § 423.137(j) with the following modification. Based on commenters' feedback, we have removed the requirements for Part D sponsors to ensure that pharmacies are prepared to provide information regarding OOP costs for the Medicare Prescription Payment Plan to a participant at the POS. Although CMS is not finalizing any OOP cost transparency proposals at this time, CMS continues to strongly encourage Part D plan sponsors to educate program participants on the options for assessing OOP costs for the Medicare Prescription Payment Plan prior to arriving at the pharmacy POS (such as utilizing interactive prescription drug cost tools available on the Part D plan sponsor's website or calling the plan's customer service line).

j. Pharmacy Payment Obligations

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

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

Comment: A few commenters expressed support for the requirement that Part D plan sponsors cannot impose any fees or costs related to program implementation on pharmacies and that pharmacies cannot be held responsible for any unsettled balance. However, several commenters expressed concern about the financial burden on pharmacies from program operations. A commenter expressed specific concern about the potential negative impact of increased costs on long-term care pharmacies. Some of these commenters requested that CMS require Part D plan sponsors to reimburse pharmacies for costs associated with implementing the Medicare Prescription Payment Plan.

A commenter also requested CMS implement real-time monitoring and enforcement to ensure Part D plan sponsors do not impose program fees on pharmacies.

Response: CMS appreciates the commenters' concerns and thanks the commenters for their feedback. Consistent with section 1860D–11(i) of the Act, CMS may not interfere with the negotiations between Part D plan sponsors and pharmacies and may not institute a price structure for the reimbursement of covered Part D drugs (except as provided under section 1860D–11(i)(3) of the Act related to the Medicare Drug Price Negotiation Program). That said, CMS recognizes the important role that pharmacies will play in the implementation of this program and strongly encourages Part D plan sponsors to ensure that pharmacies receive adequate reimbursement for services provided to Part D enrollees related to participation in the Medicare Prescription Payment Plan.

As stated in the proposed rule, any additional transaction fees or other costs pharmacies incur from processing claims under the Medicare Prescription Payment Plan or otherwise related to such program are considered allowable pharmacy costs associated with the dispensing of a covered Part D drug that may be paid through applicable dispensing fees. Should Part D plan

sponsors and pharmacies come to contractual arrangements that reimburse pharmacies for program operations through a non-dispensing fee mechanism (for example, remuneration for administrative services), these arrangements must be reported appropriately via the bid pricing tool and direct and indirect remuneration (DIR) reporting, as necessary.

Finally, CMS appreciates commenters' concerns related to additional program monitoring and will take them into consideration in the future.

Comment: A few commenters expressed support for CMS's requirement that Part D plan sponsors must reimburse a network pharmacy the total of a participant's OOP costs for the Medicare Prescription Payment Plan and the Part D plan sponsor portion of the payment for a covered Part D drug no later than 14 calendar days after the date on which the claim is received for an electronic claim or no later than 30 calendar days after the date on which the claim is received for any other claim. A commenter also suggested that CMS monitor Part D plan sponsors to confirm they are adhering to prompt pay requirements.

Response: CMS thanks the commenters for their support. As noted previously, CMS appreciates commenters' concerns related to additional program monitoring and will take them into consideration in the future.

Comment: A commenter suggested that concerns about pharmacy reimbursement could be addressed through the framework of medication therapy management (MTM) encounters. The commenter suggested that CMS could include Medicare Prescription Payment Plan participants as a group targeted for MTM, which would provide a potential mechanism for pharmacy reimbursement.

Response: CMS thanks the commenter for the suggestion. As noted previously, CMS strongly encourages Part D plan sponsors to ensure that pharmacies receive adequate reimbursement for services provided to Part D enrollees related to participation in the Medicare Prescription Payment Plan. Given that the Medicare Prescription Payment Plan is in its very early stages, CMS will continue to monitor the program and will evaluate program data and operations before implementing additional changes.

Regarding MTM program eligibility section 1860D–4(c)(2)(A)(ii) of the Act requires Part D plan sponsors to target those Part D enrollees who have multiple chronic diseases, are taking multiple covered Part D drugs, and are identified as likely to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary. Part D sponsors are also required by section 1860D–4(c)(2)(A)(ii)(II) of the Act to target all at-risk beneficiaries (ARBs) [18] in their Part D drug management program (DMP) for MTM. These requirements are codified in the regulation at § 423.153(d)(2).

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing as proposed the requirement that the Medicare Prescription Payment Plan does not affect the amount or timing of payment to pharmacies at § 423.137(k), including that Part D plan sponsors cannot impose any fees or costs related to program implementation on pharmacies and that pharmacies cannot be held responsible for any unsettled balances of a participant or for collecting unpaid balances from the participant on the Part D plan sponsor's behalf.

k. Monitoring, Compliance and Data Submission Requirements

In the proposed rule, we stated that existing requirements in 42 CFR 423.514(a) governing data collection for Part D plan sponsors apply to the Medicare Prescription Payment Plan. We reminded Part D plan sponsors that they must report information related to the Medicare Prescription Payment Plan on PDE records and through reporting requirements at the beneficiary level and contract-PBP levels. Part D plan sponsors must report data at the beneficiary-level on election status in the program through the MARx System and contract-PBP-level data about the program through HPMS. These data elements were formally issued for public comment through the Office of Management and Budget (OMB) ICR process.

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

Comment: Several commenters expressed general support for strong monitoring and oversight of the program to ensure implementation remains compliant with regulations and guidance.

Response: CMS thanks commenters for their support.

Comment: Several commenters recommended CMS release program participation data including PDE data associated with enrollees, quarterly data releases, and detailed breakdowns by beneficiary subgroups and demographics.

Response: CMS thanks the commenters for their suggestions. The main objective in collecting data for CY 2026 is to continue to assess the operations of the Medicare Prescription Payment Plan and ensure financial stability in the Medicare Part D program. CMS will evaluate data submissions once we review them and consider opportunities for publicly sharing the data.

Comment: A commenter requested we create a new CTM category for program complaints. Another commenter recommended that CMS use CTM and grievance data points to allow plans to demonstrate the value of the program from the enrollee perspective.

Response: CMS thanks the commenters for their suggestions. The CTM was updated in October 2024 to revise CTM category 2.54 as follows: ''Beneficiary has a cost-sharing/co-insurance issue, including Medicare Prescription Payment Plan costs''. CMS will monitor and collect data about beneficiary complaints and grievances reported via the CTM to assess compliance with program requirements and consider whether an additional CTM category for the program is needed in future years. With regard to demonstrating the value of the program, CMS thanks the commenter for the recommendation but does not plan to release aggregated complaints and grievances data at this time.

Comment: Several commenters recommended CMS utilize existing audit protocols and processes to monitor program activities and encouraged CMS to use caution in adjudicating the efforts of plan sponsors to implement the program.

Response: CMS thanks the commenters for their feedback and acknowledges the challenges associated with rapidly operationalizing a new

[18] Defined at § 423.100.

program. CMS does not intend to conduct any audits of plan sponsors' Medicare Prescription Payment Plan programs in CY 2025. CMS will monitor the program using the data sources outlined in section 60.3 of the final part two guidance to inform audit and oversight methods and processes in future years. CMS intends to engage with plan sponsors throughout the first year of the program to identify educational opportunities and disseminate best practices, with the goal of supporting all plan sponsors in offering compliant programs and will provide advance notice to plan sponsors regarding any future audit activities.

Comment: Several commenters expressed support for the proposed data collection efforts and recommended CMS collect data that could be used to ensure the program is implemented fairly, captures differences in outreach efforts to beneficiary subgroups, and monitors the program for potential unintended consequences.

Response: CMS thanks the commenters for their suggestions. CMS recognizes the importance of collecting data that assesses whether programs like the Medicare Prescription Payment Plan are aligning with the needs of communities and individuals. CMS is collecting beneficiary-level data on participation in the Medicare Prescription Payment Plan through the MARx System (OMB control number 0938–1468) and will begin collecting contract- and plan-level data through the Part D reporting requirement in HPMS beginning in CY 2025.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing all proposed provisions at § 423.137(k).

l. General Part D Sponsor Outreach and Education Requirements

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

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

We also explained that CMS has updated existing Part D resources that are required to be furnished to Part D enrollees under § 423.2267(e) to include information about the program. These include the ANOC, described at § 423.2267(e)(3), the EOC, described at § 423.2267(e)(1), and the EOB, described at § 423.128(e)(7). Each has been updated to include program information through the OMB ICR process (for the EOB) or through the general annual issuance of Part D model materials (for the ANOC and EOC).

In addition to meeting these requirements, we proposed to codify at § 423.137(m)(2) for 2026 and subsequent years required content that a Part D plan sponsor must include on its website and amend § 423.2265(b) to add paragraph (b)(16) to include information on the Medicare Prescription Payment Plan as required content for Part D plan sponsor websites. Additionally, Part D plan sponsors may also include information on the Medicare Prescription Payment Plan in their marketing materials. In developing their materials, Part D plan sponsors must ensure that the materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR part 423, subpart V.

Comment: Several commenters expressed opposition to including D–SNP and LIS members in general outreach and education for the Medicare Prescription Payment Plan, given that they receive other financial assistance for their prescription drugs. A commenter recommended CMS allow plans to use alternative language when communicating about the program with members who are unlikely to benefit from the program and recommended excluding LIS recipients from the election request form requirements. The commenter expressed concern that after the termination of the VBID model, D–SNPs formerly in the VBID model will be required to inform members about the Medicare Prescription Payment Plan even though most members are LIS recipients and therefore unlikely to benefit.

Response: CMS recognizes commenters' concerns about those who are less likely to benefit receiving program materials. As noted in the proposed rule and this final rule, CMS understands that the Medicare Prescription Payment Plan has no practical application for enrollees in plans that exclusively charge $0 cost sharing for covered Part D drugs. As such, we do not expect plans that exclusively charge $0 cost sharing for covered Part D drugs to offer enrollees the option to pay their OOP costs through monthly payments over the course of the plan year or otherwise comply with the Medicare Prescription Payment Plan requirements set forth in this final rule. However, we recognize that some plans that do not exclusively charge $0 cost sharing for covered Part D drugs may still have a high proportion of enrollees with low, stable drug costs (such as LIS enrollees) who are not likely to benefit from the program. CMS has encouraged Part D plan sponsors to provide support tailored to beneficiaries' unique situation and clearly communicate to enrollees when it appears that they are less likely to benefit from the program (for example, enrollees with low-to-moderate recurring OOP drug costs). Although Part D plan sponsors must provide the option to opt into the Medicare Prescription Payment Plan to all Part D enrollees, including enrollees who are eligible for LIS, CMS agrees that requiring D–SNPs to provide the same level of outreach and education could cause confusion for their enrollees given many receive other financial assistance for their prescription drugs. As such, CMS believes that it is sufficient for D–SNPs to provide information to their enrollees on the Medicare Prescription Payment Plan through the ANOC, EOC, EOB, and information available on their websites. Additionally, if any enrollee meets the likely to benefit threshold for

targeted outreach, a D–SNP would still be required to send the ''Medicare Prescription Payment Plan Likely to Benefit Notice''. Therefore, we are modifying § 423.137(m)(1) to exempt D–SNPs from the requirement to provide a Medicare Prescription Payment Plan election request form and additional educational information on the program in a hard copy mailing.

Comment: A commenter expressed appreciation that CMS has nimbly responded to stakeholder feedback on required communications to prospective Medicare Prescription Payment Plan participants and anticipates future revisions to these requirements as program experience accrues. The commenter recommended CMS not adopt ''one-size-fits-all'' outreach requirements and believes that plan sponsors should retain some flexibility in identifying and facilitating communications that best serve member needs. Another commenter stated that engaging stakeholders, including patient organizations, is critical to the program's success, and recommended CMS collaborate with these groups to co-develop and review educational materials and to disseminate the information to beneficiaries.

Response: CMS appreciates the commenters' feedback and recommendations. While CMS acknowledges concerns about strict program requirements, CMS believes that the Medicare Prescription Payment Plan requirements finalized in this final rule strike the appropriate balance between ensuring a uniform experience for program participants across plans and providing flexibility for Part D plan sponsors based on their members' needs. For example, in response to stakeholder concerns about those who are less likely to benefit receiving program materials, CMS is modifying § 423.137(m)(1) in this final rule to exempt D–SNPs from the requirement to provide a Medicare Prescription Payment Plan election request form and additional educational information on the program in a hard copy mailing because many of their enrollees already receive other financial assistance for their prescription drugs. CMS will consider how to continue to engage external stakeholders on program implementation and incorporate stakeholder feedback into program requirements.

Comment: Several commenters recommended CMS strengthen requirements for beneficiary outreach and education. A commenter stated that the gap in awareness about the program presents an opportunity for stakeholders to support the older adult and disability communities in the enrollment process and help beneficiaries understand how the plan will help them manage their prescription drug payments. A commenter stated that the program is a key affordability measure. A commenter expressed that education through the calendar year is important so that there is a greater chance that the beneficiary will read about the program and have some knowledge of the program prior to the annual open enrollment period in the fall. A commenter stated that without further education there is and will continue to be a lack of understanding from D–SNP LIS eligible enrollees about which program is best for their prescription drug needs. A commenter expressed support for codifying the Part D plan sponsor education and outreach requirements. Another commenter recommended that educational materials for the program explain how beneficiaries' OOP payments will change over time if they opt into the payment plan and clearly identify the circumstances under which a beneficiary will benefit the most from this payment plan.

Response: CMS appreciates commenters' feedback and will consider additional opportunities to enhance education efforts for the program. CMS agrees that educating beneficiaries about the program is important for its success. For potential Medicare Prescription Payment Plan participants who are already enrolled in the LIS program, Part D plan sponsors are encouraged to provide support tailored to their unique situation and clearly communicate to enrollees when it appears that they are less likely to benefit from the program.

Comment: A few commenters expressed opposition to CMS's proposal and recommend CMS not include language on the Medicare Prescription Payment Plan in all EOBs as it will drive beneficiary confusion about whether or not an enrollee has elected coverage. The commenters stated that including the language in the EOBs does not target messaging to enrollees who are likely to benefit. A commenter recommended that CMS add language to the notice of election approval that clarifies that the EOB will not reflect participation in the program. A commenter stated that the 2025 Medicare & You handbook could have included more helpful information about whether one is likely to benefit from enrolling in the Medicare Prescription Payment Plan.

Response: CMS appreciates the commenters' concerns about updating CMS's Part D EOB model to include language on the Medicare Prescription Payment Plan but does not agree with the recommendation. Updating the ANOC, EOC, and EOB models with Medicare Prescription Payment Plan information will help to ensure all prospective and current Part D enrollees are aware of the program. CMS appreciates the recommendation related to the Medicare & You handbook and will continue to consider how to educate beneficiaries about the Medicare Prescription Payment Plan in Medicare program materials.

Comment: A commenter stated that it will be informative to understand how much pharmacies and physicians utilize the model documentation to inform members who may benefit about the program and recommended additional member research to understand if there are enhancements needed to improve members' understanding of the program. A few commenters expressed the importance of further pharmacy education. A commenter recommended CMS establish one education resource that uses consistent formatting and documents. A commenter recommended that CMS prohibit Part D plan sponsors from forcing pharmacies through contract terms to distribute additional educational materials.

Response: CMS appreciates the commenters' support and recommendations and recognizes that pharmacies play an important role in operationalizing the Medicare Prescription Payment Plan. CMS understands the commenters' concerns about pharmacy contract terms but declines to address this issue at this time. CMS will consider how to continue to engage external stakeholders, including pharmacies, on program implementation.

Comment: A commenter expressed support for requiring Part D plan sponsors to include program information on their Part D plan sponsor websites.

Response: CMS thanks the commenter for their support.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing all proposed provisions at § 423.137(m), with one modification to § 423.137(m)(1). CMS is exempting D–SNPs from requirements at § 423.137(m)(1) that Part D sponsors must provide a Medicare Prescription Payment Plan election request form and additional educational information on the program in a hard copy mailing. We are finalizing the proposed change to § 423.137(m)(1):

m. Medical Loss Ratio

Section 1860D–2(b)(2)(E)(v)(VI) of the Act specifies that any unsettled balances with respect to amounts owed under the Medicare Prescription Payment Plan ''shall be treated as plan losses and the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids.''

Under section 1860D–12(b)(3)(D) of the Act, which adopts by reference section 1857(e) of the Act into Part D, Part D plan sponsors are required to maintain a MLR of at least 85 percent. In the final part two guidance, CMS established that, consistent with the inclusion of plan losses in the administrative expense portion of the Part D bid, unsettled balances from the Medicare Prescription Payment Plan will be considered administrative costs for purposes of the MLR calculation and therefore be excluded from the MLR numerator.

In the proposed rule, with respect to the treatment of unsettled balances from the Medicare Prescription Payment Plan, we proposed to exclude such unsettled balances from the from the MLR numerator at §§ 422.2420(b)(4)(i)(D) and 423.2420(b)(4)(i)(D).

Comment: Most commenters opposed CMS's proposal to exclude unsettled balances under the Medicare Prescription Payment Plan program from the MLR numerator. Commenters raised both policy and legal arguments. Multiple commenters stated that they believe that unsettled Medicare Prescription Payment Plan balances represent expenditures on drugs and, as such, should be considered medical spending included in the numerator for purposes of calculating the MLR. Some commenters further stated that excluding Medicare Prescription Payment Plan balances fails to reflect their connection to beneficiary care, diminishes the accuracy of the MLR calculation, and would result in an incomplete representation of a Part D plan sponsor's financial picture. A few commenters stated that CMS's proposal is inconsistent with the intent of MLR, which is to encourage Part D plan sponsors to control their administrative costs and devote more of their resources to covering prescription drug costs and quality improvement activities. Several commenters also stated that CMS's proposal unfairly penalizes Part D plan sponsors for costs that are largely out of their control. Commenters also raised legal arguments. Several commenters stated that they believe section 1860D–2(b)(2)(E)(v)(VI) of the Act, which specifies that any unsettled balances with respect to amounts owed under the Medicare Prescription Payment Plan ''shall be treated as plan losses and the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids,'' does not require that unsettled Medicare Prescription Payment Plan balances be excluded from the MLR numerator because that statutory requirement says nothing about MLR requirements. A commenter further stated that CMS's interpretation of section 1860D–2(b)(2)(E)(v)(VI) of the Act is not the best interpretation because it would require overriding the statutory language on the calculation of the MLR without explicit language to this effect or any stated rationale for doing so. Another commenter stated that CMS's proposal violates the Social Security Act. That commenter argued that the amounts paid by a Part D plan sponsor to the pharmacy for the beneficiary's covered drugs should be included in incurred claims except to the extent and in the amount that the beneficiary subsequently reimburses the plan. Because all amounts included in incurred claims represent amounts paid by the plan for covered services, the commenter believes that Medicare Prescription Payment Plan unpaid balances should be included in the MLR numerator.

Response: CMS thanks the commenters for their feedback. CMS declines to include unsettled balances in the numerator of the MLR. Section 1860D–2(b)(2)(E)(v)(VI) of the Act requires Part D plan sponsors to treat any unsettled balances with respect to amounts owed by participants under the Medicare Prescription Payment Plan as plan losses. Because CMS considers plan losses as part of the Part D plan sponsor's administrative costs in its bid, CMS believes that unsettled Medicare Prescription Payment Plan balances must be excluded from the MLR numerator so as not to incentivize Part D plan sponsors to avoid collecting unsettled balances and instead rely on their inclusion as administrative costs to recoup losses related to unsettled balances. While CMS recognizes that Part D plan sponsors may have less control over unsettled Medicare Prescription Payment Plan balances than other administrative costs, we note that this is also true of plan losses generally. Furthermore, Part D plan sponsors are permitted to recoup unsettled balances, so these costs are not entirely outside of their control. CMS disagrees that its proposal is inconsistent with the MLR requirements at section 1857(e) of the Act as adopted by reference into Part D under section 1860D–12(b)(3)(D) of the Act. The statutory requirements merely require that Part D plan sponsors have an MLR of at least 85 percent for each contract year. Since the MLR requirement was established, CMS has excluded administrative costs, including plan losses, from the MLR numerator. As explained earlier in this comment response, unsettled Medicare Prescription Payment Plan balances are plan losses for bidding purposes, which CMS has always treated as administrative expenses for MLR purposes. For the same reasons, we do not agree that such losses should be included in incurred claims except to the extent and in the amount that the beneficiary subsequently reimburses the plan.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed provisions at §§ 422.2420(b)(4)(i)(D) and 423.2420(b)(4)(i)(D) without modification.

n. Severability

We proposed that the Medicare Prescription Payment Plan 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 this proposed provision without modification.

D. Timely Submission Requirements for Prescription Drug Event (PDE) Records (§ 423.325)

CMS requires that Part D sponsors submit certain prescription drug claims information to CMS for specified Medicare Part D-related purposes as described in the Social Security Act (the Act). In accordance with the authority under sections 1860D–15(c)(1)(C), 1860D–15(d)(2), and 1860D–15(f) of the Act, CMS conditions Medicare Part D program payments to Medicare Part D plans upon the disclosure and provision of information needed to carry out payment. In addition, section 1860D–15(f)(2)(A) of the Act allows CMS to utilize information collected under

section 1860D–15(f) of the Act for the purposes of, and to the extent necessary in, conducting oversight, evaluation, and enforcement under Title XVIII of the Act and carrying out section 1860D–15 of the Act or the Medicare Drug Price Negotiation Program (''Negotiation Program'') under Part E of Title XI of the Act. Under sections 1860D–14A(c)(1)(C) and 1860D–14C(c)(3) of the Act, CMS collects information from Part D sponsors that allows for discounts under the Coverage Gap Discount Program and Manufacturer Discount Program, respectively, to be provided to applicable beneficiaries for applicable drugs. Part D sponsors submit this prescription drug claims information to CMS on prescription drug event (PDE) records through the CMS Drug Data Processing System (DDPS).[19]

A PDE record is data summarizing the final adjudication of a Part D dispensing event that is reported to CMS by the Part D sponsor using a CMS-defined file layout.[20] CMS requires that PDE records are accurate, complete, and truthful since they are used for the purposes of obtaining Federal reimbursement.[21] These records are critical not only for accurate payment, but also for a wide range of sponsor compliance assessment activities, and other Part D program integrity audits. To that end, CMS performs checks (or edits) on the PDE data to validate and help ensure its accuracy.[22] This process results in the PDE records being accepted or rejected by CMS. Accepted PDE records may be subsequently adjusted or deleted by the Part D sponsor by submitting adjustment PDE records or deletion PDE records to CMS.[23] Rejected PDE records must be reviewed, resolved, and, if appropriate, resubmitted by the plan to CMS. The resubmitted PDE record goes through the same editing process and results in CMS accepting or rejecting the resubmitted PDE record.

CMS uses accepted PDE records in the Part D payment reconciliation described at §§ 423.336 and 423.343(c) and (d), reopenings of Part D payment reconciliations described at § 423.346, the Coverage Gap Discount Program invoicing process described generally at § 423.2315, and the Manufacturer Discount Program invoicing process.[24] PDE records for selected drugs (as described at section 1192(c) of the Act) will also be used to administer the Negotiation Program.[25] [26] In order for CMS to make payments, conduct oversight, administer the various programs under Medicare Part D and the Negotiation Program, as well as perform other statutory obligations, the PDE records must be received from Part D sponsors in a timely manner. Part D sponsors that do not submit PDE data in a timely manner (as explained in the following Background and Requirements sections) may be determined to be out of compliance consistent with § 423.505(n)(1)(i) and may be subject to compliance actions described at § 423.505(n)(3).

In this rule, we proposed to codify the general PDE submission timeliness guidance that currently applies and that addresses three types of PDE submissions: initial PDE records submitted after a pharmacy claim is received by the Part D sponsor (hereinafter referred to as ''initial PDE records''), adjustment and deletion PDE records that update previously submitted records that have been accepted by CMS, and records to resolve PDE records that were rejected by CMS.[27] Further, we proposed to codify a specific PDE submission timeliness requirement for initial PDE records when those PDE records are for selected drugs.

1. Background—General PDE Submission Timeliness

CMS has always required that Part D sponsors submit their PDE data to CMS in a timely manner. Timely PDE submissions assist in the effective quality review of PDE data prior to CMS using the data in payment reconciliations and invoicing to manufacturers for the Coverage Gap Discount Program and Manufacturer Discount Program (hereinafter referred to collectively as the discount programs). We conduct analysis and validation of PDE data on an ongoing basis and identify data quality issues for Part D sponsors' review and action. This pre-reconciliation data quality review initiative promotes accuracy in the plan-reported financial data used in the Part D payment reconciliation and the invoice and reconciliation processes for the discount programs.

Accordingly, in 2011, we released guidance on the timely submission of PDE records. On May 16, 2011, CMS released a memorandum ''Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs.'' [28] The guidance described the PDE submission timeframes for initial PDE records, adjustment and deletion records, and records to resolve PDE records that CMS rejected through the PDE editing process. After consideration of industry comments, CMS modified the PDE submission timeframes and released revised PDE submission timeliness guidance on October 6, 2011.[29] As described in that guidance, initial PDE records are due within 30 days following the date the claim is received by the Part D sponsor or the date of service, whichever is greater. Adjustment and deletion PDE records are due within 90 days following discovery of the issue requiring a change to the PDE. Resolution of rejected PDE records are due within 90 days following the receipt of rejected record status from CMS. We proposed to codify PDE submission timeframes similar to those timeframes described in the October 2011 guidance and refer to

[19] OMB 0938–0982, CMS–10174, expiration April 30, 2027 (available at *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202403-0938-002*).

[20] The PDE file layouts are available at *https://www.csscoperations.com/internet/csscw3.nsf/DID/M7XCJKG0JI*.

[21] 42 CFR 423.505(k)(3).

[22] For PDE edits, see generally, DDPS Edit Lookup, available at *https://www.csscoperations.com/internet/csscw3.nsf/DIDC/FGSMOX8LWK~Prescription%20Drug%20Program%20(Part%20D)~References* (click Download).

[23] For additional information and examples that result in adjustment and deletion PDE records, see HPMS memorandum, PDE Guidance for Post Point-of-Sale Claim Adjustments, July 3, 2013, available at *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-annual*.

[24] HPMS memorandum, Medicare Part D Manufacturer Discount Program Final Guidance, December 20, 2024 (available at *https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf*).

[25] Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026 *https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf*.

[26] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 *https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf*.

[27] 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-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memo-qtr1-4*.

[28] HPMS memorandum, Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs, May 16, 2011, available at *https://www.cms.gov/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memo-qtr1-4*.

[29] 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-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memo-qtr1-4*.

those timeframes as the *General PDE Submission Timeliness Requirements*.

2. Background—Selected Drugs PDE Submission Timeliness

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169) was signed into law. It established the Negotiation Program to negotiate maximum fair prices (MFPs) for certain high expenditure, single source drugs and biological products (*i.e.,* selected drugs). The requirements for this program are described in sections 1191 through 1198 of the Act, as added by sections 11001 and 11002 of the IRA.

Under section 1193(a) of the Act, participating manufacturers must not only provide access to the MFP for a selected drug to MFP-eligible individuals (as defined in section 1191(c)(2) of the Act), but they must also provide access to the MFP to pharmacies, mail order services, and other dispensing entities with respect to such MFP-eligible individuals who are dispensed the selected drug during a price applicability period (as defined in section 1191(b)(2) of the Act). This distinguishes the Negotiation Program from Part D programs such as the Coverage Gap Discount Program and the Manufacturer Discount Program where there is no such statutory requirement for the manufacturer to provide a specified price to a pharmacy or other dispensing entity. CMS stated in section 40.4 of the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Section 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 (hereinafter referred to as the final guidance) that a Primary Manufacturer (as defined in section 40 of the final guidance) must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP.[30]

To help operationalize dispensing entity access to the MFP, in section 40.4 of the final guidance, CMS stated it will engage with a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data and payment between Primary Manufacturers and dispensing entities and to support the verification that the selected drug was dispensed to an MFP-eligible individual. The MTF will use the PDE records submitted by Part D sponsors to CMS through DDPS to verify that the selected drug was dispensed to an MFP-eligible individual. Additionally, the MTF will furnish Primary Manufacturers with certain claim-level data elements, including from PDE records, confirming that a selected drug was dispensed to an MFP-eligible individual and identifying which dispensing entity dispensed the selected drug to the MFP-eligible individual. In the final guidance, unless the dispensing entity's acquisition cost for the selected drug is equal to or less than the MFP, or, as detailed in section 40.4.5 of the final guidance, the Primary Manufacturer establishes that section 1193(d)(1) of the Act (related to 340B discounts) applies, CMS requires that the Primary Manufacturer transmit payment of an amount that provides access to the MFP within 14 calendar days of when the MTF sends the claim-level data elements that verify the selected drug was dispensed to an MFP-eligible individual to the Primary Manufacturer (''14-day prompt MFP payment window''). CMS notes that the 14-day prompt MFP payment window aligns with the timing requirement in the longstanding prompt pay rules in Part D for plan sponsors.[31] However, dispensing entities should be aware that they may not receive payment from a Part D plan sponsor for the Part D claim on the same date that the Primary Manufacturer provides a retrospective MFP refund to the dispensing entity. Due to operational differences between the Part D program and the Negotiation Program, the respective prompt payment windows for a particular dispensed prescription may start on different dates for the Part D sponsor and the Primary Manufacturer.

To help ensure prompt payments by Primary Manufacturers to dispensing entities to provide access to the MFP, initial PDE records for selected drugs under the Negotiation Program warrant a PDE submission timeliness requirement that is different from the general PDE submission timeliness requirement for initial PDE records. Under the current general PDE submission timeliness requirements, dispensing entities could wait up to approximately six weeks to receive access to the MFP (for example, 30 calendar days for the Part D sponsor to submit PDE data to the DDPS, plus approximately 1 to 3 days for the PDE data to move from DDPS to the MTF to the Primary Manufacturer, plus up to an additional 14 days for the Primary Manufacturer to transmit an MFP refund payment). If the Primary Manufacturer does not prospectively make the MFP available to the dispensing entity, then the lag between when the dispensing entity receives payment from the Part D plan and when the dispensing entity receives the MFP refund payment from the Primary Manufacturer could impose a financial strain on dispensing entities given that anticipated MFP refunds could be a material percent of the dispensing entity's purchase price. To mitigate potential financial hardship on dispensing entities such as pharmacies, which could impact Part D beneficiary access to selected drugs, and to more closely align MFP refund payments with the timing requirements in the longstanding prompt pay rules in the Part D program, CMS believes it is appropriate to create a specific new requirement for PDE submission timeliness requirements for selected drugs. Therefore, CMS proposed to shorten the PDE submission timeliness requirements for selected drugs to reduce the maximum amount of time a dispensing entity could wait to receive access to the MFP.

On May 3, 2024, when CMS released draft guidance describing the implementation of the Negotiation Program for initial price applicability year 2027 and manufacturer effectuation of the MFP in 2026 and 2027 (draft guidance), CMS noted that it was evaluating a PDE submission timeliness requirement for PDE records that is different from the general PDE submission timeliness requirement for initial PDE records.[32] To ensure that dispensing entities receive timely payment of MTF refunds, CMS stated that it was evaluating whether the 30-day window for Part D sponsors to submit PDE records should be shortened to 7 days of receipt of the claim to help

[30] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 *https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.*

[31] See 42 CFR 423.520, Prompt Payment by Part D Sponsors, which requires Part D sponsor to transmit payment to pharmacies within 14 days after receiving an electronic Part D claim that is a clean claim.

[32] Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 *https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.*

ensure dispensing entities receive timely payment of MFP refunds.

CMS received and reviewed comments from interested parties on the draft guidance related to the consideration of a shorter PDE submission timeliness requirement for selected drugs and addressed those comments on page 53 of the final guidance.[33] To inform policy development for this rulemaking, in addition to reviewing the comments received on this proposed rule, CMS revisited the comments received on the draft guidance on the topic of PDE submission timeliness requirements. Many commenters supported CMS shortening the PDE submission window and agreed with the 7-day timeliness requirement or recommended other timeliness requirements shorter than 30 calendar days. Some commenters recommended CMS not change the PDE reporting general timeliness requirement and keep the 30-day window for selected drugs. Many commenters noted that shortening the PDE submission window could increase the volume of claim adjustments and reversals during and after the 14-day prompt MFP payment window. These commenters noted that it typically takes pharmacies up to 14 days to reverse a claim when a beneficiary does not pick up a prescription and asked CMS to provide more detail on how the MTF will address claim reversals and adjustments. One commenter asserted that if CMS shortens the PDE submission window, plan sponsors would need additional implementation time to revise agreements and internal processes. While CMS addressed these comments in the final guidance by stating that it intends to propose to shorten the current 30-day window for plans to submit PDE records for selected drugs to 7 calendar days, CMS also received several comments posing technical questions on the PDE reporting process and DDPS operations, and offering input on other PDE operational matters, which CMS considered out of scope for the final guidance. However, CMS recognizes the importance of public feedback on potential operational concerns surrounding a shorter PDE submission window for selected drugs. CMS solicited comments in the proposed rule on the operational considerations of shortening the timeframe for initial PDE records for selected drugs to 7 calendar days, including potential challenges Part D sponsors may face in implementing the proposed timeframe.

CMS also solicited comments on whether it should shorten the submission timeline for selected drugs for adjustment and deletion of PDE records, and for records to resolve PDE records that were rejected by CMS. CMS stated that it was particularly interested in comments on operational feasibility, as well as comments that address whether a shorter submission timeline would help facilitate timely payments by Primary Manufacturers to dispensing entities, or whether the 90-calendar day submission timeframe for adjustments and deletions and/or for the resolution of rejected records is sufficient for the purpose of the Negotiation Program.

We proposed to codify this 7-calendar day timeframe for initial PDE records for selected drugs and refer to this timeframe as the *Selected Drugs PDE Submission Timeliness Requirement*.

3. Requirements—General PDE Submission Timeliness

We proposed to codify the existing 30-day and 90-day general PDE submission timeframes, with two slight modifications. First, we proposed that the 30-day and 90-day requirements refer to calendar days, as opposed to business days. Second, we proposed to modify the timing of the initial PDE records submission, which currently begins from the date the claim is received by the Part D sponsor or the date of service, whichever is greater. Given that the claim cannot be received by the Part D sponsor (or its contracted first tier, downstream, or related entity (for example, pharmacy benefit manager (PBM))) until on or after the date of service, we proposed to clarify that initial PDE records must be submitted within 30 calendar days of when the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim.

Based on our experience with the Part D program, these proposed 30-calendar day and 90-calendar day PDE submission timeframes are appropriate, striking a balance between allowing sufficient time for the Part D sponsors to submit PDE records while providing sufficient time for CMS to review and flag data quality issues that may require action from the Part D sponsor prior to the PDE record being used in the invoicing and reconciliation processes for the discount programs and the Part D payment reconciliations. These proposed timeframes, which CMS developed with industry feedback, have been in subregulatory guidance since 2011 and have worked well for Part D sponsors and CMS.

Therefore, we proposed the following general PDE submission timeliness requirements. We proposed that the Part D sponsor must submit an initial PDE record within 30 calendar days from the date the Part D sponsor receives the claim. We proposed that the Part D sponsor must submit adjustment or deletion PDE records within 90 calendar days of the discovery or notification of an issue requiring a change to the previously submitted PDE records. We proposed that the Part D sponsor must resolve rejected PDE records within 90 calendar days of the rejection. We proposed that these general PDE submission timeliness requirements apply unless, for the initial PDE records submissions, the proposed selected drugs PDE submission timeliness requirement applies.

Comment: Commenters supported codifying the existing general PDE submission timeliness requirements as proposed. Commenters agreed that the 30-day and 90-day requirements described in existing guidance should be codified as calendar days. Commenters also agreed with clarifying that the 30-calendar day submission timeline for initial PDE records should be based on when claims are received, as opposed to the greater of claim receipt date or date of service, as described in guidance, because claims cannot be received until on or after the date of service.

Response: We thank the commenters for their support.

After consideration of the public comments received, and for the reasons outlined in the proposed rule, we are finalizing as proposed the general PDE submission timeliness requirements at § 423.325(a).

4. Requirement—Selected Drugs PDE Submission Timeliness

We proposed to establish a selected drugs PDE submission timeliness requirement, in which CMS requires that a Part D sponsor must submit initial PDE records for selected drugs (as described at section 1192(c) of the Act) within 7 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim. The proposed PDE submission timeliness requirement is consistent with CMS' authority under section 1860D–15(f) of the Act, which authorizes CMS to collect PDE data for the purposes of, and to the extent necessary in, carrying out both section 1860D–15 of the Act and part E of title XI of the Act (that is, the Negotiation Program).

[33] *https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.*

Table 1A illustrates the general and selected drugs PDE submission timeline requirements.

TABLE 1A—PROPOSED PDE SUBMISSION TIMELINES FOR NON-SELECTED AND SELECTED DRUG CLAIMS

Submission timeframe	Non-selected drug	Selected drugs
Initial PDE	30 calendar days following date claim received by Part D plan sponsor or its contracted first tier, downstream, or related entity.	7 calendar days following date claim received by Part D plan sponsor or its contracted first tier, downstream, or related entity.
Resolution of Rejected Records	90 calendar days following receipt of rejected record status from CMS.	
Adjustment and Deletion	90 calendar days following discovery of issue requiring change.	

CMS believes Part D sponsors are compliant with the longstanding guidance pertaining to 30- and 90-day PDE submission timelines, and thus, CMS stated that it does not expect the proposed change to result in additional costs or savings and are not scoring these requirements in the Regulatory Impact Analysis section. We also noted that we are not imposing any new reporting requirements for drugs other than selected drugs. We do not believe that our proposal pertaining to 7-, 30-, and 90-day PDE submission timeline will result in additional paperwork burden and have not incorporated a burden increase in the Collection of Information section.

Comment: Some commenters opposed the proposal to establish a requirement that Part D sponsors must submit initial PDE records for selected drugs within 7 calendar days of the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim (hereinafter referred to as the ''7-day timeliness requirement'') because these commenters stated that it would create administrative and operational challenges for Part D sponsors, with a commenter stating these challenges would make timeline adherence infeasible. A couple of commenters noted that the proposed 7-day timeliness requirement would create challenges relating to CMS' Drug Data Processing System (DDPS) operations, file transmission timelines, and processes for vendors in addition to those for submitters. A few commenters recommended that CMS require initial PDE submissions to be submitted in no earlier than 10 days or 14 days. Another commenter recommended that CMS require initial PDE submissions to be submitted in no earlier than 21 days.

A couple of commenters recommended CMS allow Part D sponsors to submit initial PDE data for selected drugs to CMS on a weekly basis. A commenter noted that, while they currently submit PDE files on the same day every week, it would be more feasible to have flexibility on the time of submission to ensure processing is complete before submission. The other commenter stated that weekly submission would allow them to submit PDE records as one unified file on the same day of each week and would reduce PDE reversals and adjustments. Another commenter stated that a 7-day timeliness requirement would necessitate submission of PDEs at least twice per week.

Response: CMS thanks these commenters for their input on this topic. CMS recognizes that the proposed 7-day timeliness requirement may pose some administrative and operational challenges for Part D sponsors, vendors, and other interested parties. CMS also recognizes the importance of ensuring timely payment of MFP refunds to dispensing entities while maintaining a PDE submission timeliness requirement for selected drugs that is operationally feasible for Part D sponsors. In evaluating the impact of this proposed policy, CMS' analysis of PDE record submissions shows that a majority of PDE records are currently submitted within 7 days of receipt from Part D sponsors. Given the importance of ensuring timely payment of MFP refunds to dispensing entities starting in 2026 when the MFPs for selected drugs are in effect along with the data showing that the majority of PDE record submissions are currently being submitted within 7 days of receipt, CMS believes that a 7-day timeliness requirement strikes the right balance between ensuring timely payment to dispensing entities and setting a standard that is operationally feasible for Part D sponsors.

Comment: Some commenters encouraged CMS to align the timeframe to submit initial PDE records for selected drugs with the timeframe for non-selected drugs to allow for Part D sponsors to continue workflows to submit PDE records for selected and non-selected drugs in the same files. A commenter stated that it is infeasible to send separate files for selected and non-selected drugs due to the current system for calculation edits performed by DDPS and accumulations as beneficiaries move through benefit phases. This commenter asserted that submitters would need to separate claims from a beneficiary's history which would create ''holes'' in a beneficiary's benefit phases and impact accumulation. The commenter also requested that CMS issue sub-regulatory guidance to provide detail on how to submit subsections of PDE data that would otherwise be included in the current PDE editing practices. Finally, the commenter asserted that due to these operational concerns the 7-day timeliness requirement would effectively apply to both selected and non-selected drugs because these challenges with submitting PDE separately by drug would result in Part D sponsors needing to accelerate all PDEs to be submitted within 7 days.

Response: As discussed in our proposal, the 7-day PDE submission timeframe does not apply to all PDE records. The general PDE submission requirement for initial PDE record submissions is within 30 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim, which is consistent with guidance in place since 2011. Despite this long-standing guidance that gives sponsors up to 30 days to submit PDE records, current analysis of PDE records submissions shows that a majority of PDE records are submitted within 7 calendar days. This analysis leads us to believe that systems and operational impacts are not insurmountable.

Regarding the comment stating that the 7-day timeliness requirement would separate claims from a beneficiary's history and would create ''holes'' in a beneficiary's benefit phases and impact accumulation, it will not be necessary to

relax PDE editing to implement the 7-day PDE submission requirement for selected drugs. DDPS performs checks on PDE data for format, integrity, and validity. These checks (or edits) are at the PDE-level, meaning that, when editing, DDPS does not edit an individual PDE against other PDE records in the beneficiary's history.

The PDE record includes accumulator fields, including a Total Gross Covered Drug Cost (TGCDC) Accumulator and a True Out-of-Pocket (TrOOP) Accumulator. DDPS uses those accumulators to edit multiple data elements on an individual PDE record, not across PDE records. For example, if the PDE record is for a covered drug, and the TrOOP Accumulator is at least equal to the OOP threshold, then the Gross Drug Cost Above the OOP threshold (GDCA) on the PDE record must be greater than $0, otherwise the PDE record will reject. Likewise, if the PDE is for a covered drug and the TrOOP Accumulator is less than the OOP threshold, then the Gross Drug Cost Below the OOP threshold (GDCB) must be greater than $0, otherwise the PDE record will reject. However, DDPS does not edit to validate that the TrOOP Accumulator or the TGCDC Accumulator on an individual PDE record are accurate given all prior records in a beneficiary's history.

Outside of the PDE submission process, Part D sponsors are required to administer and track their enrollee's benefits in real time. See, for example, §§ 423.504(b)(8)(ii) and 423.505(i)(6)(ii). This 7-day PDE submission requirement for selected drugs does not modify that requirement for real time tracking of a beneficiary's accumulators. Therefore, the 7-day PDE submission requirement will not create accumulator ''holes'' in the beneficiary's accumulators in actuality or from a PDE editing perspective.

Comment: A commenter recommended that CMS allow submitters to use existing processes to extract necessary data from Part D claims to facilitate MFP refund payment from manufacturers rather than require a separate PDE submission for selected drugs. Specifically, the commenter suggested that CMS allow submitters to use a payment and billing approach like a prompt pay 835 transaction to enable submitters to take data from the claim instead of submitting a separate PDE for selected drugs.

Response: Comments regarding MFP effectuation and MTF operations, including MTF processes for payment facilitation, are outside the scope of this rule. CMS refers commenters to the final guidance for more information and responses to comments on these and related topics and may consider such feedback in future guidance related to the Negotiation Program.

Comment: A few commenters raised concerns about relying on PDE data to validate claims for MFP-eligible individuals. A couple of these commenters noted that there are some instances in which PDEs are never accepted, for example if there is an eligibility change or a change in which PDEs are reversed, and the dispenser may be at risk of repaying the Primary Manufacturer or not receiving the MFP refund in these cases. A commenter noted that payment reconciliation may not be completely resolved until 6 months after the plan year ends. A couple of commenters asked that CMS provide guidance to ensure dispensing entities are made aware by Part D sponsors if PDE records for an MFP claim are rejected and cannot be corrected by the Part D sponsor.

A commenter also recommended that CMS clarify that if a PDE is rejected and that prevents the MFP refund process from occurring, or if a PDE is later deleted due to an audit, that the Part D sponsor is not required to pay the dispensing entity the amount they would have otherwise received from the manufacturer had the PDE been successfully submitted and not deleted.

Response: CMS thanks these commenters for the input. These comments relate to various aspects of MFP effectuation and MTF operations, including MTF processes for handling PDE data and the credit/debit ledger system. Such comments are outside the scope of this rule, which establishes PDE submission timeliness requirements for Part D plan sponsors. We refer commenters to the final guidance for more information regarding verification of MFP eligibility, how the MTF will use PDE data to generate claim-level data elements, the MTF credit/debit ledger system, MFP effectuation and payment of MFP refunds, and other related issues. We may consider commenters' feedback in the development of future guidance related to the Negotiation Program.

Comment: A few commenters opposed CMS establishing shorter timeliness requirements for adjustment and deletion PDE records for selected drugs, and for resolving PDE records that CMS rejected, stating that this would create administrative and operational challenges for Part D sponsors, particularly considering the increased volume of adjustments and reversals that Part D sponsors may experience due to the proposed 7-day timeliness requirement for selected drugs. A commenter stated that if CMS does shorten the timeliness requirements for adjustments, deletions, and for resolving PDE records that CMS rejected, the window should be at least 30 days. Another commenter urged CMS to significantly shorten the 90-calendar day submission timeframe for adjustments and deletions and/or for the resolution of rejected records to 7 days.

Response: CMS thanks these commenters for their input. CMS acknowledges commenters' concerns with the operational feasibility of shortening the submission timeline for selected drugs for adjustment and deletion PDE records, and for resolving PDE records that were rejected by CMS. Based on the comments received, CMS does not believe that a 7-day timeliness requirement is operationally feasible for Part D sponsors for adjustments, deletions, and for resolving PDE records that CMS rejected and believes that the 90-calendar day submission timeframe for adjustments and deletions and/or for the resolution of rejected records is sufficient for the purpose of the Negotiation Program.

Comment: A commenter recommended that CMS exercise enforcement discretion for a minimum of 1 year while the new PDE submission timeframe is evaluated for operational effectiveness. Another commenter noted that CMS is putting forth a significant change to the initial PDE submission window for selected drugs while Part D sponsors are in the early phase of implementing other major changes to Part D. The commenter requested that if CMS does finalize the proposed 7-day timeliness requirement, it should take more time to fully analyze the effects and implications of the proposed PDE submission timeframe.

A commenter recommended that in the event of a DDPS PDE submission blackout, files submitted directly after the blackout containing data that would have been timely had the blackout not been in effect should be considered timely. Another commenter raised concerns about the 7-day timeliness requirement for selected drugs, noting that in rare cases CMS has taken up to 6 days to accept PDEs.

Response: CMS understands the concerns a 7-day timeliness requirement for selected drug claims may have on Part D sponsor operations. However, to enable manufacturers to promptly provide an MFP refund to dispensing entities, which is critical to mitigating potential financial hardship on dispensing entities, and which could impact Part D beneficiary access to selected drugs, CMS is finalizing its policy. We also reiterate the above

statement that, in evaluating the impact of this proposed policy, CMS' analysis of PDE record submissions shows that a majority of PDE records are currently submitted within 7 days of receipt from Part D sponsors.

We appreciate the input from the commenter who expressed concern for timeliness considerations in the context of a potential DDPS blackout. To the extent that CMS identifies a technological issue with the DDPS system that temporarily renders PDE submissions impossible, CMS anticipates issuing guidance to Part D sponsors to address those operational constraints.

Comment: A commenter recommended that CMS identify and establish guidance on certain rejected PDE edits which should allow the data elements from these PDE edits to flow to the MTF and then to the manufacturer for the MFP refund process to occur.

A commenter recommended that CMS use submitted PDE data, rather than accepted PDE data, for the purpose of manufacturer payment of an MFP refund to the dispensing entity. Another commenter recommended that Part D sponsors continue to pay pharmacies based on PDEs submitted and not PDEs accepted. The commenter noted that PDEs that are later rejected will be updated and resubmitted as appropriate and the MTF will true-up appropriate credit or debit amounts.

Response: CMS thanks these commenters for their input and notes that nothing in this provision is intended to impact the timing of or decisions regarding Part D sponsors paying pharmacies. Comments regarding MFP effectuation and MTF operations, including MTF processes for handling PDE data, generating claim-level data elements that are transmitted to the Primary Manufacturer, and maintaining the credit/debit ledger system, are outside the scope of this rule. CMS refers commenters to the final guidance for more information on these and related topics and may consider such feedback in future guidance related to the Negotiation Program.

Comment: Many commenters expressed support for CMS' goal of ensuring that dispensing entities receive timely payments for retrospective MFP refunds and agreed that shortening the timeliness requirement to 7 days, at minimum, may help ensure timely payment of MFP refunds to dispensers. However, many of these commenters also stated that, to expedite payment to pharmacies, CMS should prefund the MTF because, they asserted, the current proposal essentially places an unfunded mandate on dispensing entities to prefund the Negotiation Program, which CMS does not have the authority to mandate. If CMS does not prefund the Negotiation Program, these commenters urged CMS to shorten the timeliness requirement for selected drugs to 1 day, and to require the MTF to provide data to the Primary Manufacturer on a daily basis. The commenters stated that dispensing entities must be paid within 14 days of adjudicating a claim to ensure their financial viability, particularly because dispensing entities must pay their wholesalers on an approximate 2-week payment cycle, and a 7-day timeliness requirement would result in dispensing entities waiting longer than 14 days to receive MFP refunds.

A few commenters strongly supported the 7-day timeliness requirement because of its importance to dispensing entities but said that the shortened timeframe does not alleviate concerns about the financial risk associated with MFP effectuation. These commenters urged CMS to take steps to address the financial and operational challenges beyond the PDE submission timeline, such as through opportunities to shift primarily to purchasing prospectively at the MFP. A commenter asked CMS to consider how PDE submissions to DDPS could be done in real time on a daily basis.

Response: CMS appreciates the support for shortening the current 30-day timeliness requirement for selected drugs. CMS recognizes the critical importance of ensuring timely payment of MFP refunds to dispensing entities but believes that shortening the PDE submission timeframe for selected drugs to 1 day would not be operationally feasible for Part D sponsors. CMS believes that a 7-day timeliness requirement strikes the right balance between ensuring timely payment to dispensing entities while setting a standard that is operationally feasible for Part D sponsors. Comments requesting that CMS take additional steps to address operational and financial concerns with regard to the MTF, such as prefunding or prospective access to the MFP, are outside the scope of this rule. We refer these commenters to the final guidance for discussion of these topics.

Comment: Some commenters raised a concern that the 7-day timeliness requirement could impact the volume of claims adjustments during and after the 14-day prompt MFP payment window. A couple of commenters noted that there are many claim reversals that occur within the first 48 hours. A few commenters noted that individuals typically have up to 14 days to pick up prescriptions from pharmacies once they are filled and, therefore, if CMS shortens the timeliness requirement for selected drugs to 7 days, more PDE submissions would need to be reversed if individuals do not pick up their drugs within the first 7 days. A commenter noted that their organization's data shows that only one third of claims that are reversed get reversed in the first 7 days.

Some of these commenters opposed the proposed 7-day timeliness requirement due to these concerns about claim adjustments. A few other commenters supported the proposed 7-day timeliness requirement but recommended that CMS closely monitor whether the reduced submission timeframe leads to an increase in claims adjustments and assess the implications for the MFP payment process. Noting that the credit/debit ledger system described in the final guidance may see an increased volume of claim adjustments resulting from a shortened PDE data timeline, a commenter asked CMS to ensure this process is streamlined and allows for claims to be reopened instantaneously, eliminating the need for additional requests and reducing payment timelines. These commenters also encouraged CMS to provide Primary Manufacturers with the ability to audit the PDE data submitted by Part D sponsors for selected drugs to address underlying data quality issues and improve data integrity.

Response: CMS thanks these commenters for their input. Although the 7-day timeliness requirement may lead to some increase in claim adjustments or reversals, CMS does not anticipate a significant uptick because CMS' analysis of PDE record submissions, as noted above, shows that a majority of PDE records are currently submitted within 7 days of receipt from Part D sponsors. CMS maintains detailed data on PDE record submissions, including claim adjustments and deletions, and will continue to monitor this data as the 7-day timeliness requirement for selected drugs takes effect.

While comments regarding the MTF's credit/debit ledger system described in the final guidance and manufacturers' ability to audit PDE data are outside the scope of this rule, CMS notes that to address any claim adjustments or reversals that occur after the Primary Manufacturer has issued an MFP refund, the MTF will maintain a credit/debit ledger system that tracks credits and debits related to MFP refunds at the dispensing entity NPI-level, for each selected drug, for each Primary

Manufacturer that participates in the MTF PM and where payment is facilitated through the MTF PM. For additional information on the credit/debit ledger system maintained by the MTF, including how the system will handle reversals or adjustments originating from updated PDE information received from DDPS, please refer to section 40.4.3.2 of the final guidance.

Comment: A commenter expressed support for CMS' efforts to enhance the timeliness of PDE record submissions but recommended a phased-in implementation timeline of the 7-day timeliness requirement to ensure a smooth transition and mitigate potential operational challenges for Part D sponsors. The commenter stated that many Part D sponsors will need to invest significant resources to enhance their data submission processes, and a phased-in timeline would provide Part D sponsors with sufficient time to adapt to the new requirements without risking disruptions in data submission or compliance.

Response: CMS appreciates the support for enhancing the timeliness of PDE record submissions for selected drugs. Timely implementation of the 7-day timeliness requirement will be critical to mitigating potential hardships on dispensing entities such as pharmacies, which could impact Part D beneficiary access to selected drugs. As stated in section 40.4.2.2 of the final guidance, CMS is concerned that material cashflow pressures on dispensing entities will be most acute in the transition period when MFPs for selected drugs first become effective in January 2026 (and at the start of each subsequent initial price applicability year when MFPs for new selected drugs first become effective). CMS is therefore finalizing the 7-calendar day timeliness requirement for selected drugs without delay.

Comment: Many commenters submitted comments on issues not directly related to the proposed 7-day timeliness requirement for selected drugs. Examples of these topics include the Primary Manufacturers' MFP effectuation plan deadline; the 14-day prompt MFP payment window; data transmissions between the MTF DM and Primary Manufacturers; dispensing entities' concerns regarding price concessions and payment at the MFP; nonduplication of the MFP with the 340B ceiling price; and CMS or Primary Manufacturer prefunding of MTF accounts.

Response: These comments were addressed in the final guidance, and CMS refers commenters to the final guidance for more information. We consider these comments out of scope for this rulemaking.

After consideration of the public comments we received, we are finalizing this proposal without modification at § 423.325(b).

5. Severability

We proposed that the general PDE submission timeliness requirements and the selected drugs PDE submission timeliness requirement provisions finalized herein would be separate and severable from one another. Further, we proposed that if either provision 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 therefore are finalizing this provision without modification.

E. Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements

The Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169), enacted August 16, 2022, established the Medicare Drug Price Negotiation Program (hereinafter the ''Negotiation Program'') to negotiate maximum fair prices (MFPs) for certain high expenditure, single source drugs and biological products. The requirements for the Negotiation Program are described in sections 1191 through 1198 of the Act, as added by sections 11001 and 11002 of the IRA. Sections 11001(c) and 11002(c) of the IRA direct the Secretary of the United States Department of Health and Human Services (hereinafter ''the Secretary'') to implement the Negotiation Program provisions in sections 11001 and 11002 of the IRA, including amendments made by such sections, for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with the law, CMS issued the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 on May 3, 2024 (hereinafter ''draft guidance''), and the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 on October 2, 2024 (hereinafter ''final guidance'').[34] In the final guidance, CMS noted that it also planned to engage in rulemaking to propose certain policies under Medicare Part D that relate to or have implications for the Negotiation Program but involve exercising authorities under the Act that are not subject to the IRA's program instruction requirement. Accordingly, as discussed in more detail below, in this rule, CMS proposed at § 423.505(q) to require that Part D sponsors' network contracts with pharmacies require such pharmacies to be enrolled in the Negotiation Program's Medicare Transaction Facilitator (MTF) Data Module (DM) (hereinafter ''MTF DM'').

1. Background on the Medicare Transaction Facilitator

Section 1193(a) of the Act instructs CMS to enter into agreements (a ''Medicare Drug Price Negotiation Program Agreement,'' hereinafter referred to as a ''Negotiation Program Agreement'') with willing manufacturers of selected drugs (as described in section 1192(c) of the Act) for a price applicability period (as defined in section 1191(b)(2) of the Act). After entering into a Negotiation Program Agreement with CMS and in accordance with section 1193(a) of the Act, any ''Primary Manufacturer'' (as defined in section 40 of the final guidance) of a selected drug that continues to participate in the Negotiation Program and reaches agreement upon an MFP must provide access to the MFP to MFP-eligible individuals (defined in section 1191(c)(2)(A) of the Act) and to pharmacies, mail order services, and other dispensing entities that dispense drugs covered under Medicare Part D (hereinafter ''dispensing entities'') with respect to such MFP-eligible individuals. In section 40.4 of the final guidance, CMS stated that a Primary Manufacturer must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP, or (2) retrospectively providing reimbursement for the difference between the dispensing entity's

[34] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191—1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 *https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.*

acquisition cost and the MFP. Consistent with longstanding Part D prompt pay rules regarding payment by Part D sponsors to network pharmacies,[35] CMS will require that a Primary Manufacturer electing to provide retroactive reimbursement will meet its obligation to make MFP available by transmitting payment of an amount that provides access to the MFP within 14 calendar days of when certain claim-level data elements are sent to the Primary Manufacturer by the MTF DM.

In section 40.4 of the final guidance, CMS stated, based on CMS' continuous engagement with and extensive feedback from interested parties, for 2026 and 2027, CMS will engage with MTF contractors to facilitate the exchange of data and payment between pharmaceutical supply chain entities for the purposes of the Negotiation Program. The MTF will have two distinct modules, the MTF DM and the MTF Payment Module (hereinafter ''MTF PM''), a voluntary option to pass payment for MFP refunds from Primary Manufacturers to dispensing entities. The combined data and payment facilitation functionalities present in the MTF DM and the MTF PM will attempt to address the interest expressed by dispensing entities and manufacturers to have a single platform for transmitting the data necessary for program administration and supporting MFP refund payments to create greater efficiency, standardization, and predictability in the execution of a high volume of continuous payments.

The MTF DM will facilitate the exchange of certain claim-level data elements and claim-level payment elements for selected drugs to support the verification that the selected drug was dispensed to an MFP-eligible individual, as described in section 40.4.2 of the final guidance. The data supplied by the MTF DM to Primary Manufacturers will have been verified by both the Part D sponsor and CMS' Drug Data Processing System (DDPS) resulting in dual verification of both an individual's eligibility for Part D, and Part D coverage of the selected drug for each claim being transmitted. For context, when a Part D sponsor receives a claim for a selected drug from a dispensing entity, the Part D sponsor verifies that the beneficiary listed on the claim paid by the Part D sponsor is enrolled in Medicare Part D and coverage is provided under Part D for the dispensed drug. After the Part D sponsor verifies Medicare eligibility and coverage of the selected drug, the plan pays the dispensing entity no more than the MFP plus any dispensing fees for the selected drug. Then, the Part D sponsor sends the data on the Part D claim as a Prescription Drug Event (PDE) record (that is, claim summary records submitted by Medicare Part D sponsors to CMS for every prescription filled by a dispensing entity for a Medicare Part D beneficiary) to DDPS. CMS uses DDPS to perform verification steps to validate that the individual was an eligible Part D enrollee at the time of the claim, as described in section 40.4.2.1 of the final guidance. After CMS verifies MFP eligibility for the individual related to the claim, DDPS will transmit the PDE record for the Part D claim for the selected drug to the MTF DM. Therefore, because MFP eligibility status has been twice validated before the data elements are sent from the MTF DM to the Primary Manufacturer, the data elements will have been verified as involving a selected drug that was dispensed to an MFP-eligible individual.

As stated in section 40.4.2.1 of the final guidance, enrollment in the MTF DM will be mandatory for Primary Manufacturers. CMS will require all Primary Manufacturers to register with the MTF DM by a deadline to be specified by CMS and to maintain the functionality necessary to receive certain claim-level data elements from the MTF DM and return certain claim-level payment elements to the MTF DM. Each Primary Manufacturer will be required to sign data use, privacy, and security agreements with CMS and comply with data use, privacy, and security requirements to protect the data elements received from and transmitted to the MTF.

As discussed in section 40.4.2.2 of the final guidance and in more detail below, dispensing entity enrollment in the MTF DM is also needed for the administration of the Negotiation Program and the Part D program. Dispensing entity enrollment in the MTF DM allows for several key functionalities that help ensure accurate Part D claims information and payment and continued access for beneficiaries and dispensing entities to selected drugs. These functionalities include collecting and sharing of banking information from dispensing entities to Primary Manufacturers; creating and sending of Electronic Remittance Advice that uses the X12 835 standard adopted under the Health Insurance Portability and Accountability Act of 1996 (hereinafter ''ERAs'') (for electronic transfer of funds) or remittances (for paper checks) to dispensing entities; a streamlined ability to submit complaints and disputes regarding selected drugs dispensed; and the ability for dispensing entities to identify themselves as anticipating material cashflow concerns at the start of a price applicability period with respect to selected drugs as a result of potential delays created by reliance on retrospective MFP refunds within the 14-day prompt MFP payment window. Accordingly, CMS proposed to require Part D sponsors to include in their network pharmacy agreements provisions requiring dispensing entities to be enrolled in the MTF DM.

If a Primary Manufacturer elects to utilize the MTF PM, then the MTF PM will facilitate payment of an MFP retrospective refund on MFP-eligible claims of selected drugs from the participating Primary Manufacturer to the dispensing entity. Specifically, as discussed in section 40.4.3 of the final guidance, the MTF PM will: (1) provide Primary Manufacturers with a mechanism for electronic transfer of funds or payment by paper check to facilitate MFP refund payments from Primary Manufacturers to dispensing entities; and (2) provide Primary Manufacturers with a credit/debit ledger system to track the flow of MFP refunds and to handle reversals, adjustments, and other claim revisions inevitable in a dynamic claim payment system. Participation in the MTF PM will be voluntary for Primary Manufacturers, which will have the option of passing MFP refund payments to dispensing entities through the MTF PM or using their own processes outside of the MTF PM to effectuate the MFP. Primary Manufacturers that elect to use the MTF PM to pass through payments will be required to execute MTF agreements with the MTF PM outlining each party's rights, responsibilities, and potential liabilities associated with the transfer and receipt of funds through the MTF PM.

2. Network Pharmacy Contracts With Part D Sponsors

CMS has broad contracting authority with respect to Part D sponsors under section 1860D–12 of the Act. As applied to the Part D program through section 1860D–12(b)(3)(D) of the Act, section 1857(e)(1) of the Act authorizes the Secretary to adopt contract terms and conditions as necessary and appropriate and not inconsistent with the Part D statute. Additionally, section 1860D–12(b)(3)(D)(i) of the Act specifies that information provided to the Secretary under the application of section 1857(e)(1) of the Act may be used (in

[35] See 42 CFR 423.520, Prompt Payment by Part D Sponsors, which requires the Part D sponsor to transmit payment to network pharmacies within 14 days after receiving an electronic Part D claim that is a clean claim.

relevant part) for the purposes of carrying out the Part D program or Part E of Title XI of the Act (that is, the Negotiation Program). Pursuant to these authorities, CMS proposed to require Part D sponsors (or first tier, downstream, or related entities, such as PBMs, acting on the sponsors' behalf) to include in their network participation agreements with contracting pharmacies a provision that requires the pharmacy to be enrolled in the MTF DM (or any successor to the MTF DM) in a form and manner to be determined by CMS. CMS emphasized that under the proposed regulation, such provision must require the pharmacy ''to be enrolled'' in the MTF DM, as opposed to merely requiring the pharmacy ''to enroll'' in the MTF DM, to establish an ongoing obligation that the pharmacy maintain its enrollment in the MTF DM. CMS also proposed that such provision must require the pharmacy to maintain and certify to CMS that the enrollment information provided in the MTF DM is accurate, complete, and up to date, pursuant to applicable terms and conditions of participation with the MTF DM, in a form and manner to be determined by CMS. CMS proposed amending § 423.505 by adding paragraph (q) to codify this requirement.

Consistent with section 1860D–12(b)(3)(D) of the Act, such a requirement would be necessary and appropriate and not inconsistent with the Part D statute. As previously mentioned, the MTF DM will contain several key functionalities that are necessary and appropriate for operations related to administration of the Negotiation Program and the Part D program. Through each of the functionalities outlined below, dispensing entity enrollment in the MTF DM would help ensure continued access to selected drugs that are covered under Part D for beneficiaries and dispensing entities and help maintain the accuracy of Part D claims information and payment.

First, the MTF DM will provide dispensing entities enrolled in the MTF DM with remittances or ERAs to reconcile MFP refund payments when a Primary Manufacturer chooses to pass payment to the dispensing entity through the MTF PM. Interested parties strongly requested that electronic MFP refunds be accompanied by an ERA or remittance. To meet industry standards in the creation of an accurate ERA or remittance, up-to-date banking information for a dispensing entity is needed. Dispensing entities will be required to provide up-to-date banking information and, if applicable, payment center information during MTF DM enrollment. For Primary Manufacturers that make payments outside of the MTF PM, CMS plans to make available through the MTF DM dispensing entities' banking information, payment center information (if applicable), and designated destination for ERAs or remittances, as applicable.

These ERAs or remittances will assist dispensing entities in closing out their open accounts receivable, thereby minimizing cashflow interruptions. Specifically, the information contained in the ERA or remittance will connect claims payment determination and amount with how the payment was made, including the electronic funds transfer information, if applicable. CMS expects this will enable dispensing entities to review their accounts receivables (consistent with each dispensing entity's own standard business practices) for each claim for which a Primary Manufacturer owes an MFP refund and determine whether a Primary Manufacturer has paid all the claims the dispensing entity believes are MFP-eligible claims, in the amounts the dispensing entity believes are sufficient to effectuate the MFP. Moreover, CMS has consistently heard from interested parties that without an ERA or remittance, MFP refund payments may be rejected, and, in these scenarios, dispensing entities would not have means to reconcile received payments against outstanding MFP-eligible claims.

Second, there will be streamlined access for dispensing entities enrolled in the MTF DM to submit complaints and disputes within the MTF DM to help identify issues with timely MFP refund payment, supporting dispensing entities to continue efficient operations and prevent undue financial hardship, while maintaining accuracy of Part D claims information and payment. Allowing dispensing entities streamlined access to this system will support the administration of the Negotiation Program and Part D program. Through the MTF DM, a dispensing entity can submit a complaint related to MFP availability, which CMS will review. Additionally, all Primary Manufacturers will be required to utilize the MTF DM to report to the MTF DM information (claim-level payment elements) about how the Primary Manufacturer has made the MFP available for each claim for which the Primary Manufacturer received data from the MTF DM or indicate why no MFP refund payment has been made on a claim. While dispensing entities are encouraged to remediate with the manufacturer directly if they believe that they have not received a retrospective refund payment that effectuates the MFP, dispensing entities may use the complaints process within the complaint and dispute system in the MTF DM to alert CMS if the dispensing entity believes program requirements are not being met.

Third, the MTF DM will serve as a central repository for information about dispensing entities enrolled in the MTF DM that self-report that they anticipate material cashflow concerns due to the reliance on retrospective MFP refunds within the 14-day prompt MFP payment window. Interested parties have noted that small pharmacies that rely primarily on prescription revenue to maintain business operations would face material cashflow pressures due to the shift from payment by the Part D sponsor to a combination of Part D sponsor payment plus a potentially lagged MFP refund. Based on this input, CMS is concerned that this challenge will be most acute in the transition period when MFPs for selected drugs first become effective in January 2026 and at the start of each subsequent initial price applicability year when MFPs for new selected drugs first become effective (for example, at the start of a price applicability period with respect to a selected drug). CMS does not anticipate this challenge to continue with respect to a selected drug once MFP refunds for that selected drug are flowing and dispensing entities become accustomed to the 14-day prompt MFP payment window. Consider a scenario in which the dispensing entity purchases a selected drug at a price discounted from the wholesale acquisition cost (WAC), for example, at WAC minus four percent, for ten units. Initially, this expenditure creates a temporary cashflow gap. However, upon receiving the MFP refund payment, the dispensing entity's upfront cost is offset, effectively restoring its financial position. Assuming a consistent utilization rate for the drug, any temporary negative cashflow should be offset by the subsequent MFP refund payment. The timing and consistency of this pattern should lead to stable cashflow and avoid a long-term cash deficit over time. During MTF DM enrollment, CMS will ask dispensing entities to self-identify whether they are a dispensing entity that anticipates having material cashflow concerns in connection with the effectuation of MFP. The types of entities CMS anticipates may self-report through this process include sole proprietor rural and urban pharmacies with high volumes of Medicare Part D prescriptions dispensed, pharmacies who predominantly rely on prescription

revenue to maintain business operations, long-term care pharmacies, 340B covered entities with in-house pharmacies, and I/T/U pharmacies. The information self-reported by dispensing entities will be provided to Primary Manufacturers to assist in the development of their MFP effectuation plans, which should describe a process for mitigating material cashflow concerns for dispensing entities. The MTF DM will also be available to dispensing entities enrolled in the MTF that need to update their self-identification with respect to material cashflow concerns, as CMS anticipates that indication could change over time.

Fourth, CMS intends that dispensing entities will be able to view the status of MFP refunds from Primary Manufacturers through the MTF DM. The ability to track MFP refunds could also help dispensing entities better manage their cashflow or aid their financial planning to meet other administrative burdens or operational costs.

Fifth, the MTF DM will collect and share financial information belonging to dispensing entities enrolled in the MTF DM with Primary Manufacturers that pay MFP refunds to dispensing entities outside the MTF PM. Through CMS' engagement with interested parties, both manufacturers and dispensing entities have expressed the concern that they typically do not have direct financial relationships with one another, increasing dispensing entities' risk of experiencing payment delays. As such, during MTF DM enrollment, dispensing entities must provide their bank account information. CMS believes that the collecting and sharing of dispensing entities' bank account information with Primary Manufacturers will address interested parties' concerns related to the lack of an established channel to support MFP refund payments made outside the MTF PM, and help dispensing entities to continue efficient operations.

In sum, CMS believes that enrollment in the MTF DM by dispensing entities would facilitate continued beneficiary and dispensing entity access to selected drugs that are covered Part D drugs. Manufacturers and dispensing entities have asked the agency to undertake a role in assuring that MFP refund payments to dispensing entities can be made efficiently, and the development of an MTF DM has an important role in that process. With less financial uncertainty, dispensing entities are better positioned to keep dispensing selected drugs covered under Part D. Given the wide number and scope of dispensing entities that dispense drugs to Part D beneficiaries—which is currently approximately 60,000-plus community pharmacies and 80,000-plus dispensing entities in total—CMS believes that the requirement would help reach a substantial number of entities that serve Medicare beneficiaries. Requiring network pharmacy agreements to require enrollment by pharmacies in the MTF DM will help promote successful MFP effectuation under the Negotiation Program and facilitate continued access to selected drugs covered under Part D for Medicare beneficiaries.

For the reasons stated previously, CMS proposed to require Part D sponsors (or first tier, downstream, or related entities, such as pharmacy benefit managers (PBMs), acting on the sponsors' behalf) to include in their network participation agreements with contracting pharmacies a provision that requires the pharmacy to be enrolled in the MTF DM (or any successor to the MTF DM), which would entail an ongoing obligation that the pharmacy maintain its enrollment in the MTF DM, in a form and manner to be determined by CMS. CMS also proposed that such provision must require the pharmacy to maintain and certify to CMS that the enrollment information provided in the MTF DM is accurate, complete, and up to date, pursuant to applicable terms and conditions of participation with the MTF DM, in a form and manner to be determined by CMS. CMS received comments on this proposal, which are summarized and responded to as follows.

Comment: Many commenters expressed general support for the proposal. A few commenters expressed that the requirement for pharmacies to be enrolled in the MTF DM is necessary for success of the Negotiation Program. A commenter stated that the requirement would also help ensure beneficiary access to selected drugs and their maximum fair prices (MFPs).

Response: CMS thanks these commenters for their comments in support of our proposal.

Comment: A couple commenters requested CMS clarify the role of Part D sponsors and/or PBMs in enforcing the proposed contractual provision. Specifically, these commenters asked whether Part D sponsors and/or PBMs would be required to monitor or audit pharmacies' enrollment in the MTF DM and take enforcement actions where, for example, a pharmacy does not enroll in the MTF DM, provides inaccurate enrollment information, or does not keep their enrollment information up to date. A commenter stated that such actions would be difficult for Part D sponsors to carry out without access to MTF DM enrollment data. In the event that Part D sponsors and/or PBMs are required to do so, these commenters also asked how such pharmacies should be penalized. A commenter noted that their network agreement with contracting pharmacies, for example, states that the penalty for non-compliance may be termination from the network. Another commenter stated that, should CMS finalize its proposal, CMS should retain oversight responsibilities in monitoring pharmacies' compliance with the requirement to be enrolled in the MTF DM.

Response: CMS thanks the commenters for their questions. To clarify, CMS intends to monitor, oversee, and facilitate enrollment in the MTF DM, and intends to establish a participation agreement with each enrolling dispensing entity to include, among other provisions, potential penalties surrounding their engagement with and use of the MTF system.[36] This participation agreement will complement the new requirements on Part D sponsors to contractually require their network pharmacies to be enrolled in the MTF DM. Recognizing that Part D sponsors will not be users of the MTF DM, CMS also plans to work together with Part D sponsors to communicate MTF DM enrollment requirements to their network pharmacies and may also share reports with Part D sponsors and/or PBMs regarding pharmacies' enrollment in the MTF DM to assist Part D sponsors in monitoring their network pharmacies' compliance with the new requirement. Our requirement on Part D sponsors and/or PBMs to incorporate a specific contractual provision in their network pharmacy agreements does not alter the established roles of Part D sponsors and/or PBMs in monitoring compliance and enforcing terms and conditions of their own contracts. Therefore, Part D sponsors and PBMs should apply their usual enforcement actions in the event of pharmacy non-compliance, consistent with their existing contractual rights and obligations.

Comment: A couple commenters found the proposal unnecessary and expressed general opposition to codifying network pharmacies' participation in the MTF DM. A commenter explained that pharmacies

[36] CMS published these in draft form on the CMS IRA website (*https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation*) and solicited public feedback beginning on December 17, 2024, through January 31, 2025. CMS plans to finalize and post the final agreements on the CMS IRA website in Spring 2025.

are already incentivized to enroll in the MTF DM, and another commenter stated that pharmacies' information can be collected from a database owned by the National Council for Prescription Drug Programs (NCPDP).

Response: While CMS agrees that dispensing entities are incentivized to enroll in the MTF DM, the absence of an enrollment requirement may lead to variability in dispensing entities' participation in the MTF DM given the wide number and scope of pharmacies that dispense drugs to Part D beneficiaries, which is currently over 60,000-plus community pharmacies and 80,000-plus dispensing entities in total. Such variability in dispensing entity participation could result in uneven access to selected drugs that are covered Part D drugs by an MFP-eligible individual. CMS also appreciates the commenter's input regarding NCPDP; CMS intends to use NCPDP databases to the extent possible for enrollment but notes that banking information necessary for the pass through of MFP refunds to dispensing entities (and, if applicable to their third-party support entities, such as Pharmacy Services Administrative Organizations (PSAOs)), is not available in NCPDP databases.

Comment: Many commenters asserted that the proposal would result in CMS interfering with network pharmacy agreements and cited the noninterference clause at section 1860D–11(i) of the Act. Specifically, these commenters stated that CMS is interfering with PBM contracts to facilitate implementation of the IRA despite previously stating that it would not interfere in other circumstances, where interested parties, for instance, requested that CMS protect pharmacies from unfair PBM reimbursement rates and practices. A commenter stated that, if CMS has the legal authority to interfere with PBM contracts to support IRA implementation, then it should ensure fair and reasonable payment by Part D sponsors to pharmacies.

Response: CMS thanks the commenter for their comment. CMS considers the issue of Part D sponsors' reimbursement rates out of scope for this rulemaking and CMS disagrees with the commenters' assertion that the requirement on Part D sponsors to include a contractual provision in its network pharmacy agreements is in violation of the noninterference clause. As explained in the final rule titled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 29874 and 29875), we reiterated that the noninterference clause does not limit our authority to require the inclusion of terms and conditions in agreements when necessary to implement and enforce requirements under the Act. As applied to the Part D program through section 1860D–12(b)(3)(D) of the Act, section 1857(e)(1) of the Act authorizes the Secretary to adopt contract terms and conditions as necessary and appropriate and not inconsistent with the Part D statute. Section 1860D–12(b)(3)(D)(i) of the Act also specifies that information provided to the Secretary under the application of section 1857(e)(1) of the Act may be used (in relevant part) for the purposes of carrying out the Part D program or Part E of Title XI of the Act (that is, the Negotiation Program). The requirement on Part D sponsors to include a contractual provision in its network pharmacy agreements related to enrollment in the MTF DM is consistent with implementation of these authorities, necessary to promote effective administration of the Part D program and the Negotiation Program and does not violate the non-interference clause.

Comment: A couple commenters stated that CMS lacks statutory authority to require pharmacies' participation in the MTF DM as a prerequisite for participation in Part D.

Response: CMS disagrees with the commenters that CMS lacks statutory authority to propose the requirement specified at § 423.505(q). As applied to the Part D program through section 1860D–12(b)(3)(D) of the Act, section 1857(e)(1) of the Act authorizes the Secretary to adopt contract terms and conditions as necessary and appropriate and not inconsistent with the Part D statute. Additionally, section 1860D–12(b)(3)(D)(i) of the Act specifies that information provided to the Secretary under the application of section 1857(e)(1) of the Act may be used (in relevant part) for the purposes of carrying out the Part D program or Part E of Title XI of the Act (that is, the Negotiation Program). The MTF DM will contain several key functionalities that are necessary and appropriate for operations related to administration of the Negotiation Program and the Part D program. Through each of the functionalities discussed in more detail above, dispensing entity enrollment in the MTF DM will help ensure continued access to selected drugs that are covered under Part D for beneficiaries and dispensing entities and help maintain the accuracy of Part D claims information and payment.

Comment: A couple of commenters requested CMS delay the proposed requirement until after the MTF DM is fully operational, tested, and all enrollment and/or operational are known.

Response: CMS appreciates the commenters' suggestion for delayed implementation but does not agree. Primary Manufacturers will be statutorily required to provide access to any MFP for drugs selected for initial price applicability year 2026 starting on January 1, 2026, which requires timely enrollment in order for the MTF to facilitate the exchange of data and payment. In addition, CMS has been actively engaging with interested parties through MTF system calls to consider and address their feedback regarding the development of the MTF user interface.

Comment: A couple commenters who expressed support for the proposal also provided recommendations to CMS on pharmacy enrollment implementation, such as suggesting a need for CMS to conduct outreach, provide technical assistance, and offer education to pharmacies, as well as to explore leveraging existing databases to automate the MTF DM enrollment process. A commenter urged that CMS, once pharmacies are enrolled in the MTF DM, reconsider providing a deidentified beneficiary ID to Primary Manufacturers to allow them to better identify duplicate claims sent by the MTF to the Primary Manufacturer; this commenter also recommended that CMS conduct regular audits of claims submitted to the MTF.

Response: CMS thanks the commenters for their input. While these comments are out of scope for this rulemaking, CMS will consider these suggestions as part of ongoing pharmacy outreach and engagement and intends to use NCPDP databases to the extent possible for enrollment. Further, CMS notes that in section 40.4.2.1 of the ''Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027'' [37] (final guidance), CMS stated that an individual's eligibility for Part D and Part D coverage of the selected drug for each claim will be twice validated before the data elements are sent from the MTF DM to the Primary

[37] 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.*

Manufacturer; in other words, the claim-level data elements will be derived from claims that been verified for Medicare eligibility by both the Part D plan and CMS' Drug Data Processing System (DDPS), a CMS system used to process all Medicare Prescription Drug Event (PDE) records and related data, obviating the need for additional verification by the Primary Manufacturer.

Comment: Many commenters did not support the proposal because of broad disagreement with CMS' implementation of the Negotiation Program. Specifically, these commenters stated that CMS is shifting the financial and operational burden of the Negotiation Program onto pharmacies. They stated this will be a nonviable solution due to insufficient reimbursement by plans and their PBMs, coupled with the time it will take for pharmacies to wait for MFP refund payments from the manufacturers, and the cadence on which dispensing entities are required to pay their wholesalers.

Response: CMS appreciates the commenters' input. While CMS considers these comments out of scope, CMS is aware of the concerns of pharmacies regarding the Negotiation Program, and has tried, within the framework of applicable law, to implement policies that will mitigate any potential adverse impact. This new requirement will assure that dispensing entities that dispense Part D drugs are able to track and receive their MFP refund payments from Primary Manufacturers. We refer readers to the ''Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027'' (final guidance), where similar comments were raised and addressed, for more information.

Comment: Many commenters submitted comments on issues relating to the Negotiation Program and not directly related to the proposed MTF enrollment requirement in network pharmacy agreements. Examples of these topics include: CMS' implementation of the Negotiation Program; Primary Manufacturer effectuation of the MFP; the effectiveness of Primary Manufacturers' MFP effectuation plans; the 14-day prompt MFP payment window; MTF requirements for data privacy and security; pharmacies' concerns regarding administrative and operational burden in using the MTF DM; nonduplication with the 340B ceiling price; the retrospective refund amount to effectuate the MFP and the Standard Default Refund Amount (SDRA); Primary Manufacturers' voluntary participation in the MTF Payment Module; a Coverage Gap Discount Program (CGDP) derivative refund model; prefunding of MTF accounts; and pharmacies' financial challenges in waiting for retrospective MFP refund payments.

Response: These comments were addressed in the final guidance and CMS refers commenters to the final guidance for more information.[38] CMS considers these comments out of scope for this rulemaking.

After careful consideration of all the comments received, and for the reasons set forth in the proposed rule and in our responses to the comments, we are finalizing as proposed the provision at § 423.505(q).

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

A. Clarifying MA Organization Determinations To Enhance Enrollee Protections in Inpatient Settings (§§ 422.138, 422.562, 422.566, 422.568, 422.572, 422.616, and 422.631)

We proposed four modifications to existing regulations at 42 CFR part 422, subpart M, to clarify and strengthen existing rules related to organization determinations. First, we proposed to clarify the rule that if an enrollee has no further liability to pay for services furnished by a MA organization, a determination regarding these services is not subject to appeal. Specifically, we proposed to clarify that an enrollee's further liability to pay for services cannot be determined until an MA organization has made a determination on a request for payment. Second, we proposed to modify the definition of an organization determination to clarify that a coverage decision made by an MA organization contemporaneously to when an enrollee is receiving such services, including level of care decisions (such as inpatient or outpatient coverage), is an organization determination subject to appeal and other existing requirements. Third, we proposed to strengthen the notice requirements to ensure that a provider who has made a standard organization determination or integrated organization determination request on an enrollee's behalf, or when it is otherwise appropriate, receives notice of the MA organization's decision. Finally, we proposed a change to the reopening rules to curtail an MA organization's authority to reopen and modify an approved authorization for an inpatient hospital admission on the basis of good cause for new and material evidence. We address each of these provisions in detail.

1. Clarifying When a Determination Results in No Further Financial Liability for the Enrollee (§ 422.562)

Section 1852(g)(1)(A) of the Act requires an MA organization to have a procedure for making determinations regarding whether an enrollee is entitled to receive a health service and the amount (if any) that the individual is required to pay with respect to such service. Under section 1852(g)(2) of the Act, an MA organization must provide for reconsideration of an adverse determination upon an enrollee's request. The existing regulations at part 422, subpart M, set forth the administrative appeals process available to enrollees who wish to dispute an organization determination made by an MA organization. Section 422.562(c) describes limits on the applicability of the administrative appeals process in part 422, subpart M. The limitation in § 422.562(c)(1) states that if an enrollee receives immediate Quality Improvement Organization (QIO) review (as provided in § 422.622) of a determination of noncoverage of inpatient hospital care, then the enrollee is not entitled to review of that issue by the MA organization. The second limitation at § 422.562(c)(2) states that if an enrollee has no further liability to pay for services that were furnished by an MA organization, a determination regarding these services is not subject to appeal.

The organization determination and reconsideration regulations of part 422, subpart M, broadly distinguish between two categories of decisions: coverage decisions (that is, a decision on whether the MA organization will furnish, authorize, or arrange for an item, service, or Part B drug) and payment decisions (that is, a decision whether to pay or deny payment for services furnished to an enrollee). These divergent categories of organization determinations have distinct requirements related to processing timeframes (including the applicability of processing timeframe extensions), the parties eligible to submit an

[38] 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.*

organization determination or reconsideration request, notice requirements, and whether an MA organization must expeditiously process an organization determination or reconsideration request upon receiving a valid request.

When a coverage request is received, or when the MA organization issues an unsolicited coverage decision related to ongoing services, the MA organization will apply applicable coverage criteria and either approve, furnish, arrange for, or deny coverage for the services at issue. An approved coverage decision should result in the enrollee receiving the services at issue and the MA organization making payment to the treating provider when a request for payment is eventually submitted. When a request for payment for furnished services is received without a previously approved coverage decision, the MA organization will apply coverage criteria and must either make payment or deny the request within the timeframes specified in the ''prompt payment'' provisions of § 422.520. In addition, the MA organization must calculate the enrollee's applicable cost-sharing and/or financial liability for the furnished service (when issuing a partially or fully adverse decision) including considering applicable beneficiary protections related to plan-directed care. ''Plan-directed care'' occurs when a contract provider furnishes a service or refers an enrollee for a service that an enrollee reasonably believes is a plan-covered service. Upon receiving plan-directed care, an enrollee cannot be financially liable for more than the applicable cost-sharing for that service (see § 422.105). Accordingly, under existing § 422.562(c)(2), if a payment determination related to services furnished by a MA organization results in no remaining financial liability for the enrollee, including adverse decisions that fall within the plan-directed care beneficiary protections, the decision is not subject to the appeal requirements of part 422, subpart M.[39] This means that neither the enrollee nor any other party may appeal an adverse payment decision under subpart M after an MA organization determines the enrollee is not financially liable for more than the applicable cost-sharing of the services for which payment was requested.[40]

CMS has historically interpreted the limitations of § 422.562(c)(2) to apply to payment determinations, not coverage decisions (that is, those addressed under § 422.566(b)(3) and (4)). From a practical perspective, a coverage decision will affect the care an enrollee is to receive or is receiving in addition to the enrollee's cost-sharing liability. Nevertheless, we had identified that some MA organizations misapply the appeal limitation provision of § 422.562(c)(2) to certain coverage decisions, specifically those related to an enrollee's inpatient admission or level of care. These MA organizations often improperly label these adverse coverage decisions as ''contractual denials'' or ''payment decisions'' even though no request for payment has been submitted and, oftentimes, the services are still being rendered at the time of the MA organization's decision. We had seen instances, for example, where an MA organization would deny an enrollee coverage for ongoing inpatient services being received in a contract hospital and take the position that because MA beneficiary protection policies on plan-directed care prevent the enrollee from being financially liable for more than their applicable cost-sharing, when a request for payment is ultimately submitted, § 422.562(c)(2) prevents the enrollee from appealing the coverage denial. Consequently, these enrollees were left without an avenue to appeal decisions that directly affect their immediate medical care and may also alter the amount of their applicable cost-sharing if the enrollee's level of care is changed from inpatient to outpatient during their hospital stay. Further, the application of § 422.562(c)(2) in this manner may also contravene section 1852(g)(2) of the Act which requires MA organizations provide reconsideration of denials of enrollee coverage, in whole or in part, upon request by the enrollee involved.

To eliminate potential confusion related to identifying when organization determinations may not be appealable due to the lack of enrollee financial liability, we proposed modifying § 422.562(c)(2) to clarify that the provision is only applicable to contract provider payment disputes arising from a claim payment decision in which the enrollee has no additional financial liability. The reference to ''no further liability to pay'' in § 422.562(c)(2) means the enrollee's financial liability will not be affected by whether the payment determination is upheld or overturned. In scenarios where an enrollee may still have a balance due for their cost sharing amount, this amount would not be considered ''further liability to pay'' if this amount would not be affected by resolution of the payment dispute.

Specifically, we proposed to modify this paragraph to state that, based on an MA organization's determination on a request for payment, if an enrollee has no further liability to pay for services that were furnished by an MA organization, a determination regarding these services is not subject to appeal. In other words, we proposed to clarify that this limitation is only applicable if there's been a claim payment determination, which necessarily requires a submission of a claim or other request for payment from a contract provider or enrollee. Coverage decisions, whether approved or denied, will continue to be subject to the subpart M appeals process. Under our proposal, an enrollee would be considered potentially liable to pay for a service until the MA organization makes a determination in response to a request for payment, including the submission of a provider's claim for the furnished service.

As stated in the proposed rule, the proposed clarification to § 422.562(c)(2) properly reestablishes the intent to exclude contract provider payment appeals from the subpart M administrative appeals process when the enrollee no longer has any interest in the dispute because the enrollee has received the services in question and has no further liability to pay for those services. In addition, the proposed clarification would safeguard enrollees' right to appeal adverse coverage decisions that may affect the type, duration, or level of services to be, or being, furnished. However, simply because a contract provider payment decision may not implicate the subpart M administrative appeals process, an MA organization is not discharged of its obligation to pay its contract providers for services rendered. Section 1852(a)(1)

[39] We note that a state Medicaid agency has a specific right to appeal an adverse payment decision for a qualified Medicare beneficiary (QMB) or other full-benefit dually eligible individual for services in which the state Medicaid agency has made payment or may be liable, pursuant to § 405.908 and incorporated into part 422, subpart M, through § 422.562(d)(1). The right for a state Medicaid agency to appeal an adverse payment decision may exist even when § 422.562(c)(2) would otherwise preclude the right to appeal.

[40] We note that the provision at § 422.562(c)(2) only applies to services ''furnished by an MA organization'' which, as we have explained, generally occurs when a contract provider, as an agent of the MA organization, renders covered services to an MA organization's enrollee. Section 422.562(c)(2) does not limit the right for parties to appeal adverse payment determinations related to services provided by a non-contract provider as non-contract providers are not considered agents of an MA organization due to the lack of a mutual contractual relationship. Instead, non-contract providers may become assignees of an enrollee by formally agreeing to waive any right to payment from the enrollee, in accordance with § 422.574(b), and then may utilize the administrative appeals process established at §§ 422.578 through 422.616 to appeal adverse payment determinations in their capacity as an assignee of the enrollee.

of the Act and CMS regulations at § 422.101(a) and (b) require all MA organizations to provide coverage of, by furnishing, arranging for, or *making payment for* (emphasis added), all items and services that are covered by Part A and Part B of Medicare and that are available to beneficiaries residing in the plan's service area. We expect MA organizations to establish networks of providers to deliver plan-covered benefits and pay them in accordance with terms of the contracts established. Failure to abide by contract terms and contract disputes can have a negative impact on providers, their ability to properly deliver benefits, and ultimately adversely impact patients in the health care system.

We received a number of public comments on our proposals. Our summaries and responses to the comments we received are discussed below:

Comment: Numerous commenters supported the proposed modification. Many commenters expressed strong support for the proposed limitation that § 422.562(c)(2) may only be applied upon the MA organization's adjudication of a request for payment. A commenter appreciated that the proposal would protect MA enrollees' access to care in inpatient settings. Another commenter believed that the right to appeal adverse coverage decisions is an important enrollee protection that allows providers to deliver care that meets the enrollees' needs. A commenter supported CMS' observation in the proposed rule that MA plans often improperly label coverage decisions as ''contractual denials'' or ''payment decisions'', which may leave those enrollees without an avenue to appeal adverse decisions that directly affect their immediate medical care and applicable cost-sharing. A different commenter described the proposal as a critical protection for enrollees as the denial of an inpatient admission or the change from an inpatient to outpatient could have significant financial implications for the enrollee and could effectively prevent access to post-acute care.

Response: We appreciate the commenters' support and suggestions related to our proposed modification to § 422.562(c)(2). We appreciate the commenters recognizing that our proposal ensures compliance with the requirements of section 1852(g) of the Act and that enrollees are afforded sufficient due process when an MA organization makes adverse coverage decisions that affect an enrollee's current care, applicable cost-sharing, and/or access to additional covered services.

Comment: Numerous commenters suggested CMS either change or add to the proposed regulatory text at § 422.562(c)(2) to explicitly state that a ''request for payment'' must include a submission of a claim for the services at issue from either the provider or the enrollee. The commenters acknowledged CMS likely included claims within the phrase ''request for payment'' but strongly suggested CMS be explicit when modifying the regulation since MA organizations have historically misinterpreted the regulation and, therefore, may mislabel notice of admissions or concurrent coverage requests as ''requests for payment.''

Many of the same commenters suggested CMS further modify § 422.562(c)(2) to permit contract providers to appeal adverse payment decisions and adverse post-payment review reopening decisions through the MA administrative appeals process. These commenters believed MA organizations strategically focus on using post-payment review to deny contract provider claims with minimal clinical justification because contract providers may only receive external review of the denials through judicial action. The commenters posited that contract provider payment denials do not concern the ''price structure for payment'' and, therefore, would not violate the non-interference statute.

Response: In the proposed rule, we explained that existing § 422.562(c)(2) establishes a limit on the applicability of the administrative appeals process established in part 422, subpart M, by restricting any party from appealing an organization determination when the enrollee has no further liability to pay for services furnished by an MA organization. We proposed a modification to § 422.562(c)(2) to ensure the regulation is only applied to contract provider payment disputes and not to adverse pre-service or concurrent coverage decisions. Specifically, we proposed to modify § 422.562(c)(2) to state ''[b]ased on an MA organization's determination *on a request for payment,* if the enrollee has no further liability to pay for services that were furnished by an MA organization, a determination regarding these services is not subject to appeal.'' (Emphasis added). We explained that because the proposed modification requires the submission and adjudication of a request for payment, coverage decisions (that is, MA organization determinations made before or during the course of treatment that are not made in response to a request for payment) and unsolicited retrospective review decisions (further discussed in section III.A.2. of this rule) would remain appealable by enrollees under the subpart M appeals process.

When proposing the change to § 422.562(c)(2), we chose to use the phrase ''request for payment'' to ensure the regulation applies to payment requests submitted by contract providers and enrollees in any format. We appreciate commenters' concerns that using the phrase ''request for payment'' could result in confusion or misinterpretation of the types of requests that would trigger the appeal limitation of § 422.562(c)(2), especially considering that some MA organizations have previously miscategorized coverage decisions related to an inpatient admission or the provision of inpatient services as ''payment denials'' when no request for payment was ever submitted. However, we do not believe that the proposed regulation text would lead to similar mis categorizations as the phrase ''requests for payment'' is already frequently used in our organization determination and reconsideration regulations.

We explained in the proposed rule that the organization determination and reconsideration regulations of part 422, subpart M, broadly distinguish between two categories of decisions: coverage decisions (that is, a decision on whether the MA organization will furnish, authorize, or arrange for an item, service, or Part B drug) and payment decisions (that is, a decision whether to pay or deny payment for services furnished to an enrollee). These two categories of organization determinations have distinct requirements related to processing timeframes (including the applicability of processing timeframe extensions), the parties eligible to submit an organization determination or reconsideration request, notice requirements, and whether an MA organization must expeditiously process an organization determination or reconsideration request upon receiving a valid request. The existing organization determination and reconsideration regulations at subpart M label the requirements related to coverage decisions using the phrases ''requests for service or item'' (see §§ 422.568, 422.572, 422.590, and 422.619) and ''requests for a Part B drug'' (see §§ 422.568, 422.572, 422.590, 422.618, and 422.619) while payment decision requirements apply in the context of ''requests for payment'' (see §§ 422.568, 422.570, 422.584, 422.590, and 422.618). We used the phrase ''request for payment'' in proposed

§ 422.562(c)(2) in the same manner as it is used in existing subpart M (that is, a post-service organization determination request). While most requests for payment will be submitted on a claim form, as we explained in the proposed rule, enrollees will often submit requests for payment in non-claim formats. In addition, parties may at times submit retrospective review requests, which are organization determination requests submitted after the services at issue have been furnished and the only matter for an MA organization to decide is whether to make or deny payment. Therefore, we decline the commenters' suggestion to limit the applicability of § 422.562(c)(2) to when a provider submits a claim for payment.

We are, however, finalizing a modified version of our proposal that, as some commenters suggested, conditions the applicability of § 422.562(c)(2) on the submission and adjudication of a *contract provider's* request for payment. As we previously discussed, our proposal intended to include requests for payment submitted by contract providers and enrollees. We do not believe it necessary to include an enrollee's request for payment within the scope of this provision as the regulation is only applicable to services performed by contract providers who are typically obligated, under their contractual arrangements with MA plans, to submit a claim for payment for services furnished to an enrollee. We also believe this clarification will reinforce in plain language that non-contract provider requests for payment do not trigger the application of § 422.562(c)(2). We are therefore finalizing that the applicability of § 422.562(c)(2) is conditioned on the submission and adjudication of a contract provider's request for payment.

In addition, we are also replacing the proposed text in § 422.562(c)(2) that read ''a determination regarding these services is not subject to appeal'' with more precise language in the final rule to clarify that the limitation on appeal rights is only applicable to the adjudicated payment determination. The language of § 422.562(c)(2) that we are finalizing in this rule states, ''If a contract provider's request for payment has been adjudicated and the enrollee is determined to have no further liability to pay for the services furnished by the MA organization, the claim payment determination is not subject to the appeal process in this subpart.'' The proposed text could be interpreted to suggest that any determination related to an adjudicated request for payment where there is no further enrollee financial liability would not be appealable. This would mean that a pending coverage appeal submitted by the enrollee would become a non-appealable determination after a contract provider's payment request is adjudicated. However, as we explained in our proposed rule, and discussed further in this final rule, an enrollee's interest in a denied inpatient admission or reduction in level of care extends beyond the potential cost-sharing implications, such as determining access to other services in which coverage is conditioned on an approved inpatient stay. This change between the proposed and final regulation text at § 422.562(c)(2) is necessary to prevent an illogical result where a contract provider could inadvertently foreclose an enrollee's right to appeal (or continue to appeal) an adverse coverage decision by merely submitting a request for payment that is then adjudicated by the MA organization.

We are making these changes to clarify the intended limits of the applicability of the MA administrative appeal process of part 422, subpart M. More specifically, that enrollees always maintain the right to appeal an adverse coverage decision, while, pursuant to our long-held interpretation of the non-interference provision at section 1854(a)(6)(B)(iii) of the Act, contract provider payment disputes are to be excluded from the MA appeals process when an enrollee no longer has any interest in the dispute.

Comment: A couple of commenters expressed opposition to the proposed modification to § 422.562(c)(2), stating that the proposal would insert enrollees into contract provider and MA organization payment disputes. A commenter stated the proposed change was unnecessary since MA organizations, when making adverse coverage decisions related to inpatient stays, are already holding enrollees financially harmless and also afford contract providers the opportunity to dispute the adverse decision through internal resolution processes. Additionally, the commenter posited that proposed changes would require MA organizations to issue more denial notices and process more appeals.

Another commenter suggested the proposed modification to § 422.562(c)(2) would introduce confusion into the MA appeal process and would be potentially inconsistent with other statutory and regulatory requirements. The commenter explained that the proposal would create situations where an enrollee's appeal of a concurrent coverage denial could be adjudicated after the enrollee ceased receiving the services at issue and that the proposal failed to provide clear guidance on how MA organizations should address these status changes during the appeal process. The commenter requested clarification on whether appeal requests received after the completion of services should be treated as requests for payment under the proposal.

The commenter also suggested that the adjudication of appeals after an enrollee has ceased receiving the services at issue would be inconsistent with section 1852(g)(5) of the Act, which limits an MA enrollee's access to the administrative appeals process to circumstances where the enrollee is ''dissatisfied by reason of the enrollee's failure to receive any health service to which the enrollee believes the enrollee is entitled and at no greater charge than the enrollee believes the enrollee is required to pay.'' The commenter stated that merely because an organization determination was initially made on a pre-service or concurrent basis does not ''lock-in'' an appeal of that decision as a coverage dispute throughout the pendency of the appeal. The commenter concluded that an enrollee must, therefore, through each phase of appeal, have a live dispute related to either: (1) an enrollee's entitlement to receive services on an ongoing basis or in the future or (2) a charge incurred by an enrollee that is greater than what the enrollee believes they should be required to pay.

Finally, the same commenter suggested the proposal could result in the abuse of the appeal process by contract providers appealing a coverage denial to advance their own interests and to the detriment of the enrollee. The commenter provided a hypothetical example of a contract provider being appointed the enrollee's representative upon admission and, after the MA organization denies inpatient coverage, refraining from submitting a claim so it could pursue the enrollee's appeal of the coverage determination.

Response: We disagree that our proposal improperly inserts enrollees into disputes that merely concern contract provider payment amounts. We also disagree that the proposal is unnecessary even when MA organizations hold enrollees harmless from financial liability and allow providers to utilize internal dispute resolution processes. As we discussed in the proposed rule, an MA organization decision to deny an enrollee's inpatient admission to a hospital or to reduce an enrollee's level of care from inpatient to outpatient adversely affects more than how much the contract provider is paid, if

anything, for the services being (or about to be) rendered. In fact, such decisions also adversely impact an enrollee's right to receive services at the level of care they believe they require. In addition, as we explained in the proposed rule, adverse coverage decisions on inpatient hospital services may also adversely impact an enrollee's cost-sharing amounts depending on the duration of the hospital stay, the items, services, and Part B drugs provided during the hospital stay, and the enrollee's cost-sharing responsibilities. Further, adverse coverage decisions on an enrollee's inpatient hospital services can negatively affect the types of covered services the enrollee could receive in the hospital and the types of services that are available immediately after the enrollee is released from the hospital. For example, many MA organizations condition coverage for certain services on whether the enrollee is leaving or was recently in an inpatient hospital stay—this could include covered transportation from the hospital, personal home care, meal benefits, and/or post-acute care coverage. If an enrollee's admission is denied or is changed to an outpatient stay, then these services would be unavailable to the enrollee that otherwise could be covered if their inpatient admission was approved or not reduced. We believe that the failure to allow an enrollee to appeal the denial of inpatient services, despite the resulting impacts described previously, would deprive enrollees of access to benefits without adequate due process.

We agree with the first commenter that, if finalized, our proposal would result in an increase in delivered enrollee notices (as MA rules require MA organizations to timely deliver enrollees notice of adverse organization determinations) and MA organizations would have to process more appeals (as some enrollees currently being denied appeal access would file an appeal if given the opportunity). We acknowledged that, collectively, our proposed provisions would likely modestly increase required notices and appeal adjudications in the Collection of Information (COI) section of the proposed rule. We also provided estimates in the COI section of the burden associated with our proposed provisions. We note that the commenter did not dispute our proposed estimates.

We agree with the second commenter that the proposed text to § 422.562(c)(2) could have confused MA organizations as to how to treat enrollee appeals of a coverage denial after the MA organization adjudicated a request for payment and determined the enrollee had no further liability for the services. As we explained previously, we are finalizing a modified version of the proposed text that better defines the limits to the applicability of § 422.562(c)(2) and how the provision will affect, or not affect, related coverage appeals. Specifically, we are finalizing the regulation to state ''[i]f a contract provider's request for payment has been adjudicated and the enrollee is determined to have no further liability to pay for the services furnished by the MA organization, the claim payment determination is not subject to the appeal process in this subpart.'' We believe this modification appropriately balances the rights of enrollees to appeal adverse coverage decisions, while also explicitly excluding all contract provider payment disputes from the administrative appeal processes of subpart M. This change should resolve any potential confusion the commenter identified. Simply put, the modified text for § 422.562(c)(2) would not implicate an enrollee appeal of an adverse coverage decision because the provision is only applicable to the claim payment decision.

We strongly disagree with the comment stating the proposal is inconsistent with applicable statute. As explained in the proposed rule, section 1852(g)(2) of the Act establishes that an MA organization must provide for reconsideration (that is, a first level appeal) of a determination that denies coverage, in whole or in part, upon an enrollee's request. Section 1852(g)(4) of the Act creates a second level of administrative review by providing that an Independent Review Entity will adjudicate first level reconsiderations that affirm a denial of coverage, in whole or in part. Notably, the statute cited by the commenter, section 1852(g)(5) of the Act, establishes the requirements for an enrollee to appeal an adverse second level reconsideration decision to an Administrative Law Judge (ALJ) (third level appeal), the Medicare Appeals Council (fourth level appeal), and finally to Federal district court, when certain ''amount-in-controversy'' thresholds are met. The MA organization determination and administrative appeals process has long been implemented by regulation at part 422, subpart M.

Section 1852(g)(5) of the Act plainly does not apply to all phases of the administrative appeals process. It is not correct to apply a portion of the statute that establishes the third and fourth level appeals and availability of judicial review as a necessary requirement for the entire appeals process. Instead, it is section 1852(g)(2) and (4) that establish the parameters necessary to appeal an adverse organization determination to the first and second level. In any event, we disagree with the commenter's belief that an MA organization's denial of inpatient hospital services would not meet the requirements of section 1852(g)(5) of the Act if the enrollee is no longer actively receiving services. As discussed in further detail below, a denial of an inpatient admission or the provision of inpatient services prevents an enrollee from receiving covered services at the level of care to which the enrollee believes they are entitled, could increase the enrollee's applicable cost-sharing amounts, and precludes the enrollee's access to other coverable services which require an inpatient hospital stay as a condition of coverage. CMS has consistently explained that an enrollee does not have to explicitly state that they believe they are entitled to receive a particular service in order to submit an organization determination request or appeal. Instead, we impute the understanding that an enrollee believes they are entitled to receive the service at issue based on the enrollee's act of requesting an organization determination or appeal. Therefore, because a denial of an inpatient admission or the provision of inpatient services prevents the enrollee from receiving additional coverage for inpatient hospital services and forecloses their access to additional services that require an inpatient hospital stay, an enrollee for whom inpatient hospital services have been denied has met the threshold requirement of section 1852(g)(5) of the Act that the enrollee has ''fail[ed] to receive any health service to which the enrollee believes the enrollee is entitled. . . .''

The commenter stated that the proposed policy fails to address changes in an enrollee's ''status'' during the appeals process and that ''merely because an organization determination was initially made on a pre-service or concurrent basis does not 'lock in' its appeal status as a coverage dispute throughout the pendency of the appeal.'' The commenter provided an example in which an MA organization makes an adverse coverage decision before or during the provision of services, but the services are completed at some point during the appeals process.

We disagree. Section 1852(g)(2) of the Act and § 422.580 provide MA enrollees with the right to request reconsideration of adverse organization determinations when there is a denial of coverage, in whole or in part. There is no statutory or regulatory requirement that limits an enrollee's right to appeal to the

timeframe in which services are still being rendered. Instead, once a valid reconsideration request is submitted to an MA organization, it must either dismiss the request (under one of the stated rationales at § 422.582(f)) or issue a substantive decision. Further, there is no statutory or regulatory mechanism by which plans may convert a valid appeal of an adverse coverage decision to something else. Therefore, despite commenter's suggestion otherwise, a timely, valid appeal of an adverse coverage decision is to be fully adjudicated by the plan regardless of whether the appeal was submitted and/or the appeal is still being adjudicated after the services at issue have ceased being rendered. We note that similar policies exist for other types of coverage denials. For example, after an MA organization determines that covered inpatient care is no longer necessary, the enrollee may file an expedited appeal of the discharge decision to the QIO. If the QIO upholds the MA organization's decision, and the enrollee has left the hospital, in accordance with § 422.622(g)(2), the enrollee may continue their appeal to the ALJ, Departmental Appeals Board (DAB), and ultimately Federal court (if other conditions are met). In these circumstances, enrollees are provided an explicit right to continue pursuing an appeal regardless of whether they have ceased receiving services or how long the appeal process takes.

Beyond the fact that existing authority does not require or permit the termination of an appeal because the services at issue are no longer being provided, we do not believe that it would be prudent to enact such a policy. If an enrollee could only appeal a coverage denial while receiving services, then we would simultaneously disincentivize MA organizations from speedily processing these types of appeals while also incentivizing enrollees to take substantial financial risk by continuing to receive non-covered services just to maintain an appeal. In plain terms, if we were to adopt the commenter's approach, enrollees would not have a meaningful avenue to appeal coverage denials related to inpatient admissions or the provision of inpatient services. We do not believe such a policy would align with section 1852(g)(2) of the Act, which requires MA organizations to provide reconsideration of denials of enrollee coverage, in whole or in part, upon request by the enrollee involved.

Finally, we do not believe that a significant number of contract providers will intentionally abuse the MA appeal process to advance their own interests to the detriment of the enrollee. A physician, acting on behalf of the enrollee, may request an expedited reconsideration of an adverse coverage decision pursuant to § 422.578 or a standard reconsideration, if treating the enrollee, pursuant to § 422.582. Alternatively, any individual, including a contract physician, may be appointed by an enrollee as their representative to pursue an appeal on the enrollee's behalf. We have long maintained that an enrollee will welcome their physician's expertise and willingness to pursue an appeal of an adverse coverage decision on their behalf. In fact, as we explained in the proposed rule, we believe an enrollee's physician is often in the best position to receive, explain, and timely act upon an adverse organization decision on behalf of an enrollee. This may be truer for enrollees involved in a hospital stay due to the complex medical criteria at issue and the fact that the enrollee's condition may not afford an opportunity to timely and adequately pursue their appeal. In addition, we do not believe appeals of the denial of inpatient services would offer physicians more opportunity to abuse the appeal process than in any other instance. Many times, when a physician files an appeal for the enrollee, both the enrollee and the physician stand to benefit from a favorable determination. For example, a physician that successfully appeals a prior authorization denial has ensured that they will receive payment for the services to be rendered, while the enrollee has ensured coverage for their necessary care. We do not believe that merely because a physician potentially stands to benefit from a successful appeal, in addition to the enrollee, that there is a likelihood of abuse significant enough to not finalize this policy. Nevertheless, we will monitor feedback from the appeals process and will consider future rulemaking if the changes to § 422.562(c)(2) are being implemented in a manner that is inconsistent with our stated intent to exclude contract provider payment disputes from the MA administrative appeals process.

Comment: A couple commenters requested CMS clarify the meaning of ''no further liability to pay'' as used in the proposed change to § 422.562(c)(2). More specifically, a commenter questioned whether, in the context of an appeal of an inpatient admission denial, the phrase meant that the copay amount for the inpatient stay must match the copay amount for observation payment status. Another commenter recommended CMS clarify the phrase refers only to circumstances where an appeal overturn would result in less financial responsibility.

Response: In the preamble discussion of the proposed rule, we stated that we interpret existing § 422.562(c)(2) to restrict any party from appealing an adverse payment decision under the appeal processes of subpart M after an MA organization determines the enrollee is not financially liable for more than the applicable cost-sharing of the services for which payment was requested. We further explained that ''no further liability to pay'' in § 422.562(c)(2) means the enrollee's financial liability will not be affected by whether the payment determination is upheld or overturned. We further stated that merely because the enrollee has a balance due for their cost-sharing amount does not mean that the enrollee has further liability to pay when the amount would not be affected by the resolution of the payment dispute. We agree with commenters that these two statements, while similar, are inconsistent.

We, therefore, clarify that ''no further liability to pay'' in § 422.562(c)(2) means the MA organization's determination on the enrollee's financial liability amount will not decrease whether the payment determination is upheld or overturned. In scenarios where an enrollee may still have a balance due for their cost sharing amount, this amount would not be considered ''further liability to pay'' if this amount would not decrease regardless of the appeal outcome. We thank the commenters for identifying the need for clarification on this point.

Comment: Multiple commenters requested CMS to confirm that, pursuant to existing § 422.568(c)(2), enrollees already possessed the right to appeal inpatient admission and concurrent review denials before the proposed rule.

Response: Commenters are correct in their understanding. As we explained in the proposed rule, CMS has historically interpreted existing § 422.562(c)(2) to limit enrollees right to appeal adverse payment decisions from contract providers. In addition, we do not believe the regulation applies to coverage decisions that are made pre-service or concurrent to services being rendered. As explained, we proposed the modification to § 422.562(c)(2) in order eliminate potential confusion and create uniformity across the MA program as we understood many MA organizations have been misapplying the regulation and improperly denying enrollees appeal access for adverse coverage decisions.

Comment: A commenter requested CMS confirm that the proposed modification to § 422.562(c)(2) does not restrict a non-contract provider from appealing a partial payment denial, such as downcoding a billed diagnosis related group (DRG) code, even when the enrollee does not have cost-sharing implications.

Response: We confirm that our modification to § 422.562(c)(2) does not alter non-contract provider appeal rights. Both the existing § 422.562(c)(2) and the revised version of § 422.562(c)(2) we are finalizing in this rule only apply to services ''furnished by an MA organization'' which, as we have explained in our proposed rule, generally occurs when a contract provider renders covered services to an MA organization's enrollee on behalf of the MA organization. Neither existing § 422.562(c)(2), nor the revised version being finalized in this rule, limit the right for parties to appeal adverse payment determinations related to services provided by a non-contract provider as such services are not considered to be ''furnished by an MA organization.'' Thus, a non-contract provider may utilize the administrative appeals process established at §§ 422.578 through 422.616 to appeal an adverse payment decision by becoming an assignee of an enrollee once the non-contract provider formally agrees to waive any right to payment from the enrollee, in accordance with § 422.574(b). In accordance with § 422.566(b), an MA organization makes an adverse organization determination if it fully or partially denies payment for billed services. This includes, but is not limited to, when an MA organization, either on initial review or upon reopening, denies a DRG code or pays a different code altogether, bundles services which were separately billed, or makes payment at a lower level of service than billed.

Comment: Several commenters requested CMS reinterpret the phrase ''furnished by an MA organization'' in § 422.562(c)(2) in a way to ensure MA organizations pay contract providers for services performed under section 1852(d) of the Act and § 422.113(b).

Response: Pursuant to our long-held interpretation of the non-interference provision at section 1854(a)(6)(B)(iii) of the Act, contract provider payment disputes are to be excluded from the MA appeals process when an enrollee no longer has any interest in the dispute. The primary purpose of our proposed modification to § 422.562(c)(2) is to maintain the exclusion of contract provider claims from the administrative appeals process while limiting confusion to avoid the improper processing of valid enrollee appeals. Therefore, to adopt such an interpretation would be antithetical to our proposal's primary purpose.

Comment: A commenter recommended CMS provide explicit guidance on whether MA organizations should dismiss as invalid any appeal request that implicates § 422.562(c)(2). The same commenter also recommended CMS provide instructions to the Part C independent review entity to ensure proper processing by appeals forwarded by MA organizations for adjudication.

Response: We appreciate the recommendation and plan to update related subregulatory guidance after finalization of this rule. Guidance related to the MA organization determination and appeals processes is published in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, available for download at *https://www.cms.gov/medicare/appeals-grievances/managed-care.* Pursuant to standard operating procedures, we will also update the Part C IRE on this rule and the implications on second level reconsiderations and dismissed first-level reconsideration requests.

Comment: A commenter questioned whether CMS would require updates be made to the letter which would indicate services rendered would not be subject to appeal if the enrollee has no further liability to pay.

Response: We do not believe it would be necessary to update the standardized denial notice, the Notice of Denial of Medical Coverage or Payment (Form CMS–10003–NDMCP), also known as the Integrated Denial Notice (IDN). Our proposed modification to § 422.562(c)(2) clarifies that the provision would only limit an enrollee's right to appeal an adverse decision when the MA organization determines the enrollee has no further financial liability after adjudicating a contract provider claim. Because the provision only applies to contract provider claim payment decisions, pursuant to § 422.111(k), the enrollee would receive notice of the payment decision through an explanation of benefits—not the IDN. MA organizations should not need to edit their EOB templates, as MA organizations currently process contract provider payment decisions that do not provide enrollee appeal rights, in accordance with existing § 422.562(c)(2).

Comment: Multiple commenters provided feedback that was out of scope with the proposed provisions. Several commenters questioned the extent of which MA organizations may establish and enforce, through payment denials, prior authorization requirements. Specifically, the commenters requested CMS confirm whether MA organizations may deny otherwise coverable, medically necessary services as ''technical denials'' and whether such actions comply with the prior authorization protections codified through CY 2024 final rule (88 FR 22120, April 12, 2023).

Multiple commenters requested CMS reconsider the incentive structure for MA organizations in order to focus on improving enrollee health rather than focusing on cost savings through administrative denials. The commenters noted that fair adjudication is difficult and costly to obtain.

Response: We thank the commenters for their suggestions and perspective. However, these comments are outside the scope of our proposed rule. We may consider these comments when undertaking future rulemaking.

Upon consideration of the public comments received, we are finalizing our proposed revisions to § 422.562(c)(2) with modifications. Specifically, we are finalizing § 422.562(c)(2) to state that if a contract provider's request for payment has been adjudicated and the enrollee is determined to have no further liability to pay for the services furnished by the MA organization, the claim payment determination is not subject to the appeal process in this subpart.

2. Clarifying the Definition of an Organization Determination To Enhance Enrollee Protections in Inpatient Settings (§§ 422.138 and 422.566)

Section 1852(g)(1)(A) of the Act requires MA organizations to have a procedure for making determinations regarding whether an enrollee is entitled to receive health services or payment under the program. In accordance with section 1852(g)(1)(A) of the Act, §§ 422.566 through 422.572 establish the requirements related to organization determinations. Existing § 422.566(b) defines an organization determination as any determination made by an MA organization that falls within a prescribed set of discrete actions. These include, at paragraph (b)(3), an ''MA organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization'' and, at paragraph (b)(4), the ''[r]eduction, or premature discontinuation, of a previously authorized ongoing course of treatment,'' among several others. Taken

collectively, this means an organization determination may be made prior to the receipt of services (for example, prior authorization), after the receipt of services (for example, payment requests), or during receipt of services (for example, continuation or termination of services) the enrollee receives from either contract or non-contract providers.

An ''organization determination,'' as defined by § 422.566, is a decision ''regarding the benefits an enrollee is entitled to receive under an MA plan . . . and the amount, if any, that the enrollee is required to pay for a health services'' to include, among other actions, ''the MA organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization.'' When an MA organization makes an adverse organization determination (for example, denying coverage for a service), it must adhere to certain requirements that include providing notice of the decision to the enrollee in a format prescribed by CMS (see § 422.568(e)), within designated timeframes (see §§ 422.568 and 422.572), and, if the adverse decision was based on medical necessity, ensuring the decision was reviewed by a physician or other appropriate heath care professional with expertise in the field of medicine appropriate for the services at issue (see § 422.566(d)). In accordance with § 422.576, an ''organization determination is binding on all parties unless it is reconsidered under §§ 422.578 through 422.596 or is reopened and revised under § 422.616.'' An enrollee or physician who is acting on behalf of the enrollee (regardless of their affiliation with an MA organization) may request an expedited reconsideration of an adverse organization determination concerning the type or level of services that the enrollee believes they should receive (see §§ 422.578 and 422.584(a)). However, pursuant to § 422.562(c)(2), if an ''enrollee has no further liability to pay for services that were furnished by the MAO, a determination regarding these services is not subject to appeal.''

Historically, we have interpreted the definition of an organization determination to include when an MA organization makes a coverage decision on the appropriateness of an inpatient admission, or the appropriateness of inpatient services (that is, a level of care determination), contemporaneously with an enrollee's receipt of the services at issue. This would be true whether the MA organization ultimately approved the enrollee's admission to a facility, determined that the enrollee's level of care in the same facility should be reduced, or determined that the enrollee should be discharged (see §§ 422.620 through 422.624). Accordingly, these decisions would have to comply with all applicable notice and appeal requirements for organization determinations and would be binding on all parties unless they are reconsidered under §§ 422.578 through 422.596 or are reopened and revised under § 422.616.

We acknowledge that many MA organizations understand these decisions are organization determinations subject to the existing rules in subpart M including, but not limited to, timely notice of the decision. However, through routine audits, feedback from the provider community, and discussions with MA organizations, CMS identified circumstances where some MA organizations have misinterpreted the organization determination provisions to exclude decisions that rescind a previously authorized inpatient admission, deny coverage for inpatient services, or downgrade an enrollee's hospital coverage from inpatient to outpatient (often either simultaneously denying inpatient coverage while approving coverage for outpatient observation services or instructing the provider to only bill for outpatient services when submitting a subsequent claim), when the decision is made concurrently to the enrollee receiving such services. These types of decisions most often occur while enrollees are receiving inpatient services in an in-network hospital and are at times referred to as ''concurrent review decisions,'' ''level of care determinations,'' ''clinical utilization review decisions,'' or ''inpatient authorization denials.'' For the sake of clarity and consistency in describing these types of decisions, we will use the term ''concurrent review'' for purposes of this rulemaking.

We understand MA organizations conduct concurrent review on hospitalizations and other services that require review for continued care, such as long-term care stays in skilled nursing facilities (SNFs), long-term acute care hospitals (LTACHs), or inpatient rehabilitation facilities (IRFs), home health agency (HHA) services, partial hospitalizations, or intensive outpatient programs. Such review includes utilization management activities that occur during inpatient level care, post-acute care, or an ongoing outpatient course of treatment. In general, the concurrent review process includes obtaining necessary clinical information from the treating physician and other providers to determine medical necessity based on the clinical status of the enrollee and applicable Medicare coverage criteria. Concurrent review involves the evaluation of the appropriateness of the ongoing level of care, including decisions related to the extension of previously approved care.

We offer the following example to illustrate a common scenario we have seen, although we note that certain details may vary depending on the MA organization making the decision. An enrollee will present to an in-network hospital and the treating physician will order the enrollee admitted to an inpatient status. During the admission process, the hospital will provide the enrollee's MA organization with a Notice of Admission, in accordance with the contract between the hospital and MA organization, that alerts the MA organization of the admission but (in most circumstances) does not request approval for the admission. After receiving the Notice of Admission, the MA organization will monitor the enrollee's condition by reviewing the medical documentation on its own accord and, when applicable, will notify the hospital that it has made an adverse concurrent review decision related to the enrollee's inpatient admission or receipt of inpatient services on the basis that the enrollee's condition does not meet certain inpatient coverage criteria. Accordingly, if the hospital submits an inpatient claim for the services, whenever it ultimately submits a request for payment, the MA organization will automatically deny payment for inpatient services based on the concurrent review decision. In its concurrent review decision, the MA organization may either approve outpatient observation services for the enrollee or suggest that the hospital bill the entire hospital stay as outpatient services. If the treating physician disagrees with the decision, the physician may engage the MA organization in a peer-to-peer discussion with a plan physician or may appeal using the plan's internal dispute resolution processes.[41] It is important to note that in many circumstances the MA organization does not inform the enrollee of the concurrent review determination and the enrollee is not afforded the opportunity to appeal the decision (or have an appeal submitted

[41] We have received conflicting information on the nature of peer-to-peer discussions from MA organizations. Some describe the process as solely educational in nature and that it has no bearing on the prior decision. Other MA organizations appear to use the discussion either to supplement or as a part of a contract provider's appeal.

on their behalf) as required. The result of the concurrent review is the hospital may either continue to provide non-covered inpatient services or it may reclassify the enrollee's hospital status from inpatient to outpatient. Many times, the enrollee does not know a change in status has occurred until they are required to pay the outpatient deductible and applicable cost-sharing.[42]

We have seen several different justifications for why an MA organization may not process a determination to deny an enrollee's inpatient admission, or deny coverage for inpatient services, made concurrently to the provision of such services under the requirements for other organization determinations. Some MA organizations have posited that these concurrent reviews are outside the definition of an organization determination because the timing of the decision is made during an ongoing course of treatment. These MA organizations appear to mistakenly believe that the existing definition of an organization determination is limited to decisions made before services begin and payment decisions that are made after a claim is submitted, and thus, a decision on inpatient coverage made concurrent to the services being rendered does not meet the definition of an organization determination or need to comply with the applicable organization determination notice and appeal right requirements.

We have also seen other situations where an MA organization appropriately considers the downgrading of an enrollee from receiving inpatient to outpatient services as an organization determination and yet will still fail to provide proper notice of the decision to the enrollee, process a timely appeal request, or both. We have received many complaints from the provider community that when the enrollee's treating physician requests an expedited reconsideration of an adverse concurrent review decision, pursuant to § 422.578, the MA organization will not process the appeal for a myriad of reasons. Some MA organizations have concluded that a level of care denial is not an appealable subject matter, while others believe reconsideration requests may not be processed while an enrollee is receiving the services at issue. The most common reason cited by plans for not processing appeals of adverse concurrent review decisions is the erroneous view that concurrent reviews made while an enrollee is being treated in an in-network hospital are ''contractual denials'' that are ineligible for review under the administrative appeals process of part 422, subpart M. This line of reasoning relates to the provision at § 422.562(c)(2) which states that ''[i]f an enrollee has no further liability to pay for services that were furnished by an MA organization, a determination regarding these services is not subject to appeal.'' MA organizations reason that because contract providers are contractually restricted from billing the enrollee for denied services and must accept the contractual payment as ''payment in full,'' coupled with the enrollee protections against financial liability at §§ 422.504(g) and 422.562(c)(2), a concurrent review decision will ultimately result in the enrollee having no further financial liability for the inpatient services being rendered so there is no right to appeal the decision. As we have explained in section III.A.1. of this rule, this interpretation overlooks the fact that the MA organization has made an adverse decision on the authorization or provision of inpatient services which not only impacts the type of care the enrollee receives but also directly impacts the amount of deductible and cost-sharing for which the enrollee is liable, when a request for payment is eventually submitted.

CMS does not agree with the previous interpretations of the existing organization determination and appeal regulations of part 422, subpart M. In the past, we have addressed these types of misinterpretations and non-compliance by MA organizations on a case-by-case basis as those issues were presented to us. However, we realize that the inconsistent application or misapplication of MA policies governing concurrent review is becoming increasingly varied and widespread across the industry, creating substantial confusion to MA organizations and, at times, variable outcomes to providers and enrollees. In addition, we recognize that the direct consequence of the misapplication of MA policies is that many enrollees do not receive notice of a decision to downgrade their level of care from inpatient to outpatient, nor are they given opportunity to appeal such decisions as provided under § 422.562(b)(4) (the right to a reconsideration of an adverse organization determination by an MAO). After considering other options available to CMS to clarify this matter, including increasing outreach and updating non-regulatory guidance, we decided the most appropriate and effective manner to address this issue is to clarify and strengthen the existing requirements related to organization determinations.

Therefore, we, proposed to clarify that decisions made based on the review of an enrollee's need for continued care, commonly known as concurrent review, are organization determinations under the rules at § 422.566(b). Specifically, we proposed to revise § 422.566(b)(3) to clarify that a decision by an MA organization made pre-service, post-service, or concurrent with the enrollee's receipt of services in an inpatient or outpatient setting is an organization determination subject to the rules in part 422, subpart M, which includes providing the enrollee (and the provider, as appropriate) with timely notice and applicable appeal rights. We noted that while the primary focus of the previous discussion relates to the denial of inpatient hospital coverage as a result of an MA organization's concurrent review, our proposed clarification to the definition of an organization determination is inclusive of all other types of services.

In addition to adding a reference to decisions made concurrently to the enrollee's receipt of services, we also proposed to add to § 422.566(b)(3) a reference regarding applicable decisions made prior to the enrollee's receipt of services and after the services have been completed. Similar to our previous discussion related to concurrent review, we proposed these additions to clarify that the subject-matter of an MA organization decision dictates whether it has made an organization determination, regardless of when in the continuum of an enrollee seeking and receiving covered medical care the decision is made. We used the term pre-service in proposed § 422.566(b)(3) to refer to a request for an MA organization to approve coverage for a service before the service is received by the enrollee. An enrollee, enrollee's representative, or

[42] We note that because an adverse concurrent review decision is a denial of inpatient hospital coverage, such a decision could also affect an enrollee's eligibility for covered post-hospital extended care services furnished in a SNF. Section 1861(i) of the Act requires Medicare beneficiaries receive at least 3 consecutive days in a covered inpatient hospital stay within the preceding 30 calendar days in order to qualify for covered skilled SNF care. While we understand that most, if not all, MA organizations currently waive this coverage requirement, they are not required to continue to do so in future plan years. Therefore, if an MA organization that does not waive the 3-day inpatient hospital stay requirement makes an adverse concurrent review decision, the enrollee may not accrue the 3-day inpatient hospital stay necessary to receive covered skilled SNF care they otherwise could receive. A similar impediment to covered skilled SNF care could occur for enrollees that have opted into Traditional Medicare for the following year when an adverse concurrent review is made in the last 30 days of the plan year.

a provider on behalf of an enrollee, has the right to request the enrollee's MA organization approve an item, service, or Part B drug in circumstances where there is a question whether the item, service, or Part B drug will be covered. This right to receive prior approval applies to services for which an MA organization may require prior authorization as a condition for coverage as well as services for which there is no prior authorization requirement. When an MA organization receives a request for an item, service, or Part B drug, it must process the request according to the timeframes at § 422.568(b) or § 422.572(a).[43]

The reference to post-service in our proposed addition to § 422.566(b)(3) refers to applicable decisions that have been requested (or made by an MA organization in the absence of an organization determination request) after the enrollee has finished receiving the services at issue. The vast majority of post-service organization determinations are made in response to receiving a claim or other request for payment from an enrollee or provider. We are, however, aware that some MA organizations are denying payment for services before receiving a claim or other request for payment. More specifically, we have seen MA organizations decide on the appropriateness of an enrollee's inpatient admission, or the appropriateness of inpatient services, after an enrollee has been discharged from the hospital but before a request for payment has been received. These decisions have been referred to as ''retrospective reviews'' and, similar to our previous discussion on concurrent review decisions, many MA organizations making these decisions fail to comply with all applicable organization determination requirements, including providing appropriate notice and appeal rights to enrollees.

As a point of clarity, we regularly observe MA organizations making retrospective organization determinations when performing a post-payment review (a review that occurs after payment is made on the selected claim in order to determine whether the initial determination for payment was appropriate (see definition at § 405.902)).[44] The retrospective review decisions we are discussing here, however, are not reviews of an MA organization's prior payment decisions but are initial determinations impacting payment for inpatient hospital services that are made after the enrollee has been released from a hospitalization, but before a request for payment is received.

We have primarily observed MA organizations make retrospective review decisions on inpatient hospital services in a similar fashion as concurrent review. For example, an enrollee may be admitted as an inpatient in a hospital contracted with the enrollee's MA organization. During the hospital stay (or shortly thereafter), the MA organization will become aware of the inpatient admission, generally upon the hospital sending the MA organization a Notice of Admission. The hospital will finish providing services and discharge the enrollee in accordance with §§ 422.620 through 422.622. At some point after discharge, but before a claim for payment is submitted, the MA organization will notify the hospital that it is denying payment for all inpatient services and will instruct the hospital to submit an outpatient claim, while sometimes simultaneously approving the provider to bill for observation services. The MA organization does not send a notice of the denial to the enrollee. The hospital receives an opportunity to dispute the decision under the MA organization's internal dispute resolution processes, but the enrollee has no opportunity to dispute the decision under the rules of part 422, subpart M.

We find that retrospective reviews are conducted very similarly to concurrent reviews in that both reviews involve obtaining necessary clinical information from the treating physician or other providers to determine medical necessity for the services rendered, using the clinical status of the enrollee and applicable Medicare coverage criteria. In addition, both concurrent and retrospective review decisions are often made without the MA organization first receiving a request for coverage or payment. The primary difference between the two review types is that concurrent review occurs while the services are being rendered while retrospective review occurs after the services at issue are fully furnished. This means that a concurrent review decision concerns the delivery of care being received by the enrollee, while a retrospective review decision concerns whether the MA organization will make payment for the services the enrollee received. Put simply, a concurrent review decision (whether made unsolicited or in response to a request) is a coverage decision while a retrospective review decision (whether made unsolicited or in response to a request) is a payment decision.

An MA organization's refusal to pay for services, in whole or in part, including the type or level of services, the enrollee believes should be furnished or arranged for by the MA organization is an organization determination under the rules at existing § 422.566(b)(3). As we mentioned previously, we proposed adding references to § 422.566(b)(3) to clarify that the definition of an organization determination includes decisions made before, during, and after the enrollee's receipt of the services at issue. Under our proposed clarifications to what actions constitute an organization determination, a post-service payment decision, even if made without the MA organization first receiving a payment request, is subject to the rules in subpart M. In addition, as we explained in section III.A.1. of this final rule, the regulations of part 422, subpart M, treat organization determinations related to coverage for services to be or contemporaneously being rendered (coverage decisions) differently from determinations related to payment for services already furnished (payment decisions). As such, a retrospective review decision would be subject to all applicable subpart M requirements related to payment organization determinations, including those related to notice and appeal rights.[45]

[43] Beginning January 1, 2026, a request for a service or item that is subject to an MA organization's prior authorization requirement must be processed within 7 calendar days. The timeframe for processing requests for items and services not subject to an MA organization's prior authorization requirement remains 14 calendar days. See the February 8, 2024 final rule titled ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program'' (89 FR 8976).

[44] Post-payment reviews are performed under the reopening rules at §§ 405.980 through 405.986 and 422.616 (see § 405.929). Pursuant to § 422.616(d), when a payment determination is revised on reopening (including through post-payment review), any party may file an appeal of the revised determination. However, similar to initial payment determinations, when an MA organization revises a contract provider payment determination that results in no additional financial liability or cost-sharing for the enrollee, § 422.562(c)(2) precludes any party from appealing the revised payment determination under the administrative appeals processes of part 422, subpart M. Contract providers may appeal adverse payment determination revisions under the terms of the contract between the provider and the MA organization.

[45] While the focus of this discussion is on unsolicited retrospective reviews, we acknowledge that enrollees or providers may, at times, submit a

In accordance with § 422.568(d)(1), an MA organization must give the enrollee written notice when denying payment in whole or in part. The payment denial notice must use approved language in a readable and understandable form (§ 422.568(e)(1)), state the specific reasons for the denial (§ 422.568(e)(2)), inform the enrollee of their right to appeal (§ 422.568(e)(3)), describe the standard reconsideration process and the rest of the appeal process (§ 42.568(e)(4)(ii)), and comply with any other notice requirements specified by CMS (§ 422.568(e)(5)). CMS created the Notice of Denial of Medical Coverage or Payment (form CMS–10003–NDMCP), more commonly known as the Integrated Denial Notice (IDN), as a standardized notice for MA organizations to use when making adverse coverage or payment decisions. Alternatively, an MA organization may use the model Explanation of Benefits (EOB), when making an adverse payment decision as long as it includes the approved standard language from the IDN.[46] We explain in sub-regulatory guidance that an MA organization must provide notice of an adverse payment decision to an enrollee using the IDN or EOB when the enrollee submitted the request or through an EOB when the payment request was submitted by a provider (the provider would receive a corresponding remittance notice or similar notice).[47] We have not previously considered the proper notice for MA organizations to use when making payment decisions without first receiving a request for payment.

As we previously discussed, it is our understanding that retrospective review decisions are most often, if not exclusively, made on inpatient services performed by hospitals that are contracted with the MA organization. In most instances (excluding those which fall outside the plan-directed care beneficiary protection), when an MA organization makes a payment decision on contract provider services, existing § 422.562(c)(2) would preclude a party's appeal of a decision as the enrollee would generally have no additional financial liability under the terms of the contract between the MA organization and the provider. However, as we discussed in section III.A.1. of this final rule, revisions to § 422.562(c)(2) would not be applicable until an MA organization makes a decision on an enrollee's financial liability in response to a request for payment. Under proposed § 422.562(c)(2), an enrollee would not be precluded from appealing an adverse retrospective review decision as the MA organization would not yet have received a request for payment when the retrospective review decision is made. We believed this would be an appropriate outcome as an adverse retrospective review decision on inpatient hospital services typically results in the MA organization instructing the hospital to submit an outpatient claim (at times including an approval for observation services), thereby changing the cost-sharing amount for which the enrollee would be responsible. Cost-sharing, which may include deductibles, co-payments, and co-insurance, varies across the MA program, but most often has different requirements for inpatient and outpatient hospital services. Therefore, whether a hospitalization is billed as an inpatient or an outpatient stay would likely result in different out-of-pocket costs for the enrollee. We note that the difference in cost-sharing liability could be higher or lower for an enrollee after an adverse retrospective review decision on inpatient hospital services. The exact difference in amounts would depend on the enrollee's cost-sharing requirements of their particular plan, the length of their hospitalization, and, potentially, the amount and types of services which were rendered. We believed that ensuring an enrollee has adequate notice of an adverse MA organization payment decision, which may negatively affect their out-of-pocket expenses for a hospitalization, is paramount for providing a meaningful opportunity to appeal. However, because we had not previously considered which existing notice type (that is, the IDN or an EOB) would be most appropriate for MA organizations to use when making a retrospective review decision without first receiving a request, we requested comments on the type of notice MA organizations should utilize to ensure enrollees have adequate notice of the organization determination and its implications on the enrollee's cost-sharing responsibilities. Based on this feedback, CMS indicated that we may consider clarifying in future guidance how MA organizations can ensure compliance with existing notice requirements when issuing retrospective review decisions prior to receiving a request for payment.

Finally, we also proposed to make a corresponding change at § 422.138(c), to include concurrent reviews as a type of determination subject to the rules at § 422.138(c). Per CMS regulations at § 422.138(c), if the MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at § 405.986) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. We proposed to add concurrent review decisions to § 422.138(c) as subject to this requirement. In the same way that a provider and enrollee reasonably rely upon an MA organization's approval of a prior authorization before services are rendered, an approval of inpatient or outpatient services during a concurrent review is an organization determination that is relied upon by the enrollee and provider to continue delivering medically necessary services that they expect to be covered and paid for by the MA organization. As a result, an MA organization should not be able to later deny the services based on a lack of medical necessity if the continued treatment had already been approved during a concurrent review.

We received the following comments on our proposal to clarify organization determinations.

Comment: Several commenters were in support of the proposal to modify the definition of an organization determination. These commenters expressed appreciation for the clarification that such decisions are subject to timely notice and appeal rights and believe it will provide greater opportunities for providers and enrollees to challenge what the commenters referred to as unfair

request for ''authorization'' for services which have already been fully rendered. Indeed, we understand that some MA organizations currently permit the submission of late ''authorization'' requests for certain services subject to prior authorization requirements within designated timeframes after a service has been rendered and, if approved, would consider the applicable prior authorization requirements met when separately considering payment. However, as we have explained previously, once a service has been fully furnished, the only matter for an MA organization to decide is whether to make payment and any resulting enrollee financial liability or cost-sharing. Thus, similar to unsolicited retrospective review decisions, post-service authorization requests, whether permitted by MA organizations or not, must be processed as payment requests, under the applicable payment timeframes and policies. We note that our proposed policies do not prevent MA organizations from waiving prior authorization requirements on a case-by-case basis, based on good cause or any other consideration, during the claim adjudication or subsequent appeal processes when such processes are described in their EOC.

[46] An EOB is a model communication material which must also contain the information required under § 422.111(k).

[47] See section 40.12.1 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance available at *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.*

determinations of coverage or payment. A commenter noted that this change is important to protect the provider's appropriate application of the two-midnight rule requirements. Commenters were also in support of the proposal to include concurrent reviews as a type of determination subject to the rules at § 422.138(c). These commenters noted that providers and enrollees reasonably rely on concurrent review decisions when rendering medically necessary care, similar to providers' reliance on prior authorization approvals before services are rendered. Commenters believed this change will provide greater consistency, improve care coordination, and protect both enrollees and providers from unnecessary coverage denials.

Response: We thank the commenters for their support of this proposal. As noted in the proposed rule, we believe these amendments to the definition of an organization determination at § 422.566(b) constitute a reasonable approach to addressing the many concerns that CMS has received and identified through routine audits related to MA organizations' misinterpretation of what constitutes an organization determination.

Comment: A commenter urged CMS to ensure that any changes to the definition of organization determination achieve the goal of providing a seamless care experience for the enrollee, and ensure enrollees are properly notified of any changes regarding their care and right to appeal, while minimizing confusion.

Response: We appreciate the commenter's concern regarding the need to ensure seamless care, and CMS believes the proposed clarification of what constitutes an organization determination will achieve the goal of ensuring an improved care experience for enrollees. As noted in the proposed rule, we recognize that the direct consequence of the misapplication of MA policies is that many enrollees do not receive notice of a decision to downgrade their level of care from inpatient to outpatient, nor are they given opportunity to appeal such decisions as provided under § 422.562(b)(4). By providing notification to the enrollee as well as the physician or provider, as appropriate, we believe this will improve continuity of care and ensure appropriate access to the subpart M administrative appeals process.

Comment: A commenter requested that CMS ensure the proposal does not interfere with MA organizations' ability to enforce Medicare's reasonable and necessary standard.

Response: We thank the commenter for expressing this concern. We do not believe this provision interferes with the proper application of the reasonable and necessary standard in section 1862(a)(1) of the Act. We noted in the proposed rule that, in general, the concurrent review process includes obtaining necessary clinical information from the treating physician and other providers to determine medical necessity based on the clinical status of the enrollee and applicable Medicare coverage criteria. This provision does not prohibit plans from continuing to make decisions related to care, which includes making decisions related to whether the care being rendered is reasonable and necessary. This provision simply clarifies that decisions made based on the review of an enrollee's need for continued care, commonly known as concurrent review, are organization determinations subject to the rules in part 422, subpart M, which includes providing the enrollee (and the provider, as appropriate) with timely notice and applicable appeal rights. As part of the organization determination process, it is incumbent on the MA organization to obtain and review all relevant clinical information to make an organization determination on a request and to comply with requirements for basic benefits as described in § 422.101(c)(1). The intersection of these requirements ensures that MA organization decisions are made consistent with the standards related to medical necessity.

Comment: A commenter requested CMS clarify whether this proposal intends to protect enrollees from balance billing from a hospital versus to restrict a plan from assessing cost-sharing.

Response: As explained in the proposed rule, the intent of clarifying in regulation what constitutes an organization determination is to ensure enrollees receive proper notice and appeal rights, regardless of what point in the care continuum a decision is made. Our proposal related to determining whether an enrollee has any further financial liability is addressed in section III.A. of this final rule.

Comment: A commenter requested CMS provide clear guidance on enrollee liability for cost-sharing during the appeal process for concurrent denials.

Response: Under our proposal, which we are finalizing, we clarify that concurrent review is an organization determination subject to the requirements in part 422, subpart M, including notice and appeal rights. As we further explain in section III.A.1. of this final rule, an MA organization only makes a determination on the enrollee's financial liability for services received, including any applicable cost-sharing amounts, when it adjudicates a claim for payment. As we explained in the proposed rule, concurrent review decisions are coverage decisions, similar to pre-service decisions, and are not considered payment decisions. Therefore, an enrollee would only be liable for cost-sharing amounts, when applicable, after the MA organization makes a determination on such matters in response to a claim for payment. After an MA organization makes a payment determination on the enrollee's cost-sharing, in response to a claim for payment, the determination is binding and final upon the enrollee unless it is revised on appeal or reopening (see § 422.576). We acknowledge that a pending appeal on the concurrent review denial could alter the plan's payment determination if the enrollee's concurrent review appeal is ultimately successful. However, we did not propose for enrollees to receive financial liability protection during the pendency of a concurrent review appeal.

Comment: A few commenters also requested that CMS clarify what happens in the case of observation stays versus inpatient due to the change in enrollee liability. A commenter expressed concern that the proposed language regarding the denial of payment for inpatient services, while approving outpatient/observation care, could confuse enrollees regarding their financial responsibilities. This commenter stated that many enrollees may interpret a denial of inpatient coverage as an indication that no services are being covered, even though the outpatient/observation services may ultimately be more beneficial. The commenter believes this confusion may lead to unnecessary appeals, placing an undue burden on enrollees, providers, and plans alike.

Response: We appreciate the commenters' remarks on how an enrollee's liability is impacted by a decision regarding whether an inpatient hospital admission is medically necessary versus outpatient observation services. As we discussed in the proposed rule, whether a hospitalization is billed as an inpatient or an outpatient stay would likely result in different out-of-pocket costs for the enrollee. The difference in cost-sharing liability could be higher or lower for an enrollee and depends on the enrollee's cost-sharing requirements of their particular plan, the length of their hospitalization and, potentially, the amount and types of

services rendered. We believe that ensuring an enrollee has adequate notice of an adverse MA organization coverage decision, which may negatively affect their out-of-pocket expenses for a hospitalization as well as their ability to access other types of covered services, is paramount for providing a meaningful opportunity to appeal. We do not view this as undue burden but, rather, as ensuring the enrollee is afforded the reconsideration and appeal rights guaranteed by section 1852(g) of the Act.

Comment: A commenter requested CMS clarify how it envisions the interaction between the two-midnight presumption, followed by the Independent Review Entity (IRE), and MA organizations that are not bound by this presumption. Specifically, if the IRE approves inpatient status on appeal based on the admitting physician's order for inpatient care, how will this be reconciled with the fact that MA organizations do not have to adhere to the two-midnight presumption and may not find medical complexity in the record to support inpatient status. The commenter noted that a potential consequence of this change is the confusion and frustration experienced by enrollees who are in a hospital bed when they are informed that an inpatient stay has been denied, but observation status has been approved instead. This situation could lead to significant enrollee abrasion, as enrollees may not understand why they were initially admitted for inpatient status only to have their coverage status changed mid-course. Even though the care provided does not differ, the commenter noted that the change in status will create confusion regarding the increased financial responsibility or the perceived quality of care.

Response: We appreciate the commenter's concern about the potential for confusion regarding the enrollee's financial responsibility or perceived quality of care. We believe the proposed changes that we are finalizing in this rule on what constitutes an organization determination, the determination of enrollee liability, notice, and limiting the reopening of previously approved inpatient hospital admissions will mitigate confusion for enrollees and providers.

We did not propose a modification to the two-midnight rule or two-midnight presumption and offer the following only as clarification on existing policies. Pursuant to § 422.101(b)(2), MA organizations must comply with requirements related to basic benefits, including coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA organizations. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare and includes payment criteria for inpatient admissions at § 412.3. The term ''two-midnight rule'' is sometimes used to describe different things: either the ''two-midnight presumption'' or the ''two-midnight benchmark'' admission criteria. The commenter is correct that MA organizations do not have to follow the ''two-midnight presumption,'' which is the presumption that all inpatient claims that cross two midnights following the inpatient admission order are ''presumed'' appropriate for payment under Medicare Part A and are not the focus of medical review absent other evidence. The ''two-midnight presumption'' relates to medical review instructions for contractors in Traditional Medicare. However, another colloquial use of the term ''two-midnight rule'' is to describe the inpatient admission criteria in § 412.3, which include a ''two-midnight benchmark;'' MA organizations are required to follow these inpatient admission criteria.

In regard to the two-midnight presumption, we explained in the preamble of the CY 2024 final rule [48] that the ''two-midnight presumption'' does not apply to MA organizations' decision about when and how to engage in review of a particular inpatient stay.

The two-midnight presumption is a medical review instruction given to Medicare post-payment audit and compliance contractors (for example, Recovery Audit Contractors, or Quality Improvement Organizations) to help them in the selection of claims for post-payment medical necessity reviews in Traditional Medicare, which are conducted to ensure that claims have been appropriately paid under Medicare rules. Any sub-regulatory guidance issued by these contractors does not directly apply to MA organizations but likely contain useful explanations and interpretations of Traditional Medicare policies.

As clarified in the CY 2024 final rule, MA organizations are not required to use the two-midnight presumption to decide which claims to review, but may instead decide which claims are subject to review in accordance with procedures for making determinations as provided by section 1852(g)(1)(A) of the Act. MA organizations may still use prior authorization or concurrent case management review of inpatient admissions to determine whether the complex medical factors documented in the medical record support medical necessity of the inpatient admission under § 412.3. MA medical necessity reviews may be conducted before the service is provided (that is, prior authorization), during (that is, concurrent case review), or after the service is provided (that is, claim review). In all of these circumstances, MA organizations must comply with the rules on medical necessity determinations at § 422.101(c).

Finally, with respect to IRE review, if the IRE's reconsideration decision is that it was reasonable and necessary for the enrollee to receive inpatient hospital services pursuant to the inpatient hospital admission rules at § 412.3, the MA organization is responsible for effectuating that decision under the rules at § 422.618(b).

Again, we believe the clarifications on what constitutes an organization determination subject to the rules in part 422, subpart M, will enhance transparency in the MA organization decision making process for enrollees and providers.

Comment: A few commenters requested clarification around the decision-making timeframe for concurrent and retrospective reviews. A commenter requested CMS clarify that by amending the definition of organization determination to include concurrent reviews, this change would also mean that plans must make concurrent review decisions within the required decision timeframes specified in § 422.572. Another commenter recommended that concurrent and post-service requests not be subject to expedited processing and CMS should remove the requirement for plans to downgrade the request and send the ''Notice of Right to an Expedited Grievance''. The commenter explained that this requirement creates inefficiencies and administrative complexities without providing meaningful benefit to the enrollee who has already accessed the care, and expedited processing in such cases may delay the resolution of other urgent requests and divert resources from areas where they are most needed. The commenter suggested that by excluding, or at a minimum, clearly defining the circumstances under which concurrent or post-service requests can be excluded from expedited processing, CMS can help streamline operations for both plans and providers.

[48] 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, published April 12, 2023 (88 FR 22191 and 22192).

A commenter recommended CMS establish specific timeframes for MA organizations to make organization determinations for concurrent and retrospective reviews, like the existing timeframes for pre-service requests so as to ensure timely decisions and minimize disruptions in care.

Another commenter requested clarification regarding whether SNF services are considered ''inpatient services'' for the purpose of expedited reviews. This commenter noted that SNF and home health services are often critical to enrollees' ability to regain maximum function, and delays in accessing and receiving these services can jeopardize their health. The commenter recommended that SNF services also be treated as expedited reviews in most cases.

Response: We appreciate the commenters' recommendations and request for clarification. By amending the definition of organization determination to include concurrent reviews, this would require MA organizations to make a decision on such requests in accordance with the timeframes at §§ 422.568(b) and 422.572(a), as appropriate. As noted in the proposed rule, in the case of an MA organization conducting pre-service or concurrent review for inpatient services, CMS' expectation is that the facts and circumstances around that type of review will often satisfy the medical exigency standard. Therefore, CMS expects in most circumstances an MA organization must provide an expedited determination because applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function, consistent with the provisions at §§ 422.570(c)(2) and 422.631(c)(3). We wish to clarify that it was not our intention in the proposed rule to imply that *all* concurrent and retrospective reviews must be processed under the expedited timeframes. However, we continue to believe that many cases involving pre-service and concurrent review will be processed under the expedited timeframe depending on the nature of the request or decision. Currently, MA organizations in conjunction with providers make the determination regarding whether to expedite a request, and CMS does not believe it would be appropriate to establish circumstances in which the expedited timeframe would or would not apply because of the uniqueness of each case. Plans must treat each case in a manner that is appropriate for the facts and circumstances of the enrollee's medical condition.

With regard to expedited review for SNF services, again, it was not our intention to imply that inpatient hospital services are the only services that lend themselves to expedited review. As noted previously, it is up to the discretion of the provider and the MA organization depending on the facts and circumstances of each case to determine the timeframe in which a request should be processed. We also note that, as stated in the proposed rule, while the primary focus of the discussion related to the denial of inpatient hospital coverage as a result of an MA organization's concurrent review, our proposed clarification to the definition of an organization determination is inclusive of all other types of services.

We appreciate the commenter's suggestion that CMS establish specific timeframes for these types of reviews. We believe the current timeframes strike the appropriate balance to afford plans sufficient time to gather and review the facts and circumstances of each case, while providing timely notice and appeal rights to enrollees and their providers. We will continue to monitor enrollee access and plan compliance to determine if the development of additional timeframes would be appropriate in the future.

Comment: A few commenters requested CMS make clear that this proposal is a clarification of long-standing policy and not new policy.

Response: We thank the commenters for requesting this clarification. As noted in the proposed rule, historically, we have interpreted the definition of an organization determination to include when an MA organization makes a coverage decision on the appropriateness of an inpatient admission, or the appropriateness of inpatient services (that is, a level of care determination), contemporaneously with an enrollee's receipt of the services at issue. This would be true whether the MA organization ultimately approved the enrollee's admission to a facility, determined that the enrollee's level of care in the same facility should be reduced, or determined that the enrollee should be discharged (see §§ 422.620 through 422.624). Accordingly, these decisions would have to comply with all applicable notice and appeal requirements for organization determinations and would be binding on all parties unless they are reconsidered under §§ 422.578 through 422.596 or are reopened and revised under § 422.616.

Comment: A few commenters expressed concern related to MA organizations' refusal to make decisions on certain types of requests and the lack of appeal rights for the enrollee or the provider on such refusals. A commenter recommended that CMS include that a refusal by an MA organization to make any decision on a pre-service, post-service, or concurrent request by the enrollee is an organization determination and can be appealed. Similarly, a commenter recommended CMS explicitly state that an MA organization must issue a pre-service medical necessity determination in a timely manner when requested by an enrollee, provider or other authorized third party, which may include written requests and peer-to-peer communications, and that the decision or the failure or refusal to make such a decision is eligible for appeal. Another commenter recommended that CMS define in regulation the term ''pre-service'' to mean ''a request for an MA organization to approve coverage and payment for a service before the service is received by the enrollee.'' This commenter also urged CMS to clarify in regulation that enrollees have a right to receive a prior determination regardless of whether there is a prior authorization requirement or not.

Response: We thank the commenters for expressing their concerns and providing recommendations. The proposed rule does not intend to address situations where an MA organization refuses to make a decision on an organization determination (pre-service, post-service, or concurrent), and we do not believe further modification to the definition of an organization determination is necessary to address these situations at this time. When an MA organization receives an organization determination request, it is required to provide a decision within the timeframes specified at §§ 422.568 and 422.572, as applicable. Sections 422.568(f) and 422.572(f) state that if the MA organization fails to provide the enrollee with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed; therefore, if the MA organization does not issue timely notification, they are required to provide the enrollee with appeal rights. Again, we thank the commenter for the recommendation and may consider addressing this matter in future rulemaking.

We did not propose establishing a regulatory definition for the term ''pre-service'' and we do not intend to amend the regulation to this effect at this time.

We appreciate the recommendations and will consider these in future rulemaking.

We also did not propose to expand through regulation the requirement for MA organizations to process requests for prior approval even when the service being requested does not require prior authorization by the MA organization. We believe that existing regulations sufficiently address this matter. As we discussed in the proposed rule, an enrollee, enrollee's representative, or a provider on behalf of an enrollee, has the right to request the enrollee's MA organization approve an item, service, or Part B drug in circumstances where there is a question whether the item, service, or Part B drug will be covered. This right to receive prior approval applies to services for which an MA organization may require prior authorization as a condition for coverage as well as services for which there is no prior authorization requirement (see generally § 422.566(b)). When an MA organization receives a request for an item, service, or Part B drug, it must process the request according to the timeframes at § 422.568(b) or § 422.572(a).

Comment: A few commenters requested CMS clarify that this proposal applies to services and settings other than inpatient hospital coverage. A commenter agreed that the focus on inpatient hospital coverage denials is important, but recommended CMS clarify that the proposal applies to all service types across all care settings. The commenter stated that clear and consistent rules will help protect enrollees and reduce confusion for providers navigating the appeals process. Another commenter requested CMS clarify whether modifying the definition is intended to include all acute inpatient admissions (for example, from emergency room to inpatient admission) as organization determinations subject to appeal and other existing requirements, particularly for contract providers and facilities. A commenter requested CMS clarify whether retrospective review decisions apply to outpatient services since these reviews can occur with the provision of outpatient services, such as physical therapy, occupational therapy and durable medical equipment.

Response: We thank the commenter for requesting this clarification. As noted in the proposed rule, we proposed to revise § 422.566(b)(3) to clarify that a decision by an MA organization made pre-service, post-service, or concurrent with the enrollee's receipt of services in an inpatient or outpatient setting is an organization determination subject to the rules in part 422, subpart M, which includes providing the enrollee (and the provider, as appropriate) with timely notice and applicable appeal rights. We also noted in the proposed rule that while the primary focus of the discussion related to the denial of inpatient hospital coverage as a result of an MA organization's concurrent review, our proposed clarification to the definition of an organization determination is inclusive of all other types of services. We did not propose restricting this provision to inpatient hospital coverage alone. We believe the regulatory text is clear that this provision is not limited to certain services or settings.

With respect to whether this provision applies to contract providers and facilities, as explained in the proposed rule, an organization determination may be made prior to the receipt of service (for examples, prior authorization), after the receipt of service (for example, payment requests) or during the receipt of service (for example, continuation or termination of services) the enrollee receives from either contract or non-contract providers.

Comment: A commenter recommended CMS expand the scope of § 422.138(c) to include retrospective (pre-claim) approvals as well as concurrent approvals. The commenter noted that as described in the proposed rule, retrospective and concurrent reviews arise in a similar fashion, such that whether a review is retrospective or concurrent is what the commenter called ''an accident of timing''. If the MA organization approves the admission before discharge, it is a concurrent approval, but if the enrollee is discharged first, the same determination would be a retrospective approval. Because these are essentially the same types of determinations, this commenter believes that § 422.138(c) should apply with equal force to both. In addition, the commenter expressed concern that limiting the scope of § 422.138(c) to prior authorizations and concurrent approvals would create an inappropriate incentive to delay review and approval of care so that what would otherwise be a concurrent approval converts to a retrospective approval by virtue of the enrollee's discharge or completion of the course of care. Such delays would burden providers and serve no appropriate purpose.

Response: We appreciate the feedback, but the suggested changes to § 422.138 are outside the scope of this rule. The content of § 422.138 relates exclusively to prior authorization rules and in the case of paragraph (c), pre-service approvals. As we stated in the proposed rule, a retrospective review decision (whether made unsolicited or in response to a request) is a payment decision.

We solicited comment in the proposed rule regarding which existing notice type (that is, the IDN or an EOB) would be most appropriate for MA organizations to use when making a retrospective review decision without first receiving a request for payment. We received a few comments in response to this solicitation.

Comment: A few commenters were in support of using the IDN to communicate these decisions. A commenter recommended that the IDN be required because it is more conducive to relaying the level of detail warranted in a retrospective denial. This commenter noted that the EOB is generally used for payment determinations resulting from a claim, which may not clearly convey that a prior authorization approval has been rescinded and the reasoning behind such recission. The commenter requested CMS give an example of its intent and confirm that this proposal indicates that plans should not reverse an approved decision and should notify providers of a denial. Another commenter recommended that all decisions to downgrade should be communicated directly and immediately via an IDN. This commenter suggested that an EOB should not be allowed because it is frequently not timely and is likely to be confusing for individuals.

In contrast, a commenter was in support of using the existing EOB to communicate information regarding both retrospective and concurrent organization determinations. This commenter explained that the EOB is a well-established and clear document with which enrollees are already familiar, making it an effective tool for conveying details about financial liability and appeal rights, and building upon the EOB will be best for enrollees, as it avoids introducing additional paperwork or confusion and streamlines communication.

A commenter suggested CMS develop new standardized notice templates with clear and concise language for communicating concurrent and retrospective denials to enrollees. The commenter suggested the notices should include: a clear explanation of the reason for denial, information on applicable appeal rights, and a statement regarding potential enrollee liability for cost-sharing during the appeal process. Another commenter suggested CMS consider the Medicare

Change of Status Notice recently created for implementation of appeals of patient status in traditional Medicare. The commenter noted that the MA notice could similarly state that the enrollee's hospital bill ''may be lower or higher,'' due to the MA organization's decision, and that the ''MA plan can give you more information.'' Further, the notice could then describe how to start an appeal.

Response: We thank the commenters for providing feedback on which existing notice (the IDN or an EOB) would be most appropriate for MA organizations to use when making retrospective review decisions without first receiving a request for payment. We wish to make clear that the use of the IDN or EOB in this context would be for situations where the plan makes a retrospective review decision, without first receiving a payment request. In other words, the MA organization has not previously made a pre- or concurrent coverage decision and, therefore, would not be modifying a prior decision as some commenters suggested. A prior approval that has been rescinded under the reopening requirements is subject to the rules at §§ 422.138(c) and 422.616.

CMS will further consider the best approach to ensure enrollees and providers, as appropriate, have adequate notice of organization determinations, implications on cost sharing responsibilities, and proper access to the subpart M administrative appeals process. We will convey instructions on which notice plans should utilize through sub-regulatory guidance published in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, available for download at *https://www.cms.gov/medicare/appeals-grievances/managed-care.*

Comment: A few commenters opposed this proposal. A commenter stated that organization determinations are currently being made during the time in which care or services are being received (concurrent review) and at times, after an enrollee is discharged and before a claim (provider request for payment) is received and MA organizations already provide notice to providers that holds them accountable and liable with no enrollee liability. A few commenters suggested that this proposal would add a new appeal process for enrollees resulting in two redundant appeal processes for enrollees and contract providers, with separate appeal review entities, for one single appeal request. The commenters suggested the proposal will cause a significant amount of confusion for enrollees and providers, and an unreasonable number of administrative tasks and undue burden. These commenters recommended that CMS not finalize this proposal until this level of detail and impact is thoroughly researched and developed, and if CMS does intend to finalize this proposal, they request information on CMS' expectations for reconciling discrepancies between an Independent Review Entity decision for the enrollee and a MA organization decision for the provider. The commenters encouraged CMS to carefully evaluate the increased complexity, risk for enrollee and provider confusion, and significant resource investments, including increases in clinical and administrative staffing to manage the additional workload thoroughly before finalizing the proposal to ensure the policy achieves its intended goals. A commenter also suggested that CMS reflect these additional significant costs in its cost projections.

Response: We appreciate the commenters' perspectives; however, we disagree that providing notice of an adverse concurrent review decision solely to the provider, and processing any appeal under the MA organization's internal dispute resolution processes, is in accordance with our organization determination or reconsideration requirements or provides sufficient due process to enrollees that are directly affected by the adverse decisions. As we explained in the proposed rule, adverse coverage decisions on inpatient hospital services may also adversely impact an enrollee's cost-sharing amounts based on the duration of the hospital stay, the items, services, and Part B drugs provided during the hospital stay, and enrollees' cost-sharing responsibilities. Further, adverse coverage decisions on an enrollee's inpatient hospital services can negatively affect the types of covered services the enrollee could receive in the hospital and the types of services that are available immediately after the enrollee is released from the hospital. For example, many MA organizations condition coverage for certain services on whether the enrollee is leaving or was recently in an inpatient hospital stay—this could include covered transportation from the hospital, personal home care, meal benefits, and/or post-acute care coverage. If an enrollee's admission is denied or is changed to an outpatient stay, then these services would be unavailable to the enrollee that otherwise could be covered if their inpatient admission was approved or not reduced. We believe that the failure to allow an enrollee to appeal the denial of inpatient services, despite the directly resulting impacts described previously, could deprive enrollees of access to benefits without adequate due process. CMS believes our proposed amendments to the definition of an organization determination at § 422.566(b) constitute a reasonable approach to addressing these concerns.

We disagree that this proposal would require MA organizations to provide two separate, overlapping appeal processes for enrollees and contract providers when appealing a single adverse concurrent coverage decision. Under our proposal, when an MA organization issues an adverse coverage decision contemporaneously to when the enrollee is receiving the services at issue or a retrospective review decision after the services have been furnished, the enrollee (or physician on the enrollee's behalf) would appeal the denial under the existing appeal procedures at part 422, subpart M. In these cases, similar to all other MA administrative appeals under subpart M, the MA organizations' internal dispute resolution processes that apply to contract provider disputes would be inapplicable. As always, MA organizations and contract physicians may engage in voluntary peer-to-peer discussions as a means for the physician to present evidence in support of the enrollee's appeal when necessary.

With respect to reconciling decisions made by the IRE and the MA organization's decision for the provider, if the IRE makes a favorable determination, the MA organization must effectuate the decision, pursuant to the requirements at §§ 422.618 and 422.619. Payment issues involving participating (contract/network) providers are subject to the terms and conditions set forth in contracts between MAOs/providers and should be handled accordingly. However, as we noted in the proposed rule, a concurrent review decision is not considered a payment decision and, thus, would not be excluded from the appeals process under our proposed § 422.562(c)(2). We more fully discuss this matter in section III.A.1. of this final rule.

We appreciate the comments related to the burden associated with the proposed clarification and have addressed these comments in the Collection of Information section of this rule.

Comment: A commenter expressed concern related to what it described as a potential technical error in the proposed rule. Specifically, at 89 FR 99465, CMS states ''. . . a retrospective review decision (whether made

unsolicited or in response to a request) is a payment decision.'' However, in the proposed regulatory text at § 422.566(b), CMS appears to classify retrospective review as an organization determination. The commenter recommended CMS not finalize this proposal until it can meet with MA organizations and providers to better understand the issue. The commenter noted that while the change seems technical, it is important that both MA organizations and providers share a clear understanding of CMS' regulations, as it appears the stated intent of the preamble is not conveyed in the regulatory text, and plans need to clearly understand how CMS is classifying each of these decisions to ensure the appropriate notice and appeal processes in each situation.

Response: We disagree with the commenter that there is a technical error in the proposed rule. The existing definition of an organization determination includes both coverage decisions and payment decisions (see § 422.566(b)). As explained in the proposed rule, a retrospective review decision (whether made unsolicited or in response to a request) is a payment decision. Under our proposed clarifications to what actions constitute an organization determination, a post-service payment decision, even if made without the MA organization first receiving a payment request, is subject to the rules in subpart M. In addition, the regulations of part 422, subpart M, treat organization determinations related to coverage for services to be or contemporaneously being rendered (coverage decisions) differently from determinations related to payment for services already furnished (payment decisions). As such, a retrospective review decision would be subject to all applicable subpart M requirements related to payment organization determinations, including those related to notice and appeal rights. It was our intention to classify retrospective review decisions as a type of payment decision which is subject to the organization determination process, and we believe the regulatory text and relevant discussion in the proposed rule is accurate.

Comment: A commenter recommended CMS categorize post-service payment decisions as ''claims'' to help improve operational efficiencies and support uniformity. For example, it would ensure that notification of appeal rights could be included on the explanation of benefits for the enrollee and is beneficial for accurate reflection in annual reporting and audit protocols across MA organizations. This commenter recommended that if CMS classifies post-service payment decisions as ''service,'' MA organizations should be provided 30 days to review the request, in alignment with claims timeframes, to promote operational consistency and efficiency. The commenter suggested that since the service in question has already been rendered, aligning the review period to 30 days would not adversely impact the enrollee's ability to receive care.

Response: We thank the commenter for their recommendations. We believe that by suggesting we treat all initial post-service payment decisions as claims, the commenter was requesting that we require retrospective review decisions be processed under the existing requirements applicable to payment decisions (for example, appeal processing timeframes). We explained in the proposed rule that a post-service payment decision, even if made without the MA organization first receiving a payment request, is subject to all applicable subpart M requirements related to payment organization determinations, including those related to notice and appeal rights. In line with the discussion in the proposed rule, we agree with the commenter that post-service payment decisions would be subject to the processing timeframes for payment organization determinations at § 422.568(c).

After consideration of the comments received, we are finalizing the revisions to § 422.566(b)(3) and the corresponding change at § 422.138 on what constitutes an organization determination to include an MA organization's refusal, pre- or post-service or in connection with a decision made concurrently with an enrollee's receipt of services, to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization.

3. Strengthening Requirements Related to Notice to Providers (§§ 422.568, 422.572, and 422.631)

Section 1852(g)(1)(B) of the Act requires MA organizations to provide an explanation of determinations regarding whether an individual enrolled with a plan is entitled to receive a health service under this section and the amount (if any) that the individual is required to pay with respect to such service. In accordance with section 1852(g)(1)(B) of the Act, § 422.568 establishes the timeframe and notice requirements for standard organization determinations. Section 422.568(e)(5) establishes an additional framework for promulgating expanded notice requirements. Under § 422.568(f), if a MA organization fails to timely meet applicable notice requirements, the failure constitutes an appealable adverse organization determination.

Existing § 422.568(d) requires MA organizations to provide enrollees written notice if an MA organization decides to deny coverage for a service or an item, Part B drug, or payment in whole or in part, or decides to reduce or prematurely discontinue the level of care for a previously authorized ongoing course of treatment. Section 422.568(e) specifies that an MA organization's written notice of a coverage denial must use approved notice language, state the specific reasons for the denial, inform the enrollee of their right to request and the procedures for requesting a standard or expedited reconsideration, and must also comply with other notice requirements specified by CMS.[49] CMS created the Notice of Denial of Medical Coverage or Payment (Form 10003–NDMCP), also known as the Integrated Denial Notice (IDN), as a standardized denial notice that MA organizations may use to comply with the written notice requirements of § 422.568(e). This notice is approved by the Office of Management and Budget, subject to Paperwork Reduction Act procedures and is posted on the CMS website.[50] While MA organizations are required to provide timely notice of an approved organization determination, written notice is not required. This means that MA organizations may provide oral notice of approved coverage decisions.

The existing notice requirements for standard organization determinations at § 422.568(b)(1) only specify that MA organizations must provide the enrollee with notice of its decisions. This is a notable difference from the requirements related to expedited organization determinations at existing § 422.572(a) and (b) that require MA organizations to provide timely notice of any expedited organization determination to the enrollee and the physician or prescriber involved, as appropriate. Likewise, for Part B drug requests, regulations at § 422.568(b)(3) require notice to the prescribing physician or other prescriber involved, as appropriate.

However, existing CMS guidance instructs MA organizations to notify the provider, as well as the enrollee, whenever a provider submits an

[49] Section 422.568(e) also regulates the notice requirements for payment denials, which are largely the same, with the exception that payment denial notices do not need to include information on expedited reconsideration processes.

[50] *https://www.cms.gov/medicare/forms-notices/beneficiary-notices-initiative/ma-denial-notice.*

organization determination on behalf of the enrollee (see Section 40.12.1 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance [51]). Similar references are also made in the text of the IDN, as CMS explains to enrollees that ''If your doctor requested coverage on your behalf, [the MA organization has] sent a copy of this decision to your doctor.''

We do not find a compelling reason that a provider should not receive notice of a standard organization determination when the provider submitted a request on behalf of an enrollee or when it is otherwise appropriate for the provider to receive notice of the determination. Indeed, under existing regulations at § 422.566(c)(1)(ii), a provider is already permitted to request an organization determination on an enrollee's behalf. This longstanding policy is premised on a reasonable belief that an enrollee will welcome and be informed of their provider or physician's willingness to pursue an organization determination on their behalf. We saw no reason that a provider or physician to whom an enrollee has already entrusted their care or has sought to request coverage for their care, should not receive notice of an organization determination that directly affects such care. In fact, we believe an enrollee's provider is often in the best position to receive, explain, and timely act upon the MA organization decision for an enrollee.

Similar requirements for integrated organization determinations apply to applicable integrated plans at § 422.631. Under § 422.631(d)(1)(i), applicable integrated plans are required to send an enrollee a written notice of any adverse decision on an integrated organization determination (including a determination to authorize a service or item in an amount, duration, or scope that is less than the amount previously requested or authorized for an ongoing course of treatment) within the timeframes set forth in § 422.631(d)(2). Existing § 422.631(d)(1)(ii) states that an integrated organization determination not reached within the timeframes specified constitutes a denial and thus is an adverse decision. Section 422.631(d)(1)(iii) specifies the integrated organization determination notice requirements for applicable integrated plans must be written in plain language, available in a language and format accessible to the enrollee, include the date the determination was made and will take effect, the reason for the determination, the enrollee's right to an integrated reconsideration and to have someone file an appeal on their behalf, procedures for an integrated reconsideration, circumstances for an expedited resolution and enrollee's rights to continue benefits while their appeal is pending. CMS created the coverage decision letter (CDL) (Form CMS–10716), an OMB approved notice, for use by applicable integrated plans to comply with the written notice requirements at § 422.631(d)(1)(iii). The existing notice requirements at § 422.631(d)(1)(i) only specify that an applicable integrated plan must provide the enrollee with notice of its decisions. However, integrated organization determinations for Part B drug requests are governed by the provisions at § 422.568(b)(3) that require notice to the prescribing physician or other prescriber involved, as appropriate. Likewise, existing CMS guidance instructs applicable integrated plans to notify the provider, as well as the enrollee.

We, therefore, proposed strengthening requirements related to notice of a standard organization determination at § 422.568 in paragraph (b)(1) and the introductory text for paragraph (d) and integrated organization determinations at § 422.631(d)(1)(i) to require MA plans and applicable integrated plans to notify an enrollee's physician or provider, as appropriate, of an organization determination or integrated organization determination on a request for a non-drug item or service (in addition to the existing requirement related to notifying an enrollee). We noted that ''as appropriate'' meant, as with similar requirements in §§ 422.568(b)(3) and 422.572(a), that notice should be given to the provider or prescriber who submitted an organization determination request on behalf of an enrollee or in other circumstances where it would be in the enrollee's best interest for their provider or prescriber to receive notice of a decision related to an enrollee-submitted request.

We also proposed corresponding amendments to §§ 422.568(f), 422.572(f), and 422.631(d)(1)(ii) to state that if the MA organization or applicable integrated plan fails to provide the enrollee, physician, or provider involved, as appropriate, with timely notice of an organization determination or integrated organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed. We noted that the proposed change at § 422.572(f) is a technical change to expedited organization determination requirements. Under existing rules at § 422.572(a), MA organizations are required to provide notice of an expedited organization determination to the physician or prescriber, as appropriate. However, existing § 422.572(f), which establishes that a MA organization's failure to timely meet expedited organization determination notice requirements constitutes an adverse decision, only refers to the MA organization's responsibility to provide timely notice to the enrollee. We, therefore, proposed a technical change to § 422.572(f) to clarify that the failure to provide timely notice of an expedited organization to the enrollee and the physician or prescriber, when appropriate, would itself constitute an appealable adverse organization determination.

In addition, we proposed a technical change at § 422.631(a) to reference the correct Part B drug regulation at § 422.568(b)(3) rather than the current reference to § 422.568(b)(2) to govern the timeframes and notice requirements for integrated organization determinations for Part B drugs. The final rule titled ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program,'' which appeared in the February 8, 2024 **Federal Register**, redesignated § 422.568(b)(2) as § 422.568(b)(3).

We did not believe this proposal would have a substantial impact on the practices of MA organizations or applicable integrated plans as we are codifying longstanding guidance that we believe the majority of plans already implement based on the relatively few complaints from providers and enrollees. In addition, we also understood that due to the contractual relationship MA organizations have with their providers, most contract providers should already receive notice of relevant organization determinations, including those that the provider submitted on behalf of the enrollee. However, we noted that the few complaints that we do receive on this issue reinforce how disruptive the lack

[51] *https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf.*

of provider notice can be for enrollees attempting to promptly receive covered medical services. When an enrollee is the only party to receive written notice of a decision, not only can this result in a delay in their receipt of approved medical care but could also delay the submission of a valid appeal when coverage is denied.

As explained in the proposed rule, this approach supports the modification to the definition of an organization determination at § 422.566(b) by ensuring providers will always receive notice of a decision notwithstanding when in the continuum of care the decision is made. As discussed in section III.A.2. of this final rule, CMS identified that some MA organizations routinely misinterpret existing organization determination provisions related to decisions that rescind prior authorization of an inpatient admission, deny coverage for inpatient services, or downgrade an enrollee's hospital coverage, from inpatient to outpatient, when the decision is made concurrently to the enrollee receiving such services. In these cases, the MA organizations were not providing enrollees or their providers proper notice of the adverse organization determination or providing appeal rights. Our proposed clarifications to the definition of an organization determination at § 422.566(b)(3) sought to clarify that applicable decisions made before, during, or after the enrollee's receipt of services are organization determinations and thus are subject to notice requirements pursuant to §§ 422.568, 422.572, and 422.631. Our proposal at §§ 422.568 and 422.631 would, therefore, require the MA organization or applicable integrated plan to provide notice to the enrollee and physician or provider that must comply with the standard organization determination or integrated organization determination requirements. We noted, however, that in the case of an MA organization conducting pre-service or concurrent review for inpatient services, our expectation was that the facts and circumstances around that type of review will often satisfy the medical exigency standard. Therefore, we expected in most circumstances an MA organization must provide an expedited determination because applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function, consistent with the provisions at §§ 422.570(c)(2) and 422.631(c)(3).

We received the following comments regarding our proposal to strengthen requirements related to notice to providers.

Comment: Several commenters expressed appreciation and support for our proposal to require MA organizations and applicable integrated plans to notify an enrollee's physician or provider, as appropriate, of an organization determination or integrated organization determination on a request for a non-drug item or service. Commenters stated that this change would increase communication and transparency between the enrollee, the provider, and the MA organization, and put the provider in a better position to advocate on behalf of the enrollee in the event care alternatives need to be explored or adverse decisions appealed. Commenters also noted that requiring notices be sent to providers will put them in a better position to provide assistance in a timely manner, which will increase care coordination and efficiency.

Response: We thank the commenters for their support. As noted in the proposed rule, we believe this change is of benefit to enrollees, physicians and providers and is likely the existing practice of many MA organizations.

Comment: Multiple commenters agreed with our expectation that MA organizations conducting pre-service or concurrent review for inpatient services should apply the medical exigency standard and, therefore, should provide an expedited determination with appropriate notice to the physician or provider. Commenters further recommended that this expectation be codified.

Response: We appreciate the commenters' agreement with our expectation that MA organizations conducting pre-service or concurrent review for inpatient services should provide an expedited determination and appropriate notice to the physician or provider. As we explained in the proposed rule, existing §§ 422.570(c)(2) and 422.631(c)(3) establish the ability for physicians to request and automatically receive an expedited organization determination when a physician indicates that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. This means that a coverage request for inpatient hospital services, made concurrently or before services begin, could be automatically expedited when properly justified by a physician. Because this existing process for requesting expedited review already provides an avenue for physicians (and enrollees) to request expedited review for pre-service and concurrent review request, we do not believe it necessary to codify new processing timeframes unique to these coverage requests at this time. We may address this matter in future rulemaking.

Comment: A commenter, while supporting the proposal, recommended that an enrollee's physician be notified in addition to their provider as set forth in the proposal. They stated that many physicians practicing in inpatient rehabilitation hospitals are not employees of the inpatient rehabilitation facility (IRF) but practice with privileges in these hospitals. Further, they indicated that notification to both the physician and the IRF provider would ensure all involved in the care of the MA enrollee are aware of the status and decision of the MA organization's determination and can expedite the admission or appeal once notice is received from the MA organization.

Response: While we appreciate this comment, we proposed this policy in a manner that balances enrollees and their treating providers receiving timely notice of relevant decisions while minimizing new burden placed on MA organizations. We believe that requiring notice to multiple points of contact within a single provider entity could be duplicative, unnecessary and unduly burdensome to MA organizations. To this end, and in an effort to minimize the burden related to the proposed requirements, we will monitor the implementation of the rule and may engage in future rulemaking on this matter, as necessary.

Comment: A commenter expressed concern with the proposed corresponding language at §§ 422.568(f), 422.572(f), and 422.631(d)(1)(ii) stating that if the MA organization or applicable integrated plan fails to provide timely notice of an organization determination (or integrated organization determination) to the enrollee, physician, or provider involved, the failure itself would constitute an adverse organization determination that may be appealed. They believed this revision would encourage MA organizations to avoid reviewing organization determinations because it would benefit MA organizations for those requests to be denied. Instead, they recommended untimely organization determinations—whether standard or expedited—be considered favorable organization determinations.

Response: We appreciate the commenter's perspective but disagree with the recommendation. The

proposed change at § 422.572(f) provides that when an MA organization fails to provide the enrollee, physician, or provider involved, as appropriate, with timely notice of an expedited determination, the MA organization's inaction constitutes an adverse organization determination and may be appealed. We proposed this modification as a technical change to have § 422.572(f) mirror existing regulations at § 422.572(a), requiring MA organizations to provide notice of an expedited organization determination to the physician or prescriber, as appropriate. The change at § 422.631(a) was made to reference the correct Part B drug regulation at § 422.568(b)(3) rather than the current reference to § 422.568(b)(2) to govern the timeframes and notice requirements for integrated organization determinations for Part B drugs. Finally, similar to the previous provisions, § 422.631(d)(1)(ii) states that an integrated organization determination not reached within the required timeframes constitutes a denial and thus is an adverse decision. We did not propose reversing the underlying policy to have an MA organization's failure to timely process and respond to organization requests to result in constructive approval of the request. We believe such a policy would have profound ramifications that were not considered here and are out of the scope of our proposed technical change.

Comment: A commenter requested clarification on how SNF discharge information would be communicated to providers and whether this notification would be in writing. The commenter further raised concerns regarding what they believed to be misaligned timeframes for MA organizations to notify enrollees that they are terminating SNF coverage and the 72-hour timeframe for expedited determinations. The commenter noted that the discrepancy could lead to medically necessary services being discontinued before a decision is received and recommended that CMS align these two timeframes to better protect enrollees from disrupted care. Another commenter suggested we extend our proposal to post-acute care discharge appeals submitted by the enrollee.

Response: We thank the commenters for inquiring about notice and timeframe requirements when an MA organization is discharging an enrollee from a covered stay in a post-acute care setting. The notice and appeal requirements related to non-hospital inpatient services are codified at §§ 422.624 through 422.626. Our proposal did not address nor modify the notice or timeframe requirements for post-acute care discharge notices or the related appeals process. We also do not believe it necessary to extend this proposal to post-acute care discharge appeals as pursuant to § 422.624(b), enrollees currently receive notice, in person and from the provider, of the MA organization's or provider's decision to terminate covered services through the standardized CMS–10123–NOMNC, Notice of Medicare Non-Coverage. In addition, in accordance with existing § 422.626(d)(5), the IRE already is responsible for providing notice of an appeal decision to the enrollee, MA organization, and the provider of services.

Comment: A few commenters questioned how denial notices should be delivered to enrollees in specific situations. A commenter questioned how notices should be delivered to the enrollee in an inpatient setting when either oral or written delivery may not be appropriate or timely given the enrollee's condition. They further questioned if the provider/physician would be responsible for communicating the contents of the denial notice to the enrollee and whether notice requirements apply in a substance use disorder residential facility when there is no difference in the enrollee's cost share by level of care. Another commenter questioned if providers, in addition to the MA organization, were required to provide notice regarding discharge to the enrollee in writing.

Response: We proposed, among other items, adding a requirement that MA organizations provide notice to an enrollee's provider, in addition to notice to the enrollee, when making an organization determination on a non-drug item or service. We did not propose changing the existing notice delivery requirements. CMS provides guidance on delivery requirements in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, available for download at *https://www.cms.gov/medicare/appeals-grievances/managed-care.*

We agree with the commenter that delivery of a notice by an MA organization to an enrollee could be difficult when the enrollee is receiving care as an inpatient. We believe MA organizations should continue to make their best efforts to meet all delivery requirements, and we appreciate when MA organizations strive to provide actual notice to the enrollee when the MA organization is aware that the enrollee is located in a contract facility. However, we believe that our proposed requirement for physicians and providers to receive notice of organization determinations, as appropriate, would assist in ensuring that the enrollee's treating provider also receives notice and will have the opportunity to discuss the decision with the enrollee or the enrollee's representative. We reiterate that we did not propose modifying the inpatient discharge notice requirements established at §§ 422.622 through 422.626, nor did we propose a requirement to make providers responsible for communicating organization determinations to enrollees on behalf of the MA organization.

Comment: A commenter supported our proposal but recommended that we go further and require MA organizations to provide plain language in their notifications around denial of coverage and ensure that communications clearly articulate information related to appeal rights. They stated that providers are often placed in the middle between the health plan and the enrollee and the burden often falls on them to not only explain coverage to the enrollee, but be blamed if coverage is denied.

Response: We thank the commenter for their support and appreciate providers' efforts, when necessary, to articulate denial and appeals information to MA enrollees. We did not propose changing the existing model notices used to notify enrollees of an organization determination (such as the CMS–10003–NDMCP, Notice of Denial of Medical Coverage or Payment, also known as the Integrated Denial Notice (IDN)). We note that our current enrollee notices are written in plain language, consumer tested for understandability and frequently updated to ensure readability and accuracy. Additionally, form instructions corresponding with our notices, such as the IDN, provide detailed guidance to MA organizations—including instructions regarding completion of the denial rationale (see section titled ''Why did we deny your request?''). The IDN is available at: *https://www.cms.gov/medicare/medicare-general-information/bni/downloads/integrated-denial-notice-instructions-cms-10003.pdf.* We will continue to strive to improve our notices to ensure enrollee understanding of denials, terminations and appeal rights.

We appreciate the feedback we received from commenters on the proposed requirements. We are adopting the proposed revisions to §§ 422.568, 422.572, and 422.631 without modification.

4. Modifying Reopening Rules Related to Decisions on an Approved Hospital Inpatient Admission (§§ 422.138 and 422.616)

Under the regulations at § 422.576, an organization determination is binding on all parties unless it is reconsidered under the rules at §§ 422.578 through 422.596 or is reopened and revised under § 422.616. The reopening rules at § 422.616 permit an organization or reconsidered determination made by an MA organization that is otherwise final and binding to be reopened and revised by the MA organization under the applicable rules in part 405, subpart I, at §§ 405.980 through 405.986. The reopening rules in part 405, subpart I, are implementing section 1869(b)(1)(G) of the Act, which states that the Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established in regulations. While the reopening rules in §§ 405.980 through 405.986 are applicable to the Traditional Medicare program, the regulatory provisions at 42 CFR part 405 historically have been cross-referenced in the managed care regulations and have been applied to the MA program consistent with the provisions at §§ 422.562(d) and 422.616 since the inception of the MA program (and to MA's predecessor, the Medicare+Choice program). Thus, the ability of an MA organization to reopen and revise an organization determination for the reasons set forth in regulation is well established in the MA program. For purposes of this provision, the discussion is specific to the application of the reopening rules to organization determinations made by an MA organization that involve inpatient hospital admission decisions.

Section 422.616(b) permits a reopening at the instigation of any party and, in accordance with § 422.616(d), once an adjudicator issues a revised determination, any party may file an appeal. Pursuant to the applicable reopening regulations at § 405.980(b), an organization determination or reconsideration may be reopened by an MA organization within 1 year from the date of the initial determination or redetermination for any reason. However, in recently promulgated prior authorization rules at § 422.138(c), if an MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at § 405.986) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616.[52] Under § 422.138(c), in the case of an approved organization determination for the furnishing of a covered item or service made through prior authorization or a pre-service determination, an MA organization is not permitted to reopen that decision within 1 year from the date of determination for any reason as is otherwise permitted at § 405.980(b)(1). While the rules at § 422.138(c) currently allow for reopening of a favorable prior authorization decision within 4 years from the date of the initial determination or redetermination for good cause, as defined in § 405.986, we believe a proposed modification to the MA reopening rules at § 422.616 is necessary with respect to favorable organization determinations on inpatient hospital admissions.

We are aware that some MA organizations are reopening and revising or otherwise rescinding a prior approval for an inpatient hospital admission based on a medical necessity determination during the enrollee's receipt of the previously authorized services or during the adjudication of the subsequent inpatient claim for payment. For example, when deciding to admit an enrollee, the hospital requests and receives approval for the admission from the enrollee's MA organization. Later, however, the MA organization obtains and reviews additional medical documentation and determines that the enrollee does not meet the necessary criteria to support payment for inpatient hospital services and rescinds or overrides its prior approval. As discussed in the context of our proposal to strengthen the notice requirements in § 422.568, some MA organizations are not consistently providing notice or appeal rights to the enrollee for these decisions.

The rules at § 405.980(b) permit reopening of a decision if there is a finding of good cause as defined in § 405.986. If good cause is found, an organization determination may be reopened within 4 years from the date of the determination. Under the rules at § 405.986, good cause may be established when (1) there is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion; or (2) the evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision. New and material evidence is evidence that was not readily available or known to the person or entity requesting or initiating the reopening at the time the initial determination was made by the MA organization and may result in a different conclusion than reached in the initial determination. Such evidence may include any record used in the furnishing of care and supporting the medical necessity of such care. This includes, but is not necessarily limited to, medical records, progress notes, and physician orders. Under the reopening rules, a change of legal interpretation or policy by CMS in a regulation, ruling, or general instruction is not a basis for reopening an organization determination.

Under existing rules at § 422.138(c), in cases where an enrollee's inpatient admission into the facility is approved prior to admission, this decision is binding and may not be reopened and revised by the MA organization unless there is good cause for a reopening pursuant to the rules at § 405.986. The inpatient hospital admission rules at § 412.3(d)(1) and (3) are clear that the coverage criteria set forth therein are based on the admitting physician's expectation at the time of admission about whether the hospital care will cross two-midnights or is otherwise appropriate, as supported by the medical record. Since the physician's expectation at the time of admission is based on the clinical information known at that time as well as the documented medical record at the time of admission, any subsequent clinical information obtained after an MA organization has made its initial organization determination would not have the effect of creating a good cause reopening on the basis of new and material evidence that was not available or known at the time of the determination or decision and that may result in a different conclusion. As part of the organization determination process, it is incumbent on the MA organization to obtain and review all relevant clinical information to make an organization determination on a request for inpatient hospital admission and to comply with requirements for basic benefits as described in § 422.101(b)(2).

Due to the ongoing issues we have seen with previously approved inpatient hospital admissions later being inappropriately revised or rescinded, and to augment the regulations at § 422.138(c), we proposed to amend § 422.616(a) to state that the reopening provisions are subject to the rules at § 422.138(c) and proposed a new paragraph (e) of § 422.616 that would place a limitation on reopening

[52] See 88 FR 22120, 22185 through 22217.

determinations related to favorable inpatient hospital admissions. Specifically, we proposed § 422.616(e) to state that if an MA organization approved an inpatient hospital admission under the rules at § 412.3(d)(1) or (3), any additional clinical information obtained after the initial organization determination cannot be used as new and material evidence to establish good cause for reopening the determination.

These proposed amendments to the reopening rules at § 422.616 present a reasonable approach to curtailing the reopening of approved hospital admission decisions and are consistent with the rules on inpatient admission decision-making. Decisions on inpatient admissions under § 412.3(d)(1) or (3) are based on whether the complex medical factors documented in the clinical record support the admitting physician's clinical expectation or judgment. Section 412.3(d)(1) states that, except as specified in paragraphs (d)(2) and (3) of § 412.3, an inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the beneficiary to require hospital care that crosses two midnights. Section 412.3(d)(1)(i) states that the expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record to be granted consideration (with respect to determining the appropriateness of payment for an inpatient stay). Section 412.3(d)(1)(ii) states that if an unforeseen circumstance, such as a beneficiary's death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least two midnights, the beneficiary may be considered to be appropriately treated on an inpatient basis, and payment for an inpatient hospital stay may be made under Medicare Part A. The exception in § 412.3(d)(2) relates to inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n). The exception in § 412.3(d)(3) states that where the admitting physician expects a beneficiary to require hospital care for only a limited period of time that does not cross two midnights, an inpatient admission may be appropriate for payment under Medicare Part A based on the clinical judgment of the admitting physician and medical record support for that determination. The physician's decision is based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. In these cases, the factors that lead to the decision to admit the beneficiary as an inpatient must be supported by the medical record in order to be granted consideration.

Based on these rules, we determined it was appropriate to limit reopening of a decision involving inpatient hospital admission by prohibiting reopening for good cause based on new and material evidence. Any additional clinical information obtained after the initial organization determination cannot have the effect of creating a good cause reopening because the determination was made based on what was known by the physician and documented in the medical record at the time of admission. Under the rules at § 405.986(a)(2), good cause for reopening may also be established if the evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination or decision. The proposed rule did not seek to modify or limit the applicability of reopening for obvious error per the rules at § 405.986(a)(2) with respect to favorable inpatient hospital admission decisions. For example, there could be a situation where the admitting physician documents something related to the enrollee's condition incorrectly into the clinical record that the plan relied upon when making the favorable decision and the facts and circumstances of such a mistake, including the significance and materiality of the error, may support a reopening of the favorable decision on the basis of obvious error. The need for a plan to reopen a favorable inpatient hospital admission decision on the basis of obvious error under the rules at § 405.986(a)(2) should be a rare occurrence given the breadth of clinical documentation that is considered when making a decision on an inpatient hospital admission.

We acknowledged that our proposed limitation on the type of clinical information that may be considered new and material evidence to form the basis to reopen a favorable determination related to an inpatient hospital admission is a departure from corresponding Traditional Medicare reopening policies and would, at times, restrict certain clinical information from forming the basis of new and material evidence to reopen that would otherwise be available in Traditional Medicare. While we strive to create and apply policies consistently between the MA program and Traditional Medicare, the programs' inherent differences require a tailored approach in this scenario. In particular, under Traditional Medicare, an initial determination related to an inpatient admission would only be made after a beneficiary had received the service and a claim for payment has been submitted (see § 405.920) and, therefore, generally after a beneficiary's medical record supporting that service has been fully developed. In contrast, MA enrollees may receive a favorable determination related to an inpatient hospital admission before or contemporaneously to the enrollee's receipt of services (see § 422.566(b)(3)). This means the enrollee's medical records are continuing to be updated to reflect the changing medical circumstances. Thus, it is more likely that clinical information obtained after an initial organization determination could lead to an MA organization reopening a decision for an enrollee than a beneficiary in Traditional Medicare, even though the inpatient admissions criteria in § 412.3 apply in the same manner to both programs. MA enrollees should be able to rely upon an approved inpatient admission made in advance of the receipt of services, or concurrently with the receipt of services, despite changing medical circumstances. They should not be concerned that an MA organization may revise or rescind an approved admission due to clinical information that was not available or in existence when the provider determined the need for admission and the MA organization approved the admission.

Finally, for clarity in the applicability of the reopening rules to prior authorization and pre-service determinations, we also proposed a technical amendment to the parenthetical text in paragraph (c) of § 422.138 to add a cross reference to the rules at § 422.616, including proposed new paragraph (e) related to decisions to approve an inpatient hospital admission.

We received the following comments on our proposal to modify our rules related to reopening determinations for good cause.

Comment: Commenters primarily expressed strong support for this proposal. These commenters noted that this change will be critical to improving timely and appropriate reimbursement, limiting retroactive denials by MA organizations, and reinforcing the two-midnight rule's focus on physician judgment at the time of admission (that is, time of the inpatient order).

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

noted in the proposed rule, we believe these amendments to the reopening rules at § 422.616 constitute a reasonable approach to curtailing the unsubstantiated review of previously approved inpatient hospital admission decisions and are consistent with the rules on inpatient admission decision-making at § 412.3. Any additional clinical information obtained after the initial organization determination cannot have the effect of creating a good cause reopening because the determination was made based on what was known by the physician and documented in the medical record at the time of admission.

Comment: A few commenters, while expressing support for our proposal, recommended that CMS expand this proposal to include other care settings and services and requested that we clarify why the proposal was limited to inpatient hospital admissions. A commenter suggested we revise the regulatory text to cover items and services regardless of site of service. This commenter was concerned that MA plans could misconstrue the proposal to only include hospital services. Other commenters suggested we expand this provision to include SNF, HHA, and IRF services. Noting that providers in post-acute care settings encounter similar situations in their interactions with various MA organizations, a commenter recommended this expansion to safeguard financial stability and the ability to provide high quality care in these settings. Similarly, another commenter was concerned that the proposal does not go far enough to protect enrollees from increased out of pocket costs that may be associated with downgrades and to protect providers, or hospitals, from significant erosion of payment amounts after prior authorization was provided for inpatient level of care. This commenter recommended that CMS consider being more explicit about MA plans being required to pay for covered items or care at the setting or location for which it has provided prior authorization. A commenter recommended that CMS expand this proposal to limit retrospective down coding and payment denials for services other than inpatient care to curtail plan behavior that harms physician practices and their ability to deliver care.

Response: We thank the commenters for their support of our approach. We agree this change will establish more certainty for providers and enrollees and will also reduce the volume of post-service appeals. We also appreciate hearing perspectives that may inform the need for future rulemaking in this area involving other service settings. Our proposal was intentionally focused and limited in this rulemaking, given that we had identified approved inpatient hospital admissions as being the area of greatest concern. We addressed the issue of reopenings with respect to inpatient hospital admissions first because of unique circumstances, such as urgent and emergent admissions where prior approval may not be permitted, but is often requested, as well as the prevalence of concurrent review in this setting. We also note that inpatient hospital admission determinations are unique among covered items or services in that they are dependent on physician judgement at the time of the inpatient order. We reiterate that under existing prior authorization rules at § 422.138(c), if an MA organization approves the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. The rule at § 422.138(c) applies to all MA covered items and services, so there is a safeguard under existing regulations if there has been prior approval for an item or service. Again, we appreciate the comments and will take them under consideration for potential future rulemaking.

Comment: A commenter requested clarification in the case where additional clinical information includes significant new and material information relevant to an organization decision, such as an indication of a ''never event.'' Specifically, the commenter questioned if an MA organization would be permitted to reopen the organization determination in this case. This commenter requested that CMS permit the reopening of an approved hospital admission when additional clinical information indicates a never event.

Response: We appreciate the commenter's request for clarification in the case of a never event. Never events are events that are preventable, serious and unambiguous adverse events that should never occur. These events are subject to national coverage determinations (NCDs) that establish uniform national policies to prevent Medicare from paying for certain serious, preventable errors in medical care.[53] Our proposed changes to § 422.616 were limited to reopening inpatient hospital admission decisions on the basis of good cause for new and material evidence and did not seek to modify an MA organization's ability to reopen an approved inpatient hospital admission decision for other reasons pursuant to the rules at § 405.980, such as good cause for obvious error or for fraud or similar fault. Nonetheless, since a never event that occurs during the inpatient hospital admission would likely not be a factor at the time the inpatient admission was approved, the change being made in this rule wouldn't impact applicable requirements for submitting claims for payment in the case of a never event, such as submission of a no-payment claim.

Comment: A commenter expressed concern that because the proposal would foreclose MA organizations' ability to reopen determinations for good cause, MA plans will increase efforts to find obvious error to reopen approved initial determinations. This commenter requested that CMS provide greater clarity about reopening for obvious error, and clearly delineate the confines of this pathway to restrain the potential for abuse by MA organizations.

Response: We appreciate the commenter's perspective that foreclosing the opportunity to reopen for new and material evidence will incentivize plans to reopen for obvious error. The regulation at § 405.986(a)(2) permits reopening if the evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision. As we stated in the proposed rule, there could be a situation where the admitting physician documents something related to the enrollee's condition incorrectly into the clinical record that the plan relied upon when making the favorable decision and the facts and circumstances of such a mistake, including the significance and materiality of the error, may support a reopening of the favorable decision on the basis of obvious error. We reiterate our belief that the need for a plan to reopen a favorable inpatient hospital admission decision on the basis of obvious error under the rules at § 405.986(a)(2) should be a rare occurrence given the breadth of clinical documentation that is considered when making a decision on an inpatient hospital admission. Nonetheless, we will monitor the use of reopening for

[53] *https://www.cms.gov/newsroom/press-releases/cms-issues-three-national-coverage-determinations-protect-patients-preventable-surgical-errors.*

obvious error and provide sub-regulatory guidance, as necessary.

Comment: A commenter suggested CMS clarify that there are limited, valid reasons for reopening an approved inpatient hospital stay. This commenter noted that in addition to suspected fraud, waste, or abuse, CMS should articulate an exception for when a pre-service request for an admission for a service or procedure was approved, but during concurrent review, it is discovered that the service or procedure was not provided. The commenter suggested that, in these rare circumstances, MA plans should be able to reopen an approved admission to confirm whether a different service was provided instead.

Response: We thank the commenter for the suggestion, but we do not believe an exception for this circumstance is warranted. Under the rules at § 412.3, an inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the beneficiary to require hospital care that crosses two midnights (that is, the two-midnight rule). This expectation of the physician is based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The regulations at § 412.3 require that, as a condition of payment, an order for inpatient admission must be present in the medical record. Under § 412.3(d)(1), the admitting physician's order specifies the beneficiary's need for acute hospital care and the expectation that this acute hospital care will cross two midnights, not the need for a particular procedure or service. We acknowledge that an inpatient hospital admission might also be appropriate for a procedure included on the inpatient-only list per the rules at § 412.3(d)(2) and under the case-by-case exception to the two-midnight rule at § 412.3(d)(3). The revision to § 422.616 we are finalizing in this rule specifically refers to approved inpatient admissions under § 412.3(d)(1) and (3). In the case of a prior approval for an inpatient admission per § 412.3(d)(2), plans will continue to be able to reopen those decisions on the basis of good cause for new and material evidence.

Comment: A few commenters requested CMS clarify that both prior authorization and pre-service organization determinations are subject to this proposal.

Response: The commenter is correct that the proposed change to the reopening rules applies to approved hospital inpatient admission decisions made because of a request for a pre-service organization determination, including those pre-service organization determinations that involve prior authorization. Even if a service is not subject to an MA organization's prior authorization rules, an enrollee has the right to request an organization determination on a pre-service basis. Under the rules in § 422.138(c), in the case of an approved organization determination for the furnishing of a covered item or service made through prior authorization or a pre-service determination, an MA organization is not permitted to reopen that decision within one year from the date of determination for any reason as is otherwise permitted at § 405.980(b)(1). The rules at § 422.138(c) allow for reopening of a favorable prior authorization decision, as modified under this final rule to include concurrent review decisions, within 4 years from the date of the initial determination or redetermination for good cause, as defined in § 405.986. In this final rule, we are modifying the MA reopening rules at § 422.616 to prohibit the reopening of a favorable inpatient hospital admission decision, including a decision subject to § 422.138(c), for good cause based on additional clinical information obtained after the initial decision.

Comment: A commenter expressed concern that this proposal may increase initial denials which could disrupt patient care and increase administrative burden. This commenter recommended that CMS provide additional policy guidance to ensure MA organizations do not increase their rate of initial denials.

Response: We appreciate the commenter's concern but believe that, overall, this modification to the reopening rules will result in more robust MA organization decision making on inpatient hospital admissions, consistent with Medicare criteria for inpatient admission, which include the requirements of § 412.3. Following implementation, we will monitor any changes that may indicate increased denials of these types of requests.

Comment: A few commenters opposed our proposal and/or expressed concern that further limiting MA organizations' discretion to reopen decisions on inpatient hospital admissions would hamper efforts to identify and correct fraud, waste, and abuse. These commenters recommended that CMS maintain the ability for MA organizations to reopen inpatient admission decisions for new and material evidence.

Response: We thank the commenters for sharing this perspective. However, we do not agree that it would hamper efforts related to identifying potential fraud and abuse, as the right to reopen for that reason remains available to MA organizations under the rules at § 405.980(b)(3).

Comment: A commenter suggested that this proposal would apply a more stringent standard on MA organizations in comparison to the Traditional Medicare program and result in penalizing plans for using prior authorization, as permitted by statute.

Response: We disagree with the commenter's concern that this change would impose a more stringent standard and would result in penalizing MA organizations for utilizing prior authorization. With the exception of the rule at § 422.138(c) and the proposed change to § 422.616, MA organizations retain the right to reopen a decision consistent with the applicable rules in part 405, subpart I, at §§ 405.980 through 405.986. We believe any variance between Traditional Medicare and the MA program in how the reopening rules are applied is fully supported by the nature of the MA program. As stated by the commenter, MA organizations are permitted to use utilization management tools such as prior authorization. Prior authorization affords MA organizations the opportunity to review the medical necessity of care prior to such care being furnished. Plans are responsible for making thorough decisions on prior authorization requests consistent with the rules at § 422.138. We acknowledged in the proposed rule that limiting the type of clinical information that may be considered new and material evidence to support reopening a favorable determination related to an inpatient hospital admission is a departure from corresponding traditional reopening policies, but reiterated that this departure was necessitated by differences in the timing of inpatient hospital admission determinations between MA and Traditional Medicare. This approach would, at times, restrict certain clinical information from being used as new and material evidence to reopen a decision that would otherwise be available in Traditional Medicare. While we strive to create and apply policies consistently between the MA program and Traditional Medicare, including by continuing to apply the inpatient admissions criteria in § 412.3 in the same manner to both programs, the programs' inherent differences require a tailored approach in this scenario that considers the timing of available clinical information. Under Traditional Medicare, an initial determination related to an inpatient

admission would only be made after a beneficiary had received the service and a claim for payment has been submitted (see § 405.920) and, therefore, generally after a beneficiary's medical record supporting that service has been fully developed. In contrast, MA enrollees may receive a favorable determination related to an inpatient hospital admission before or contemporaneously to the enrollee's receipt of services (see § 422.566(b)(3)). This means the enrollee's medical records are continuing to be updated to reflect the changing medical circumstances. Thus, it is more likely that clinical information obtained after an initial organization determination could lead to an MA organization reopening a decision for an MA enrollee than a beneficiary in Traditional Medicare, even though the inpatient admissions criteria in § 412.3 apply in the same manner to both programs. MA enrollees should be able to rely upon an approved inpatient admission determination made by the MA plan in advance of the receipt of services, or concurrently with the receipt of services, despite changing medical circumstances. Enrollees should not be concerned that an MA organization may revise or rescind an approved inpatient hospital admission due to clinical information that was not available or in existence when the provider determined the need for admission and the MA organization approved the admission.

Comment: A few commenters expressed concern related to a perception that CMS would be inserting itself into MA organization and participating provider contractual relationships. A commenter stated that the proposal would also include cases in which enrollees are unaffected, and the only issue involves the level of payment from plans to providers. This commenter suggested that such a limitation would be inconsistent with the Part C non-interference statutory clause, and that these situations are addressed through private sector negotiation.

Response: We thank the commenter for this perspective but disagree that limiting the ability to reopen an approved inpatient hospital admission for new and material evidence runs afoul of the non-interference clause at section 1854(a)(6)(B)(iii) of the Act. The proposed limitation related to reopenings does not relate to the payment arrangements negotiated between MA organizations and contract providers. Instead, what we proposed would reinforce the inpatient hospital admission rules at § 412.3(d)(1) and (3) that the coverage criteria are based on the admitting physician's expectation at the time of admission about whether the hospital care will cross two-midnights or is otherwise appropriate, as supported by the medical record. Since the physician's expectation at the time of admission is based on the clinical information known at that time as well as the documented medical record at the time of admission, any subsequent clinical information obtained after an MA organization has made its initial organization determination would not have the effect of creating a good cause reopening for new and material evidence that was not available or known at the time of the determination or decision and that may result in a different conclusion.

Comment: A commenter stated that CMS did not address the scenario where the requesting provider failed to provide an accurate or complete medical record or other pertinent information to the health plan in the first place. The commenter also stated that a plan may require the requestor to provide certain information through prompts in an electronic authorization portal and that, in some cases, that information may not be accurate or complete. Under these circumstances, pertinent information may not have been available or known at the time the MA organization made its decision. In that scenario, the commenter states that an MA organization would be left trying to either establish fraud or similar fault that the evidence considered in making the decision clearly shows on its face that an obvious error was made. The commenter believes that failing to provide an accurate or complete medical record may not rise to the level of fraud, or indicate an obvious error made at the time of the determination.

Response: We thank the commenter for this perspective but disagree that foreclosing the opportunity for an MA organization to reopen a previously approved inpatient hospital admission for new and material evidence is unduly restrictive. We believe this approach is appropriate given the inpatient hospital admission rules, coupled with the nature of the MA program and MA organizations' responsibility to make thorough decisions on pre-service requests. The inpatient hospital admission rules at § 412.3(d)(1) and (3) are clear that the coverage criteria set forth therein are based on the admitting physician's expectation at the time of admission about whether the hospital care will cross two-midnights or is otherwise appropriate, as supported by the medical record. Since the physician's expectation at the time of admission is based on the clinical information known at that time as well as the documented medical record at the time of admission, any subsequent clinical information obtained after an MA organization has made its initial organization determination would not have the effect of creating a good cause reopening on the basis of new and material evidence that was not available or known at the time of the determination or decision and that may result in a different conclusion. As part of the organization determination process, it is incumbent on the MA organization to obtain and review all relevant clinical information to make an organization determination on a request for inpatient hospital admission and to comply with requirements for basic benefits as described in § 422.101(b)(2). Any additional clinical information obtained after the initial organization determination cannot have the effect of creating a good cause reopening because the determination was made based on what was known by the physician and documented in the medical record at the time of admission. We note that whether fraud or obvious error could support the reopening of a previously approved inpatient admission would be based on the unique facts and circumstances of a given case, such as if there's evidence that pertinent clinical information was intentionally withheld in order to secure approval of an inpatient admission.

Comment: A few commenters expressed concern related to the unintended impact the proposal may create on expediting seamless care for the enrollee and stated the belief that MA organizations should be permitted to revisit the decision to approve a request once all the information is received. These commenters further noted that there are already guardrails to prevent arbitrary reopening, and that prior to finalizing this proposal, CMS should ensure this change does not interfere with MAOs' ability to enforce Medicare's reasonable and necessary standard.

Response: We thank the commenters for expressing their concerns. We do not believe this provision interferes with the proper application of the reasonable and necessary standard in section 1862(a)(1) of the Act. As noted in the proposed rule, the inpatient hospital admission rules at § 412.3(d)(1) and (3) are clear that the coverage criteria set forth therein are based on the admitting physician's expectation at the time of admission about whether the hospital care will cross two-midnights or is otherwise appropriate, as supported by the medical record. Since the physician's expectation at the time of

admission is based on the clinical information known at that time as well as the documented medical record at the time of admission, any subsequent clinical information obtained after an MA organization has made its initial organization determination would not have the effect of creating a good cause reopening on the basis of new and material evidence that was not available or known at the time of the determination or decision and that may result in a different conclusion. Thus, we disagree with the commenter's belief that the MA organization should be allowed to revisit the admission decision based on information received at a later time. As part of the organization determination process, it is incumbent on the MA organization to obtain and review all relevant clinical information to make an organization determination on a request for inpatient hospital admission and to comply with requirements for basic benefits as described in § 422.101(b)(2). The intersection of these requirements ensures that MA organization decisions are made consistent with the standards related to medical necessity.

Comment: A commenter recommended that CMS continue to allow changes to existing prior authorizations when such changes do not result in increased financial responsibility for the enrollee. The commenter further suggested if changes to a prior authorization are appropriate as additional information becomes available, those changes should continue to be allowed if the enrollee is held harmless. The commenter also stated that changes to the approved level of care should not require additional enrollee notification or be subject to enrollee appeal unless the enrollee faces higher out of pocket cost due to the change.

Response: Under the existing prior authorization rules at § 422.138(c), if an MA organization approves the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. In this final rule, we are modifying the rules at §§ 422.616 and 422.138(c) to state that an inpatient hospital admission that was approved on a pre-service or prior authorization basis or through a concurrent determination cannot be reopened for good cause on the basis of new and material evidence. The change in this rule to restrict reopening for good cause on the basis of new and material evidence is limited to approved hospital inpatient admissions. So, for example, if there's good cause under the rules at § 405.986 for an MA plan to reopen a previously approved service that does not involve an inpatient hospital admission, the plan retains the authority to do so.

We disagree with the commenter's suggestion that level of care changes should not require notice to the enrollee unless the enrollee faces higher out of pocket costs due to the change and that prior authorization approvals that do not impact an enrollee's financial responsibility should be permitted. As we discuss elsewhere in this rule in the context of the provision related to when notice of a decision is required, decisions related to changes in level of care are organization determinations that affect enrollee services and warrant notice and an opportunity to appeal.

Comment: A commenter requested that CMS clarify that this change would not apply to situations where an authorization was previously denied but the MA plan received additional information that may subsequently lead to an approval.

Response: We thank the commenter for requesting this clarification. The change we proposed to the reopening rules at § 422.616 to prohibit an MA organization from reopening a decision for new and material evidence applies exclusively to any approved prior authorization or pre-service approval on an inpatient hospital admission.

Comment: A few commenters urged CMS to consider the impact of MA organizations reopening prior authorizations on approved physician services. A commenter noted that, under this proposal, enrollees and their contract providers will still have no CMS administrative remedy to appeal under part 422, subpart M, any denials that occur after claim submission, and given the growth in post-service claim denials and the tactics to circumvent CMS rules governing coverage determinations by labeling them as payment policies, CMS should strengthen enrollee and provider appeal rights that occur after claim submission. This commenter was concerned that without further CMS intervention, many types of denials for coverage and payment that occur after the claim will continue to be invisible to CMS and affected parties will have no appealable interest to remedy them. Some commenters recommended that CMS set further parameters around post-claim audit activity for other types of services and urged CMS to curtail the use of post-payment audit schemes that create unnecessary barriers and increases administrative costs.

Response: We appreciate this feedback, but as we did not propose to modify existing post-payment review activities or appeal rights for contract providers these recommendations are outside the scope of this rulemaking. Payment disputes between MA organizations and contract providers are subject to the plan's internal dispute resolution process. With respect to reevaluation of prior authorizations for services provided by physicians, these reviews are subject to the rules at §§ 422.138(c) and 422.616. We will take the commenter's concerns into consideration for potential future rulemaking.

Comment: A commenter recommended revising the remainder of § 422.138 to reference both concurrent and retrospective reviews. This commenter noted that paragraph (b) sets out the appropriate purposes of prior authorizations, and the commenter does not believe there is any policy rationale for permitting other pre-payment coverage review processes (that is, concurrent and retrospective reviews) to be conducted for purposes other than those set forth in paragraph (b). They also suggested paragraph (a) be revised to reflect the section's applicability to the full range of pre-payment coverage determinations (prior authorizations, concurrent reviews, and retrospective reviews).

Response: We appreciate the commenter's remarks, but note that referencing retrospective reviews in § 422.138, as the commenter suggests, would be in conflict with our position that a retrospective review decision is an organization determination that relates solely to payment. The rules in § 422.138(c), related to prior authorization and pre-service approval of items and services, as modified under this final rule to include concurrent review, are designed to address circumstances where an MA organization would use information that is received after the initial approval as a means to reopen and overturn the approval decision. As a retrospective review decision (whether made unsolicited or in response to a request) is an initial decision made by a plan on whether to pay for services already furnished, we do not believe there is similar concern for plans reopening these types of decisions since, as a practical matter, the plan would already have access to medical records for the entire hospital stay and would be less prone to reopen the retrospective decision later. We, therefore, do not

believe it necessary to add a reference to retrospective review decisions to the rules in § 422.138(c).

After consideration of the comments received, we are finalizing the amendment to § 422.616(a) to state that the reopening provisions are subject to the rules at § 422.138(c) and finalizing the addition of new paragraph (e) to § 422.616, placing a limitation on reopening determinations related to favorable inpatient hospital admissions without modification. In finalizing new paragraph (e) to § 422.616, we are omitting the unitalicized heading that was included in the proposed rule. We are also finalizing the technical amendment to the parenthetical text in paragraph (c) of § 422.138 to add a cross reference to the rules at § 422.616 with a minor modification to fix an editorial error that was inadvertently made in the proposed regulation text revision (specifically, reinstating ''or'' between ''prior authorization'' and ''pre-service determination''.

Lastly, in providing feedback to our proposals, commenters also raised concerns or provided recommendations related to the following:

- A commenter urged CMS create a provider-specific electronic form for reporting suspected MA violations to CMS.
- A commenter recommended that we extend the timeframe for filing an appeal to 120 days to be consistent with Traditional Medicare.
- A commenter stated the main problem that remains to be addressed is that there is no avenue for enrollees to appeal their inpatient denials via subpart M that does not require some action from the MA organization. They suggested enrollees or their advocates be able to file an appeal directly to the IRE.
- A commenter strongly urged CMS to prohibit MA organizations from applying arbitrary, short prior-authorization periods that lead to time-consuming reauthorizations, which often disrupt care, and recommended clarity and consistency on the course of treatment.
- A commenter requested that CMS ensure that providers are only required to submit new information, if applicable.
- A commenter recommended CMS clarify content requirements for adverse organization determinations continue to apply to partially adverse organization determinations.

We appreciate the feedback provided by commenters. We note, though, that the items outlined previously were outside the scope of the rulemaking.

B. Clarifying the Definition of ''County'' (§ 422.116)

Network adequacy of MA organizations is assessed by CMS at the county level, including county-equivalents, across all geographic areas in the United States and its territories. CMS uses the county level for purposes of determining the number and type of providers and facilities, based on time and distance, with which an MA organization must contract to ensure there is adequate access to Parts A and B services for beneficiaries. The minimum number of providers and facilities, provider specialty type, and time and distance requirements are codified at § 422.116(d) and (e). CMS's longstanding policy, interpretation, and application of existing network adequacy regulations uses the term ''county'' to mean the areas designated by the Census Bureau as the primary political and administrative division of States. The Census Bureau also considers certain geographic areas as county-equivalents. County-equivalents include, but are not limited to, boroughs, certain designated cities, parishes, municipalities and the District of Columbia. CMS uses the Census Bureau's designation of county and county-equivalent in establishing network adequacy standards to ensure consistency in the application of CMS's network adequacy requirements across the country.

For purposes of determining network adequacy, CMS proposed to codify its longstanding policy of treating county equivalents the same as counties for network adequacy determination purposes by defining ''county'' in § 422.116. In § 422.116, we proposed to create a new paragraph (a)(1) and redesignate the current paragraphs (a)(1) through (4) as paragraphs (a)(2) through (5). We also proposed to define ''county'' in new paragraph (a)(1) as the primary political and administrative division of most States and includes functionally equivalent divisions called ''county equivalents'' as recognized by the United States Census Bureau (for economic census purposes).

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

These proposals were discussed in sections III.E. and III.N.1 of the proposed rule (89 FR 99384 and 89 FR 99424, respectively) and are being reorganized and finalized, in section III.B. of this final rule.

Comment: Several commenters supported CMS's proposal to modify the definition of service area in § 422.2, to align with our proposal to include a definition of county in § 422.116 that includes ''county-equivalent'' for network adequacy purposes. Commenters noted that these changes would promote consistency, provide clarity regarding the definition of service area, improve access to care, and ensure that information regarding plan networks is accurate for enrollees making decisions about their coverage.

A commenter, who supported CMS's proposals, requested clarification on how CMS intends to address flexibility in meeting network adequacy standards within the updated service area definition, particularly for plans operating in rural and underserved areas.

Another commenter requested that CMS provide timely updated guidance regarding these changes and allow organizations time to ensure that they can close any network adequacy gaps that would result in areas such as a ''county-equivalent'' Planning Region, which may not fully overlap with a previously mapped county.

Response: We thank the commenters for their support of our proposals. We note that CMS currently uses counties and county-equivalents to establish network adequacy standards and to apply the network adequacy requirements. The changes herein serve to clarify, in our regulations, that CMS uses the Census Bureau's designation of county and county-equivalent in establishing network adequacy standards. Therefore, we agree with commenters that this clarification would promote consistency. It does not impose any new requirements and therefore should not require additional guidance. Under the current rules, and the changes we are finalizing, organizations will continue to be able to use the exception request process outlined at § 422.116(f) in any service area, including in rural and underserved counties and county-equivalents, where they are unable to satisfy CMS network

adequacy requirements. We agree that these proposals will allow us to continue to ensure consistency in CMS's application of network adequacy standards throughout MA organizations' existing and future service areas.

Comment: Some commenters opposed these proposals. These commenters noted that they did not agree that CMS should treat a county equivalent the same as a county for network adequacy purposes because it would increase the number of geographic areas throughout the country that would be subject to network standards and that it could possibly trigger the need for additional exception requests to be submitted as part of network adequacy reviews.

Response: We reiterate that the proposed policy was a codification of CMS's longstanding policy to use the term ''county'' to mean the areas designated by the Census Bureau (that is, the primary political and administrative division of States, including county-equivalents which include, but are not limited to, boroughs, certain designated cities, parishes, municipalities and the District of Columbia), in establishing network adequacy standards. Therefore, the codification of CMS's established policy of treating a county-equivalent the same as a county for network adequacy purposes, by defining ''county'' in § 422.116, will not result in additional burden for organizations, additional standards for network adequacy determination purposes, or additional exception request submission requirements.

After reviewing and considering the public comments received on these proposals, CMS is finalizing its proposals to modify the definition of service area in § 422.2, and to add a definition of county in § 422.116 that includes county-equivalent for network adequacy purposes. The finalization of our proposals clarifies our longstanding policy and interpretation of the term ''county'' for network adequacy determination purposes.

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

Section 1852(a)(3)(D)(ii)(I) of the Act requires that an item or service offered as an SSBCI have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. The April 23, 2024 final rule titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE)'' (the ''April 2024 final rule'') (89 FR 30448) finalized requirements at § 422.102(f)(3) that, by the date on which it submits its bid to CMS, an MA organization must establish a bibliography of relevant acceptable evidence that an item or service offered as an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. In the April 2024 final rule, we also codified at § 422.102(f)(5) that CMS may decline to approve an MA organization's bid, if CMS determines that the MA organization has not demonstrated, through relevant acceptable evidence, that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting. In addition, in the April 2024 final rule (89 FR 30448), we modified and strengthened the requirements in § 422.2267(e)(34) for the SSBCI disclaimer that MA organizations that offer SSBCI must use whenever SSBCI are mentioned. Specifically, we required that the SSBCI disclaimer list the relevant chronic condition(s) the enrollee must have to be eligible for the SSBCI offered by the MA organization. We also finalized specific font and reading pace parameters for the SSBCI disclaimer in print, television, online, social media, radio, other voice-based ads, and outdoor advertising (including billboards). Finally, we required that MA organizations include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI. These requirements further help to ensure that the marketing of and communication about these benefits is not misleading or potentially confusing to enrollees who rely on these materials to make enrollment decisions.

Section 1852(a)(3)(A) of the Act provides CMS the authority to approve supplemental benefits. Supplemental benefits must meet the regulatory and statutory requirements for approval, including that the benefits may not be approved if the agency finds that including such supplemental benefits would substantially discourage enrollment by Medicare+Choice (now Medicare Advantage) eligible individuals with the organization. Further, per section 1854(a)(5)(C) of the Act, CMS is not obligated to accept any or every bid submitted by an MA organization. Based on our experience reviewing, approving, and denying bid proposals throughout the years, we relied upon these authorities to propose in regulation a non-exhaustive list of non-primarily health related items or services that do not meet the standard of having a reasonable expectation of improving or maintaining the health or overall function of the enrollee standard as described in section 1852(a)(3)(D)(ii)(I) of the Act and at CMS regulations at § 422.102(f)(1)(ii). We believe that codifying a non-exhaustive list of examples of items or services that do not meet these standards will provide transparency and greater certainty for MA organizations and enrollees about the rules that govern these benefits.

As discussed in the proposed rule we proposed to codify a non-exhaustive list of nonprimarily health related items or services that do not have a reasonable expectation of improving or maintaining the health of a chronically ill enrollee and therefore cannot be offered as SSBCI.

Those items include—

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

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

Regarding cosmetic services, CMS explained in previous guidance (see Health Plan Management System (HPMS) memorandum ''Final Contract Year (CY) 2025 Standards for Part C Benefits, Bid Review and Evaluation,'' dated May 6, 2024, pp. 30–31) that coverage for procedures that are cosmetic in nature are not permitted to be offered as SSBCI because these benefits do not meet the statutory requirement of a ''reasonable expectation of improving or maintaining the health or overall function of the enrollee.'' Some plans have proposed to offer cosmetic services for aesthetic purposes only, such as botulinum toxin injections for lines and wrinkles, in their bids. CMS has previously disapproved these proposals during its bid review because purely cosmetic procedures are not health related and

thus cannot be permitted as a supplemental benefit.

As explained in more detail in the proposed rule at 89 FR 99391, some cosmetic procedures may be acceptable to be offered as an SSBCI benefit if used to treat medical conditions that affect health or overall function and would not be considered purely cosmetic in nature. For example, the use of botulinum toxin injections is acceptable when treating medical conditions such as an overactive bladder, headache prevention in adults with chronic migraine, and increased muscle stiffness in adults with limb spasticity.

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

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

CMS also does not consider hospital indemnity insurance to meet the definition of a supplemental benefit. MA organizations offering supplemental benefits must incur a non-zero direct medical cost, except that in the case of an SSBCI that is not primarily health related the MA organization may instead incur a non-zero, direct non-administrative cost (§ 422.100(c)(2)(ii)(B)). Reductions in cost sharing fit into the definition of a supplemental benefit as they are increases in the MA organization's share of the overall payment for the covered health care item or service. However, payment for hospital indemnity insurance premiums would not fit this definition because an MA organization paying for separate, third-party insurance for the enrollee does not incur a direct cost on behalf of the enrollee. Rather, it shifts payment for medical costs to another payer. See also Contract Year 2026 proposed rule at 89 FR 99392 for further discussion.

Finally, CMS has received and declined proposals from MA organizations to offer broad membership programs, inclusive of multiple unrelated services and discounts, such as Amazon Prime, Costco, and others, as SSBCI. A generic membership is not permissible as SSBCI because it is not limited to items or services that have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. That is not to say that an MA organization cannot contract with any of these retailers to offer covered benefits in some capacity (for example, benefits administered via a restricted debit card). However, a generic membership that would include items or services that do not have a reasonable expectation of improving or maintaining the health or overall function of the enrollee and no mechanism to ensure that enrollees receive only covered benefits is not compliant with CMS rules regarding supplemental benefits and thus not allowable as SSBCI. Additionally, we note the statutory prohibition against MA organizations offering cash or monetary rebates (section 1851(h)(4)(A) of the Act).

CMS proposed to codify the examples discussed here as items and services that cannot be offered as SSBCI at § 422.102(f)(1)(iii) and solicited comment on all aspects of this proposal. CMS also solicited comment on other items and services not listed here that would be appropriate to include in the list of items that may not be offered as SSBCI and stated that we may consider finalizing revisions to the proposed policy in response to comments received.

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

This final rule will codify and clarify existing guidance and practices, including the practice of providing technical assistance during bid review and is not expected to have additional impact above current operating expenses for MA organizations. This final rule will not impose any new collection of information requirements.

CMS thanks commenters for their input to help inform our final rule on items that are not allowable as SSBCI. CMS received the following comments on this proposal, and our responses follow.

Comment: Commenters were largely supportive of CMS codifying the proposed list of items that are not allowable as SSBCI. MA plans stated that knowing what proposed SSBCI benefits CMS will not accept ahead of time helps streamline the bid submission and review processes.

Response: We agree that codifying this list will be helpful to MA plans in submitting bids to CMS and serve to improve the efficiency of the bid submission and review process.

Comment: Some commenters requested that CMS also codify a list of allowable SSBCI. Some commenters requested that CMS update sub-regulatory guidance (for example, chapter 4 of the Medicare Managed Care Manual) to assist plans. These commenters stated that such guidance would be helpful for plans as they plan and prepare their annual bids.

Response: We thank commenters for the suggestion and will consider codifying a non-exhaustive list of allowable SSBCI in regulation in the future. In the interim, we remind commenters that a discussion of examples of allowable SSBCI was discussed 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'' (herein after referred to as the June 2020 final rule) (85 FR 33801).

Comment: Some commenters requested that CMS create a process that allows plans to solicit feedback from CMS on allowable SSBCI, prior to bid filing.

Response: CMS will consider this suggestion for the future. CMS also reminds plans that they may submit questions or solicit feedback concerning

specific benefits being considered before the bid deadline.

Comment: A commenter requested that CMS explain what is meant by ''broad membership-type programs inclusive of multiple unrelated services and discounts'' and to further explain what inclusive services are non-allowable as SSBCI.

Response: As discussed in the proposed rule, a generic membership (for example, Amazon Prime, Costco, and others) is not permissible as SSBCI because it cannot be limited to items or services that have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. For example, a Costco membership could include services such as discounts for non-covered items and cash bonuses, none of which are acceptable as a supplemental benefit per CMS rules. Further, plans submit specific, proposed supplemental benefits in their annual bids for CMS to review and approve each year. A plan cannot propose to offer supplemental benefits that are generic or non-specific in nature as part of this submission. A generic membership could include coverage and discounts for items not specified in the plan's benefit submission, which is prohibited. These memberships also may include items that CMS would not consider an approvable benefit or a benefit that is disallowed (for example, streaming services, discounted travel bookings, discounts to fast food chains, etc.). Finally, section 1851(h)(4)(A) of the Act prohibits plans from giving enrollees cash. Many of these memberships include cash back benefits, which are strictly prohibited by statute. For these reasons, these generic memberships cannot be offered as SSBCI.

Comment: A commenter expressed concern that the requirement for SSBCI to have ''a reasonable expectation of improving or maintaining the health of a chronically ill enrollee'' is too vague, specifically citing a lack of clarity on whether items such as food and non-medical adaptive equipment (for example, grabbers, raised toilet seats, door levers, motion detecting interior lights for hallways) would be allowable. The commenter recommended CMS reconsider the language in this section to add clarity and specificity so that non-medical items and services that help frail, elderly beneficiaries are not excluded from coverage.

Response: Section 1852(a)(3)(D) of the Act explicitly requires SSBCI to have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. We note that the April 24, 2019, HPMS memo titled ''Implementing Supplemental Benefits for Chronically Ill Enrollees,'' [54] and the June 2020 final rule (85 FR 33801) discuss these items. As mentioned in the proposed rule and in the discussion above, the 2019 HPMS memo stated that MA organizations may offer food and produce to assist chronically ill enrollees in meeting nutritional needs assuming all requirements for SSBCI under § 422.102(f) are met, and that such items may include items such as (but not limited to) produce, frozen foods, and canned goods.

Additionally, also noted in the 2019 HPMS memo, certain home structural modifications that may assist in the chronically ill enrollee's overall function, health, or mobility may be covered as SSBCI if those items and services have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee (such as, widening of hallways or doorways, permanent mobility ramps, easy use doorknobs and faucets). Regarding grabbers, raised toilet seats, door levers, and motion detecting interior lights for hallways, CMS considers these items primarily health related per CMS requirements at 42 CFR 422.100(c)(2)(ii) and permissible as a standard supplemental benefit. CMS has approved bid proposals that include these items in prior years.

Comment: Several commenters requested more clarity on food and nutrition specifically. A commenter requested that CMS further clarify how plans may provide food to prevent and manage diet-related diseases. Other commenters asked CMS to clarify how plans may provide ''Food is Medicine'' [55] within the parameters of supplemental benefits requirements.

Response: We thank commenters for their input. As outlined above and noted in the proposed rule, CMS has stated in previous guidance that plans may offer food and produce to assist chronically ill enrollees in meeting nutritional needs as SSBCI.[56] A food benefit helps maintain the health and overall function of a chronically ill enrollee, and therefore is an appropriate SSBCI, when the food assists in meeting the nutritional needs of the beneficiary.

Similarly, CMS would not consider non-healthy food—that is food that does not assist in meeting the nutritional needs of a chronically ill enrollee—as an appropriate SSBCI. In response to comments requesting further clarity on this subject, CMS is finalizing a revision to the proposal to add ''non-healthy food'' to the non-exhaustive list of items that are not allowable as SSBCI. CMS is not providing a list of specific foods that may or may not be considered ''non-healthy food.'' Rather, CMS reiterates its longstanding guidance regarding food as an allowable SSBCI, specifically, that plans may offer food and produce to assist chronically ill enrollees in meeting nutritional needs as SSBCI, assuming all requirements for SSBCI under § 422.102(f) are met. Plans should apply this standard to determine what is allowable and design their food benefits to ensure that those benefits assist in meeting the nutritional needs of a chronically ill enrollee.

CMS regulations at 42 CFR 422.102(f)(3) require MA plans to establish a written bibliography of relevant acceptable evidence concerning the impact that any item or service included as SSBCI in its bid has on the health or overall function of its recipient. If a plan were to submit a bid proposal that includes non-healthy food as SSBCI, CMS may ask the plan to provide a bibliography of evidence for how the proposed food benefit assists in meeting the nutritional needs of a chronically ill enrollee. If necessary, in these instances, CMS could give the plan the opportunity to propose limitations on the proposed benefit, or otherwise modify their bid proposal. As noted previously, our 2019 HPMS memo stated that MA organizations may offer food and produce to assist chronically ill enrollees in meeting nutritional needs and that plans may include items such as (but not limited to) produce, frozen foods, and canned goods. In adding ''non-healthy food'' to the list of items that are not allowable as SSBCI, CMS is not departing from that 2019 guidance. Non-healthy food does not have a reasonable expectation of improving or maintaining the health or overall function of an enrollees, and therefore, may not be offered as an SSBCI.

Based on the comments received, we are finalizing the provisions at § 422.102(f)(1)(iii) as proposed, with one modification to add ''non-healthy food'' as an example of an item that is not allowable as SSBCI at § 422.102(f)(1)(iii)(I).

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

[55] *https://odphp.health.gov/foodismedicine.*

[56] See HPMS Memo issues on April 24, 2019, titled ''Implementing Supplemental Benefit for Chronically Ill Enrollee'': *https://www.cms.gov/medicare/health-plans/healthplansgeninfo/downloads/supplemental_benefits_chronically_ill_hpms_042419.pdf.*

D. Risk Adjustment Data Updates

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

The current regulation at 42 CFR 422.2 defines Hierarchical Condition Categories (HCC) as ''disease groupings consisting of disease codes (currently *ICD–9–CM* codes) that predict average healthcare spending. HCCs represent the disease component of the enrollee risk score that are applied to MA payments.'' HCCs are used in risk adjustment model calibrations, in risk score calculations to determine individual risk scores, and in § 422.311 as part of describing risk adjustment data validation audit reports and the voluntary dispute resolution process available for MA organizations to dispute errors identified during those audits. The current definition at § 422.2 references the *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM),* which was the standard medical data code set HHS adopted for health conditions from October 16, 2002, to September 30, 2015 (45 CFR 162.1002(a)(1) and 45 CFR 162.1002(b)(1)). For the period starting on October 1, 2015, HHS adopted an updated version of the ICD, *ICD–10–CM,* as the standard medical data code set for health conditions (45 CFR 162.1002(c)(2)). Valid ICD diagnosis codes—referred to as disease codes in the current HCC definition—are only those from the ICD version that is in place during a respective year. For example, for dates of service starting on October 1, 2015, only valid *ICD–10–CM* codes would have been included in HCCs, since *ICD–9–CM* codes were no longer in use.

CMS proposed to remove the reference to a specific version of the ICD from the definition of HCC in § 422.2, while maintaining a reference to the ICD in general to keep the definition in § 422.2 current as newer versions of the ICD become available and are adopted by the Secretary and updates are made to the HCCs in model calibrations to reflect newer versions of the ICD. The ICD is updated as advances are made in healthcare, and as new editions are issued, the code set standard adopted by HHS may change to use the most current edition. See section 1173(c) of the Act for the Secretary's authority to adopt code sets, as well as 45 CFR part 162 (specifically, §§ 162.1000 through 162.1011) for the diagnosis code sets adopted for transactions under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[57] We also proposed to substitute the terms ''disease codes'' with ''diagnosis codes'' and ''disease groupings'' with ''diagnosis groupings'' to be consistent with ICD terminology.

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

We received the following comments on this proposal, and our responses follow:

Comment: A few commenters expressed support for the proposal to remove the reference to a specific version of the ICD, while maintaining a reference to the ICD in general, and for substituting the terms ''disease codes'' with ''diagnosis codes'' and ''disease groupings'' with ''diagnosis groupings'' to be consistent with ICD terminology, in the definition of HCC in § 422.2, with an additional commenter stating that it did not oppose the proposal.

Response: We thank the commenters for their support and for their feedback.

Comment: A commenter opposed the proposed change, stating that CMS has adequate flexibility to address risk adjustment updates through the established rulemaking process, including changes to the use of HCCs, diagnosis codes, and related definitions. Further, the commenter is concerned that removing the reference to a specific version of the ICD and substituting terms such as ''disease codes'' with ''diagnosis codes'' could allow CMS to implement future modifications to the risk adjustment model without undergoing the full rulemaking process. The commenter further stated that the introduction of broad language and new definitions could create unnecessary disruption and uncertainty in the program, and result in variability in interpretation and implementation, increasing administrative complexity for plans.

Response: Thank you for the comment. Removing the reference to a specific version of the ICD from the HCC definition in regulation does not alter the risk adjustment methodology or modify the risk adjustment models; further, as we stated, it does not change the meaning of the term HCC or how HCCs are used, therefore we do not believe this technical update will result in uncertainty in interpretation or implementation. CMS updates the risk adjustment methodology for payment in accordance with section 1853(b)(2) of the Act, and § 422.312, which require that CMS annually provide notice of planned changes in the Medicare Advantage (MA) capitation rate methodology and risk adjustment methodology—including the risk and other factors to be used in adjusting rates under § 422.308 for payments for months in that year—and provide the public an opportunity to comment on the proposed changes. As per statute, CMS publishes the Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (the Advance Notice) no fewer than 60 days before the publication of the Announcement of MA Capitation Rates and Part C and Part D Payment Policies (the Rate Announcement), where we finalize our policies for the upcoming payment year, providing a minimum 30-day period for public comment on the changes proposed in the Advance Notice.

After consideration of the comments received, CMS is finalizing the change to the HCC definition at § 422.2 as proposed.

2. Clarifying the Obligation of PACE Organizations To Submit Risk Adjustment Data (§ 460.180(b))

Section 1894(d)(1) of the Act provides that CMS shall make payments to PACE organizations in the same manner as MA organizations. To do so, PACE organizations must submit data in accordance with the risk adjustment data requirements for MA organizations at § 422.310. Codified at 42 CFR 460.200, PACE organizations are required to collect data, maintain records, and submit reports as required by CMS to establish payment rates. CMS proposed to codify the longstanding practice of requiring the collection and mandatory submission of risk adjustment data by PACE organizations by adding a new paragraph at 42 CFR 460.180(b)(3) that requires the data PACE organizations submit be in

[57] Public Law 104–191, 110 Stat. 1936.

accordance with risk adjustment data submission requirements in § 422.310.

As stated in the proposed rule, the new paragraph CMS proposed adding to § 460.180(b) codifies longstanding practice; it does not change existing reporting requirements set forth and approved under OMB 0938–1152 (CMS–10340) and OMB 0938–0878 (CMS–10062), nor does it make any changes to payment for PACE organizations. For this reason, CMS does not expect that this regulatory change will result in additional costs or savings.

We received the following comments on this proposal, and our responses follow:

Comment: A few commenters either expressed general support for or did not oppose the proposal. A commenter acknowledged that codifying this existing practice should not create any new requirements or make changes to payment for PACE programs but asked that CMS maintain consideration for administrative burden any additional data collection efforts place on providers.

Response: We appreciate the commenters' support and thank them for their comments.

After consideration of the comments received, CMS is finalizing the change to § 460.180(b) as proposed.

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

Currently, we require the submission of risk adjustment data from organizations that operate Cost plans under section 1876 of the Act in the same manner as MA organizations. Codified at 42 CFR 417.486(a), the contract of section 1876 Cost plans must provide that the plan agrees to submit to CMS: (1) all financial information required under subpart O of part 417 and for final settlement; and (2) any other information necessary for the administration or evaluation of the Medicare program.

CMS proposed to amend § 417.486(a) to add a new § 417.486(a)(3) to codify the longstanding practice of requiring the collection and mandatory submission of risk adjustment data as specified in 42 CFR 422.310 by 1876 Cost plans. This change to § 417.486(a) codifies longstanding practice; it does not change existing reporting requirements set forth and approved in OMB 0938–1152 (CMS–10340), nor does it make any changes to payment for Cost plans. For this reason, CMS does not expect that this regulatory change will result in additional costs or savings.

We received one comment on this proposal. The commenter did not oppose the proposal and did not provide any specific further comment. We appreciate the comment.

After consideration of this comment, CMS is finalizing the change to § 417.486(a) as proposed.

E. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.166 and 423.186)

1. Introduction

CMS develops and publicly posts a 5-star rating system for Part C,[58] more commonly referred to as Medicare Advantage (MA), and Part D plans as part of its responsibility to disseminate comparative information, including information about quality, to beneficiaries under sections 1851(d) and 1860D–1(c) of the Act. The Part C and Part D Star Ratings system is used to determine quality bonus payment (QBP) ratings for MA plans under section 1853(o) of the Act and the amount of MA beneficiary rebates under section 1854(b) of the Act. We use multiple data sources based on the collection of different types of quality data under section 1852(e) of the Act to measure quality and performance of contracts, such as CMS administrative data, surveys of enrollees, and information provided directly from health and drug plans. CMS regulations, including §§ 417.472(j) and (k), 422.152(b), 423.153(c), and 423.156, require plans to report on quality improvement and quality assurance and to provide data which help beneficiaries compare plans. The methodology for the Star Ratings system for the MA/Part C and Part D programs is codified at §§ 422.160 through 422.166 and 423.180 through 423.186, respectively, and we have specified the measures used in setting Star Ratings through rulemaking. In addition, the cost plan regulation at § 417.472(k) requires cost contracts to be subject to the parts 422 and 423 Medicare Advantage and Part D Prescription Drug Program Quality Rating System. (83 FR 16526 and 16527). As a result, the regulatory change finalized 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 [59] evolves over time to increase the health and wellbeing of enrollees. In the Contract Year 2026 proposed rule, we proposed to update the Breast Cancer Screening (Part C) measure by expanding the age range to align with updated clinical guidelines. In addition, we proposed other policies to amend the Part C and Part D Star Ratings but are not addressing those proposals in this final rule; those other proposals may be addressed in a future rule.

2. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184)

The regulations at §§ 422.164 and 423.184 specify the criteria and procedures for adding, updating, and removing measures for the Part C and D Star Ratings program. In the ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' final rule which appeared in the **Federal Register** on April 16, 2018 (83 FR 16532), we stated we are committed to continuing to improve the Part C and Part D Star Ratings system and anticipated that over time measures would be added, updated, and removed. We also specified at §§ 422.164(d) and 423.184(d) rules for measure updates based on whether they are substantive or non-substantive. The regulations, at paragraph (d)(1), list examples of non-substantive updates. (See also 83 FR 16534 through16537.) Due to the regular updates and revisions made to measures, CMS does not codify a list in regulation text of the measures (and their specifications) adopted for the Part C and Part D Star Ratings program. CMS lists the measures used for the Star Ratings each year in the Medicare Part C & D Star Ratings Technical Notes or similar guidance issued with publication of the Star Ratings. In the Contract Year 2026 proposed rule, CMS proposed to update the Breast Cancer Screening (Part C) measure for performance periods beginning on or after January 1, 2026.

We are committed to continuing to improve the Part C and Part D Star Ratings system by focusing on improving the health and wellbeing of enrollees. Consistent with §§ 422.164(c)(1) and 423.184(c)(1), we continue to review measures that are nationally endorsed and in alignment with the private sector. For example, we regularly review measures developed by the National Committee for Quality Assurance (NCQA) and Pharmacy Quality Alliance (PQA).

[58] We generally use ''Part C'' to refer to the quality measures and ratings system that apply to MA plans and cost plans.

[59] *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

3. Updating Measures

a. Breast Cancer Screening (Part C)

CMS proposed a substantive update to the existing Breast Cancer Screening measure because the measure steward, NCQA, updated the measure as a result of changes in the applicable clinical guidance. In April 2024, the U.S. Preventive Services Task Force (USPSTF) issued final updated guidance for the age at which breast cancer screenings should begin.[60] Subsequently, NCQA announced their intention to update their breast cancer screening measure for measurement year 2025 to include biennial mammography screening for women aged 40–74 years at average risk of breast cancer (see *https://www.ncqa.org/blog/updates-to-breast-cancer-screening-age-range-for-hedis-my-2025/*). CMS proposed to expand the age range for the Breast Cancer Screening measure to women aged 40–49, for an updated age range of 40–74, for the 2027 and subsequent measurement years. The expanded age range for this screening measure significantly increases the size of the population covered by this measure and is therefore a substantive measure specification change within the scope of § 422.164(d)(2). The legacy measure with the narrower age range of 50–74 years will remain available and used in Star Ratings until the updated measure has been on the display page for two years and has been adopted through rulemaking. For measures such as this, NCQA requires plans to submit the data as the total rate and rates for each age stratification so data will be available to calculate the legacy measure rate until the expanded rate is adopted through rulemaking for the Star Ratings. We solicited comments on adding this updated measure to the 2029 Star Ratings program.

Comment: There was unanimous support among commenters on this provision for expanding the age range for the Breast Cancer Screening measure.

Response: CMS thanks the commenters for their support of our proposal to expand the age range for this measure beginning with the 2029 Star Ratings.

Comment: A few commenters suggested expanding the measure from biennial screening to annual and to continue screening until comorbid conditions limit life expectancy. Another commenter suggested additional screening methods for those at high risk. A couple of commenters suggested that this change would disproportionately impact plans that serve, for example, more disabled and Institutional Special Needs Plan enrollees.

Response: Medicare enrollees should work with their providers and plans to determine the frequency of breast cancer screenings and whether they should continue past age 74 given their individual circumstances, as we know that early detection provides more treatment options to support the health and wellbeing of Medicare enrollees. The Breast Cancer Screening measure excludes Medicare enrollees 66 years of age and older who are enrolled in an Institutional Special Needs Plan or living long-term in an institution since these individuals have difficulty in accessing mammograms, and ultrasounds, as an alternative, are not currently recommended in the USPSTF guidelines. We have shared all of these comments with NCQA as they consider making updates to the measure in the future.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing adding the updated Breast Cancer Screening (Part C) measure to the 2029 Star Ratings. The updated measure will be on the display page for the 2027 and 2028 Star Ratings prior to being included in the 2029 Star Ratings.

Table 2 summarizes the updated Breast Cancer Screening 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, Stars 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 III.C.E.2. of this final rule, CMS does not codify a list of the specific measures for the Part C and Part D Quality Rating System in regulation text; doing so would be unnecessarily lengthy and cumbersome due to the relative regularity with which measure specifications are updated.

TABLE 2—SUMMARY OF REVISED INDIVIDUAL STAR RATING MEASURE FOR PERFORMANCE PERIODS BEGINNING ON 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								
Breast Cancer Screening.	Percent of female plan members aged 40–74 who had a mammogram during the past 2 years.	Staying Healthy: Screenings, Tests and Vaccines.	Process Measure Weight of 1.	HEDIS ...	The calendar year 2 years prior to the Star Ratings year.	00093–02–C–PARTC.	Clustering	MA–PD and MA-only.

[60] *https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening#bcei-recommendation-title-area.*

IV. Improving Experiences for Dually Eligible Enrollees

A. Member ID Cards, Health Risk Assessments, and Individualized Care Plans (§§ 422.101, 422.2267, 423.2267)

Dually eligible individuals face fragmentation in many parts of the health care system, including their experiences as enrollees of Medicare and Medicaid managed care plans. One way in which we seek to address such fragmentation is through policies that integrate care for dually eligible individuals. ''Integrated care'' refers to delivery system and financing approaches that (1) maximize person-centered coordination of Medicare and Medicaid services; (2) mitigate cost-shifting incentives between the two programs; and (3) create a seamless experience for dually eligible individuals.

In recent years, we have advanced integrated care by—

- Incorporating features of the Medicare-Medicaid Financial Alignment Initiative's (FAI) Medicare-Medicaid Plans (MMPs) into dual eligible special needs plan (D–SNP) requirements, including enrollee participation in plan governance, screening for social risk factors in health risk assessments (HRAs) (which applies to all SNPs), integrated enrollee materials, and mechanisms for joint Federal-State oversight;
- Implementing provisions of the Bipartisan Budget Act of 2018 to unify appeals and grievance processes across Medicare and Medicaid; and
- Increasing opportunities for enrollment in D–SNPs with aligned Medicaid managed care plans operated by the same parent organization.

However, there remain aspects of care for dually eligible individuals that can be misaligned, confusing, or duplicative even when a dually eligible individual is enrolled in Medicare and Medicaid managed care plans operated by the same parent organization.

We proposed to establish new Federal requirements for D–SNPs that are applicable integrated plans (AIPs) to: (1) have integrated member identification (ID) cards that serve as the ID cards for both the Medicare and Medicaid plans in which an enrollee is enrolled; and (2) conduct an integrated health risk assessment for Medicare and Medicaid, rather than separate HRAs for each program. We explained that these proposals would continue our work to advance integrated care by applying MMP features into D–SNP requirements. More importantly, these proposals would improve and simplify experiences for dually eligible enrollees in AIP D–SNPs. We also proposed to amend the requirements related to HRAs and individualized care plans (ICPs) for all SNPs (that is, D–SNPs, chronic condition SNPs, and institutional SNPs). Third, we proposed to codify timeframes for SNPs to conduct HRAs and develop ICPs and prioritize the involvement of the enrollee or the enrollee's representative, as applicable, in the development of the ICPs.

Comment: Several commenters offered overall support for our collective package of proposals to improve experiences for dually eligible enrollees. These commenters emphasized that the proposals would remove barriers to fully integrated care and promote greater integration for dually eligible individuals, improve health outcomes, and reduce burden on enrollees and administrative costs.

Response: We welcome the commenters' support for our proposals. These proposals will help to continue our work to further integrate elements of the Medicare and Medicaid programs to improve experiences for dually eligible individuals.

Comment: A few commenters expressed concern about CMS requiring additional changes for SNPs in addition to other recent requirements and at the same time MMPs transition to D–SNPs. These comments included a request that CMS not make major changes that would cause States to reopen procurements supporting integrated D–SNPs.

Response: We thank the commenters for sharing these perspectives. We note that the proposed requirements are already being implemented by MMPs, and—based on our work with the States—we expect the vast majority of MMPs to transition to a D–SNP under the same parent organization as the MMP. Thus, we expect these parent organizations to have experience implementing these requirements, which aim to simplify processes and reduce burden for enrollees and plans. We believe the procurement comment is referring to State procurements of Medicaid managed care plans that are affiliated with integrated D–SNPs. We do not believe our proposals at § 422.101(f)(1)(i) through (x) would affect these State procurements. As stated in response to other comments in this section, the proposed timeframes for HRAs and ICPs serve as maximum timeframes. Nonetheless, we will remain mindful of the overall State and Federal contexts as we implement this final rule and consider future rulemaking.

1. Integrating Member ID Cards for Dually Eligible Enrollees in Certain Integrated D–SNPs

Sections 422.2267(e)(30) and 423.2267(e)(32) require MA and Part D plans, including D–SNPs, to provide member ID cards to enrollees. Medicaid managed care plans, which include managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs) also send member ID cards to enrollees which they use to access the items and services provided under that plan.

However, when a dually eligible individual is enrolled in both a Medicare Advantage (MA) plan and a Medicaid managed care plan, the plans usually issue the enrollee separate member ID cards—one for their MA plan and one for their Medicaid managed care plan—to access services for each program. This is administratively confusing, as providers may not always know which insurance to charge for which services, and confusing for enrollees, who may not always be aware of when to present which card.[61] Through studies and conversations with dually eligible enrollees, we have learned that individuals dually eligible for Medicare and Medicaid view having one insurance card instead of two as a benefit of integrated care.[62] As such, we proposed to continue our effort to integrate materials for dually eligible enrollees by requiring that certain D–SNPs provide one integrated member ID card to serve as the ID card for both the Medicare and Medicaid plans in which the enrollee is enrolled.

In the past several years, we have partnered with States to make integrated materials more broadly available, with the goal of streamlining the managed care enrollee experience and reducing burden and confusion for dually eligible individuals. As of January 2025, approximately 992,000 dual eligible individuals were enrolled in integrated care plans that used integrated materials. That includes all MMPs in the FAI, which use integrated Medicare and Medicaid materials including the member ID card, annual notice of change, evidence of coverage (Member

[61] CMS commissioned studies on experiences and terms pertaining to integrated care and solicited feedback from States and plans on integrated member ID cards.

[62] Rachelle Brill, Listening to Dually Eligible Individuals: Person-Centered Enrollment Strategies for Integrated Care. Center for Consumer Engagement in Health Innovation, June 2021. Online at *https://communitycatalyst.org/wp-content/uploads/2023/06/Person-Centered-Enrollment-Strategies-for-Integrated-Care.pdf.*

Handbook), Formulary (List of Covered Drugs), Summary of Benefits, and Provider and Pharmacy Directory.

In the final rule titled ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' which appeared in the May 9, 2022, **Federal Register** (hereinafter referred to as the May 2022 final rule), we finalized a pathway at § 422.107(e) by which States can require D–SNPs with exclusively aligned enrollment (EAE) to use integrated Medicare and Medicaid materials including the Summary of Benefits, Formulary, and combined Provider and Pharmacy Directory—essential information for dually eligible enrollees to be able to understand and utilize their managed care benefits. Eleven States currently require D–SNPs that are AIPs, as defined at § 422.561, to use at least some integrated materials for CY 2025, as shown in table 3.

TABLE 3—STATES REQUIRING VARIOUS INTEGRATED MATERIALS AMONG AIPS

Material	Summary of benefits	Provider and pharmacy directory	Formulary (list of covered drugs)	Annual notice of change	Evidence of coverage (member handbook)
State(s)	CA, DC, ID, MA, MN, NJ, NY, TN, VA, WI.	CA, HI, ID, MA, MN, NJ, VA, WI.	CA, HI, ID, MA, MN, NJ, VA, WI.	CA, DC, MN, NJ, TN ...	CA, DC, MN, NJ, TN.

In addition, in some cases, dually eligible enrollees in D–SNPs and an affiliated Medicaid managed care plan with EAE receive a single ID card that serves as the ID card for both health plans. According to State Medicaid agency contracts (SMACs) for contract year 2025, 13 States (Arizona, California, Florida, Hawaii, Idaho, Massachusetts, Minnesota, New Jersey, New Mexico, Oregon, Tennessee, Virginia, and Wisconsin) require D–SNPs to use a single integrated member ID card for both Medicare and Medicaid benefits.

In the proposed rule (89 FR 99486), we posited that establishing a Federal requirement for integrated member ID cards for AIP D–SNPs would improve experiences for dually eligible individuals (in such plans not already deploying an integrated ID card) and build on our past work to integrate Medicare and Medicaid. Therefore, under our authority to interpret, implement and carry out the Part C and D programs under sections 1851(h), 1852(c), 1860D–1(b)(1)(B)(vi), 1860D–4(a), and 1860D–4(*l*) of the Act, we proposed to add a requirement at §§ 422.2267(e)(30) and 423.2267(e)(32) that AIPs provide enrollees one integrated member ID card that serves as the ID card for both the Medicare and Medicaid plans in which they are enrolled.

We did not propose substantive changes to the Medicare or Medicaid requirements for the content of the ID cards. Therefore, the integrated ID cards would need to comply with the applicable Medicare requirements at §§ 422.2267(e)(30) and 423.2267(e)(32) and as further described in the Medicare Communications and Marketing Guidelines and, when applicable, the Medicaid requirements at § 438.3(s)(7), finalized in the final rule titled ''Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program,'' which appeared in the September 26, 2024, **Federal Register** (hereinafter referred to as the September 2024 Medicaid final rule).

Medicaid managed care plans are not required by Federal regulations to issue enrollee identification cards; however, it is a standard business practice for plans to routinely issue such cards for pharmacy benefits for Medicaid enrollees. The September 2024 Medicaid final rule requires, in accordance with 42 CFR 438.3(s)(7), Medicaid managed care plans that provide coverage for covered outpatient drugs and choose to issue enrollee identification cards to assign and exclusively use unique Medicaid-specific Bank Identification Number (BIN) and Processor Control Number (PCN) combination, and group number identifiers for these cards. This requirement will be implemented the first rating period for contracts with managed care plans beginning on or after 1 year following November 19, 2024. A more in-depth discussion of how the requirements at § 438.3(s)(7) will affect integrated member ID cards can be found at 89 FR 99486.

Our proposal would not add new requirements in the 13 States that currently require integrated member ID cards in their SMACs. Similarly, we expect—independent of this proposal—several additional States will require integrated member ID cards when MMPs transition to D–SNPs in 2026 (because these States already require integrated member ID cards for the MMPs). This proposal would require current AIPs in three additional States and Territories (District of Columbia, New York, and Puerto Rico) to implement integrated member ID cards. It would also apply to any new AIPs. However, we do not believe that the proposed requirement to integrate member ID cards would create additional burden in these States and Territories as the issuance of member ID cards is a normal and customary practice throughout the insurance industry. Since we will be working with several States to update an array of integrated materials as we transition MMPs to become integrated D–SNPs in 2026, and to give AIPs time needed to implement such updates as appropriate during the annual material creation cycle, we proposed to require the use of the integrated member ID card for enrollments effective January 1, 2027. Thus, our proposed updates to marketing and communication provisions at §§ 422.2267(e)(30) and 423.2267(e)(32) would be applicable for all contract year 2027 marketing and communications beginning October 1, 2026.

We continue to believe requiring that AIPs use integrated member ID cards is an important step to further integration and make enrollees' experience with Medicaid and Medicare less confusing, less burdensome, and more accessible. To our knowledge, our proposal represented the first time we proposed a Federal requirement for any integrated materials for any type of D–SNP. We chose to focus on ID cards because having one ID card is important to dually eligible individuals [63] and—relative to integrating other materials—is operationally manageable for integrated plans and requires the least of State Medicaid agencies. We solicited comment on this proposal and feedback

[63] Rachelle Brill, Listening to Dually Eligible Individuals: Person-Centered Enrollment Strategies for Integrated Care. Center for Consumer Engagement in Health Innovation, June 2021. Online at *https://communitycatalyst.org/wp-content/uploads/2023/06/Person-Centered-Enrollment-Strategies-for-Integrated-Care.pdf.*

on successes, challenges, and other experiences to date with integrated member ID cards.

We invited comment on whether the final rule should provide that any requirement for integrated ID cards should apply to AIPs and *all* HIDE SNPs, including those that do not also qualify as AIPs. However, in the proposed rule, we chose to limit our proposal to AIPs because we assumed that integrated member ID cards would be more complex to administer in situations where some D–SNP enrollees have aligned enrollment, but others are enrolled in a Medicaid plan operated by a different organization or a Medicaid fee-for-service program. In contrast to an AIP, where all of the D–SNP's enrollees would receive the integrated ID card, a non-AIP would need a reliable and timely mechanism for differentiating among enrollees within the plan to determine which ID card to send. We are unaware of any D–SNPs or other MA plans that currently deploy the types of integrated ID cards envisioned in our proposal for plans that do not have exclusively aligned enrollment. We solicited comment on the accuracy of these assumptions and, as noted previously, whether in the final rule to apply the proposed requirement to AIPs and *all* HIDE SNPs. We also welcomed comments on different situations in which commenters believe that integrated member ID cards could be helpful to include in potential future rulemaking.

Finally, we welcomed comment on other considerations for future rulemaking on ID cards, including ways to prevent stigma and ensure their security and utility for dually eligible enrollees.

In the proposed rule at 89 FR 99508, we discussed our burden estimate for this proposal. We did not receive any comments on burden estimates for this proposal and are finalizing the proposed burden estimates without change. We received the following comments on this proposal and our responses follow:

Comment: Commenters overwhelmingly supported our proposal to require integrated member ID cards for dually eligible enrollees in AIP D–SNPs. Commenters noted that an integrated member ID card would remove barriers to fully integrated care and eliminate confusing and duplicative aspects of D–SNPs. A few commenters expressed appreciation for our extended effective date of January 1, 2027.

Response: We thank the commenters for their support.

Comment: A few commenters issued conditional support for our proposal for an integrated member ID card. One commenter was concerned that one ID card could lead to confusion among enrollees. Another commenter expressed their concern that a single ID card would cause beneficiaries to believe that they may not switch their D–SNP plan without also having to change their Medicaid plan, and vice-versa. The commenter further discussed their concern that a single ID card for dually eligible enrollees may limit an enrollee's perception of their ability to switch plans.

Response: We thank the commenters for their concern. As we discussed in the proposed rule beginning at 89 FR 99485, we have learned through studies and conversations with dually eligible enrollees that they view having one insurance card instead of two as a benefit of integrated care. In 2025, 13 States are already requiring D–SNPs to use integrated member ID cards for both Medicare and Medicaid benefits. Based on these experiences, we believe that the benefits of an integrated member ID card outweigh any potential for confusion. Further, as we discuss in more detail later in this section, we believe that our plan to provide technical assistance, as well as existing feedback mechanisms for enrollees to discuss their experiences with a plan, including with member ID cards, will allow us to quickly respond to any points of confusion that occur as a result of integrating member ID cards.

We also note that—in addition to numerous other potentially applicable enrollment periods at §§ 422.62 and 423.38—all dually eligible and other Part D low-income subsidy enrolled individuals may elect to use a once-per-month special enrollment period (SEP) under § 423.38(c)(4) to enroll in fee-for-service Medicare and a standalone prescription drug plan. Dually eligible individuals may also use the integrated care SEP described in § 423.38(c)(35), which allows full-benefit dually eligible individuals to enroll once per month in a FIDE, HIDE, or AIP when the enrollment is used to align enrollment with the integrated D–SNP and Medicaid managed care organization. Information about enrollment periods is distributed annually through the Medicare & You handbook and the Evidence of Coverage (also known as Member Handbook) provided through plans, and available by calling 1–800–MEDICARE. We believe that these SEPs reduce the type of ''lock-in'' scenario for which the commenter expressed concern. An integrated member ID card also does not limit an enrollee's ability to change Medicaid managed care plans as allowable in 42 CFR part 438.

Comment: Several commenters requested specific information be included on an integrated member ID card. A few commenters suggested that we require an enrollee's Qualified Medicare Beneficiary (QMB) status be printed on the card to prevent improper billing, or other language to denote to what extent the individual is exempt from cost sharing. Other commenters requested that the specific benefit design or plan type be included so that providers are aware of care coordination requirements or limitations of an enrollee's coverage. A commenter requested that we require a date of issue for the integrated ID card to help with timeline issues as people churn on and off Medicaid.

Response: We thank the commenters for their input to include specific information to help enrollees, advocates, and practitioners better identify the type of plan or type of enrollment an enrollee may have. We note that in this rulemaking, we did not propose substantive changes to the Medicare or Medicaid requirements for the content of the ID cards. However, based on our work with States that currently require integrated member ID cards, States may require that plans using integrated member ID cards add language to indicate that providers may not bill the enrollee.[64] We will take the other suggestions for specific benefit design or plan type into consideration for future rulemaking.

Comment: Several commenters requested that we provide a model material or standard framework for an integrated member ID card that would clearly and realistically include the necessary information, while accounting for available space. Some commenters note that since there currently is not a requirement for an integrated member ID card, individual States are approaching integrated member ID cards in their own ways, and that a variety of approaches could complicate the design. Commenters assert that a model material for an integrated member ID card would reduce administrative burden and prevent fragmentation.

Response: We thank the commenters for their thoughts on this issue and agree that a model material could help alleviate administrative burden and prevent fragmentation. We are working with interested States on developing and implementing such a model material.

[64] See, for example, CY 2025 California AIP D–SNP model materials. Link available here: *https://www.cms.gov/medicare/medicaid-coordination/about/dsnps.*

Comment: Several commenters requested that, if we finalize our proposal, we also provide clear guidance, technical assistance, and training to plans and States to facilitate successful implementation.

Response: We appreciate these comments. As we discuss later in this final rule, in the past several years, we have partnered with States to make integrated materials more broadly available, with the goal of streamlining the managed care enrollee experience and reducing burden and confusion for dually eligible individuals. We plan to continue to provide technical assistance and guidance to States, as well as partner with States to provide technical assistance and guidance to plans to facilitate successful implementation.

Comment: A few commenters offered suggestions for implementation and design of an integrated member ID card, including seeking provider and enrollee feedback on card design, and careful consideration to accessibility factors, such as too much information or multiple addresses.

Response: We thank the commenters for their responses and appreciate the care toward the design, efficacy, and accessibility of the design. We note there are regulatory requirements addressing the required information displayed on member ID cards at §§ 422.2267(e)(30), 423.2267(e)(32), and 423.120(c). These regulations state that the member ID card must include the plan's website address, customer service number, and contract/PBP number. If a plan is a PPO, the card must also include the phrase ''Medicare limiting charges apply.'' The card must also include the Medicare prescription drug benefit program mark, Part D BIN or RxBIN and Part D processor control number (RxPCN) as well as an Rx identification number (RxID).

In the proposed rule at 89 FR 99486, we discussed that § 438.3(s)(7) requires States that contract with MCOs, PIHPs, or PAHPs that provide coverage of Medicaid outpatient drugs to require those managed care plans to assign and exclusively use unique Medicaid-specific Bank Identification Number (BIN) and Processor Control Number (PCN) combination, and group number identifiers for all Medicaid managed care enrollee identification cards for pharmacy benefits that are utilized by plans to make the Medicaid drug program run more efficiently and improve the level of pharmacy services provided to Medicaid enrollees. We discussed the fact that Medicaid managed care plans are not Federally required to issue member ID cards but it is a standard business practice for managed care plans to routinely issue ID cards for pharmacy benefits for Medicaid enrollees. To the extent AIPs cover outpatient drugs for which Medicaid (not Medicare) would be the primary payer, § 438.3(s)(7) would still apply to the AIP and the required information would need to be included on the member ID card.

As we noted in the proposed rule at 89 FR 99486, we did not propose substantive changes to the Medicare or Medicaid requirements for the content of the ID cards. Therefore, the integrated ID cards would need to comply with the applicable Medicare requirements at §§ 422.111(i), 422.2267(e)(30), 423.2267(e)(32), and 423.120(c), and any applicable Medicaid requirements including, as discussed previously, § 438.3(s)(7). We are working with interested States in developing model ID cards and will work to create a streamlined and readable document while ensuring that the needed content to access services is included on the card.

Comment: Several commenters requested that we monitor for any issues that may arise if this provision is implemented. Commenters suggested that we monitor for the impact of the integrated member ID card on care coordination, enrollee satisfaction, and overall health outcomes. Commenters also suggested we engage stakeholders and solicit direct feedback from dually eligible individuals. A few commenters also suggested that we monitor for issues surrounding staggered enrollment, or for any issues that may arise for individuals who may be disenrolled, then reenrolled. Commenters expressed concern that beneficiaries in this situation may get lost in the system and not receive care while waiting for a member ID card.

Response: We thank the commenters for their suggestions. We plan to monitor implementation, including for issues surrounding staggered enrollment, in partnership with the States. We also encourage D–SNPs to consult with their enrollee advisory committees on challenges with ID cards.

Comment: Many commenters supported our proposal that the integrated member ID card policy be applicable to all AIPs and agreed with our reasoning that production of member ID cards is operationally feasible for AIPs but far less so for non-AIPs. In response to our solicitation of comments about whether or not we should extend the requirements to all HIDE SNPs, including those that do not qualify as AIPs, many commenters expressed opposition to such an expansion, citing potential confusion for non-integrated plan enrollees and operational difficulties for plans when enrollees are not receiving both Medicare and Medicaid from the same organization. A few commenters expressed support for an expansion to all HIDE SNPs; one noted their support was due to their belief that the structure of HIDE SNPs suggests that even a non-AIP HIDE SNP likely has the operational capacity to send an integrated member ID card only to aligned enrollees. Another commenter supportive of this position encouraged us to work toward expanding this policy to all HIDE SNPs and eventually all D–SNPs in the future by building a data sharing mechanism across Medicaid managed care, MA, and the Medicaid fee-for-service program to facilitate timely sharing of relevant data across plans. Another commenter further noted that though expanding this requirement to non-AIP HIDE SNPs may present some challenges for the health plans, this is a rare opportunity to provide a tangible benefit to dually eligible enrollees who have repeatedly requested one integrated member ID card.

Response: We thank commenters for their input. Based on the operational challenges we cited in the proposed rule (89 FR 99487), we are not planning to require integrated member ID cards beyond AIPs. However, we appreciate the comments discussing how this provision could be applied to non-AIP HIDE SNPs or other plans.

Comment: A few commenters recommended that we allow flexibility in implementing integrated member ID cards. A commenter requested that we take into consideration the burden that this requirement may impose on plans as they prepare to launch in 2026. The commenter also requested that we not make major changes that would require plans to reopen Medicaid competitive bidding processes. Another commenter asked CMS to take into consideration that States may have their own requirements. Another commenter suggested that there may be unique situations that may require an extension of the timeline.

Response: We thank the commenters for their input. As proposed, the requirement for AIPs to deploy integrated member ID cards would first apply for contract year 2027 (for which marketing and communications begins in October 2026). We proposed this timeline since we will be working with several States to update an array of integrated materials as we transition MMPs to become integrated D–SNPs in 2026, and to give AIPs time needed to implement such updates as appropriate during the annual material creation

cycle. However, we note that several States already require the use of an integrated member ID card through their State Medicaid agency contract, and other States may choose to do so for contract year 2026. As in the past, we plan to continue working closely with States on all integrated materials, including member ID cards, and will utilize that process to address unique situations that may arise based on State-specific policies. Lastly, as we discussed in the proposed rule at 89 FR 99486, we do not believe that this proposed requirement to integrate member ID cards would create additional burden in any States and Territories as the issuance of member ID cards is a normal and customary practice throughout the insurance industry.

Comment: A commenter suggested that, to help enrollees make educated decisions, CMS should require additional integrated materials such as materials explaining coverage, provider availability, and/or appeals.

Response: We thank the commenter for their suggestion. As discussed in the proposed rule, beginning at 89 FR 99485, in the past several years, we have partnered with States to make integrated materials more broadly available, with the goal of streamlining the managed care enrollee experience and reducing burden and confusion for dually eligible individuals. In the proposed rule, we discussed previous rulemaking (the May 2022 final rule), where we finalized a pathway at § 422.107(e) by which States can require D–SNPs with exclusively aligned enrollment (EAE) to use integrated Medicare and Medicaid materials including the Summary of Benefits, Formulary, and combined Provider and Pharmacy Directory—essential information for dually eligible enrollees to be able to understand and utilize their managed care benefits. In 2025, eleven States require D–SNPs that are AIPs to use at least some integrated materials. The State templates are publicly available at *https://www.cms.gov/medicare/medicaid-coordination/about/dsnps.* In addition, AIPs must use an integrated coverage decision letter as a result of an adverse integrated organization determination under § 422.631. The template is also available on the CMS website mentioned previously.

After considering the comments and for the reasons described in the proposed rule, and our responses to comments, we are finalizing without modification our proposal to require integrated member ID cards for AIP D–SNPs.

2. Integrating Health Risk Assessments for Dually Eligible Enrollees in Certain Integrated D–SNPs

Medicare requirements at § 422.101(f)(1) require D–SNPs to conduct a comprehensive HRA for each enrollee, both at the time of enrollment and annually thereafter. Separately, Medicaid managed care regulations at § 438.208(b)(3) require Medicaid managed care plans to make a best effort to conduct an initial screening of enrollee needs within 90 days of a new enrollee's effective enrollment date, and States may require additional assessments such as long-term services and supports (LTSS) and home and community-based services eligibility screenings.

In the FAI, MMP enrollees complete a single integrated HRA, encompassing both Medicare and Medicaid requirements. In contrast, dually eligible individuals enrolled in both a D–SNP and a Medicaid managed care plan may end up completing multiple assessments during the year, some of which may be duplicative, as managed care plans aim to meet all applicable enrollee assessment requirements across both programs, and to gather information about enrollee needs and preferences and create individualized care plans. Completing two separate, but potentially overlapping, assessments creates unnecessary burden for enrollees, who may have to answer the same detailed personal questions more than once.

In the final rule titled ''Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,'' which appeared in the January 19, 2021, **Federal Register** (hereinafter referred to as the January 2021 final rule), we clarified that D–SNPs receiving capitation for Medicaid services may combine their Medicare-required HRA with a State Medicaid-required assessment to reduce burden for enrollees, as long as the assessment meets all applicable requirements (86 FR 5879). We also noted that, to the extent there is overlap and the HRA required by § 422.101(f)(1)(i) can be aligned with other assessments conducted by a SNP, the model of care (MOC) should describe that alignment, consistent with the standards in MOC 2, Element B in Chapter 5, section 20.2.2 of the Medicare Managed Care Manual. We explained that the factors outlined in the MOC guidelines allow SNPs the flexibility to align the HRA required by § 422.101(f)(1)(i) with other assessment tools. In addition, the contract year (CY) 2025 Medicare Part C Reporting Requirements, which describe MA plan reporting on HRA completion, allow D–SNPs to count a Medicaid HRA that is performed within 90 days before or after the effective date of Medicare enrollment as meeting the Part C obligation to perform an HRA, so long as the requirements in § 422.102(f) regarding the HRA are met.[65] As outlined in both the January 2021 rule and the most recent Part C Reporting Requirements, we have allowed a certain degree of flexibility for SNPs to streamline their Medicare and Medicaid assessments. However, we have not previously required that D–SNPs integrate Medicare and Medicaid enrollee HRAs into a single HRA for dually eligible individuals.

Some States have implemented their own requirements, through SMACs, to reduce burden and duplication. Other States, while not explicitly requiring integrated HRAs, have implemented requirements to improve integration and coordination across Medicare and Medicaid HRAs and services. We have also heard from a few D–SNP parent organizations that are actively working to reduce duplication between their Medicare and Medicaid HRAs. Discussion of these States' requirements can be found at 89 FR 99487.

Under our authority at section 1856(b) of the Act to establish standards for MA plans by regulation, we proposed to adopt specific standards to implement the requirement at section 1859(f)(5)(A)(ii)(I) of the Act that all MA SNPs conduct an initial assessment and an annual reassessment of the individual's physical, psychosocial, and functional needs. We proposed to add a new paragraph at § 422.101(f)(1)(v) that would require D–SNPs that are AIPs (as defined in § 422.561) to conduct a comprehensive HRA that meets all requirements at § 422.101(f)(1)(i) through (v) as well as any applicable Medicaid requirements, including those at § 438.208, such that enrollees in the AIP complete a single integrated HRA for Medicare and Medicaid. We posited in the proposed rule that our proposal would meaningfully reduce assessment burden for dually eligible individuals and improve their experience as managed care enrollees (where States aren't already requiring something similar). It may also improve integration of care within D–SNP AIPs and their

[65] 2025 Part C Reporting Technical Specifications: *https://www.cms.gov/files/document/cy-2025-part-c-technical-specifications.pdf.*

affiliated Medicaid managed care plans by collecting all enrollee assessment information in one place, potentially facilitating better care coordination across Medicare and Medicaid services. The proposal would also continue our efforts to incorporate MMP features into D–SNP requirements. Finally, we believe the proposal for a new Federal requirement would not create a significant burden for health plans because similar State requirements to integrate Medicare and Medicaid HRAs are already in place in some States, and at least a few health plans have taken on these efforts themselves.

We proposed only to require D–SNPs that are AIPs to meet this new requirement based on our belief that it is most feasible for D–SNPs whose enrollees are exclusively aligned with an affiliated Medicaid MCO to implement a fully integrated HRA. Because all FIDE SNPs are AIPs beginning in 2025, the proposal encompasses all FIDE SNPs. Numerous HIDE SNPs and some coordination-only D–SNPs with exclusively aligned enrollment are also AIPs. We considered whether we should apply this proposed new requirement to *all* HIDE SNPs or all D–SNPs, even those without exclusively aligned enrollment. However, in a scenario where some D–SNP enrollees receive their Medicaid benefits from a different organization or through the Medicaid fee-for-service program, it could be challenging for the D–SNP to assess aligned enrollees with an integrated HRA and to assess non-aligned enrollees with a different, Medicare-only assessment. We welcomed comment on whether this requirement should be applied to all HIDE SNPs or suggestions as to whether application to a different subset of D–SNPs should be proposed in future rulemaking.

The proposal would not change any specific Medicare or Medicaid requirements for the timing of or elements included in an HRA (although we are finalizing a separate proposal to address an issue related to the timing of required HRAs in this final rule). Nor would the proposal preclude deployment of assessments that are modular (such as a base level assessment that meets all Medicare and Medicaid requirements with optional additional sections that are specific to people for substance use or other factors) or include additional elements for people with special needs. For example, some States may require more expansive assessment questions to develop a service plan for 1915(c) waiver services, or plans may conduct additional assessment for people who screen positive for substance use disorder or other conditions. The proposal would not require that all enrollees complete such an assessment, nor would it preclude plans from conducting such additional assessments separately from the HRA. Rather, our proposal simply would require that the base HRA and screening apply across both programs, such that enrollees are not asked to complete independent HRAs for Medicare and Medicaid. We welcomed comment on potential challenges that health plans and other stakeholders foresee, or have already experienced, in implementing HRAs that integrate LTSS assessments. We also welcomed comment on any potential conflicts with State Medicaid assessment requirements our proposal may create.

In addition to separate Medicare and Medicaid managed care assessment requirements, different Medicare and Medicaid enrollment timeframes and effective dates can be a barrier to D–SNP AIPs administering a single, integrated HRA. In the final rule titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,'' which appeared in the April 23, 2024 **Federal Register** (hereinafter referred to as the April 2024 final rule), we noted at 89 FR 30704 that Medicare and Medicaid managed care enrollment start and end dates can be misaligned. Sections 1851(f)(2) and 1860D–1(b)(1)(B)(iv) of the Act, and regulations codified at §§ 422.68 and 423.40 respectively, generally require that Medicare enrollments become effective on the first day of the first calendar month following the date on which the election or change is made, although section 1851(f)(4) of the Act and §§ 422.68(d) and 423.40(c) allow CMS flexibility to determine the effective dates for enrollments that occur in the context of special enrollment periods.

Medicaid managed care regulations at § 438.54 do not specify the timelines or deadlines by which any enrollment must be effective. We believe it would still be feasible to assess an enrollee using an integrated HRA in situations where some States have cut-off dates after which enrollment in a Medicaid managed care plan is not effectuated until the first day of the next month after the following month, given that the enrollee's Medicaid eligibility would already be verified. We solicited comment about whether this would present operational challenges to implementing an integrated HRA for AIP D–SNP enrollees.

We posited in the proposed rule (89 FR 99488) that our proposal would reduce confusion, assessment burden, and fragmentation for dually eligible individuals enrolled in AIP D–SNPs and potentially lead to more effective coordination of care. We also believe our proposal would not be overly burdensome for AIP D–SNPs to implement, given there are existing requirements in eight States [66] either to use a single, integrated HRA or take action to reduce duplication in HRAs. In the proposed rule at 89 FR 99509, we discussed our burden estimate for this proposal. We did not receive any comments on burden estimates for this proposal and are finalizing the proposed burden estimates without change. We received the following comments on this proposal and our responses are as follows:

Comment: Commenters overwhelmingly supported our proposal to require an integrated HRA for D–SNPs that are AIPs. Commenters noted that such a requirement would reduce burden on enrollees and plans, and such a requirement furthers CMS's goal of creating a more integrated care delivery system for dually eligible individuals.

Response: We thank commenters for their support.

Comment: A few commenters suggested that we allow flexibility for States with regard to the implementation of an integrated HRA, as States may have their own requirements or existing Medicaid assessments that cannot be integrated into a single HRA.

Response: We thank the commenters for their thoughts on this matter. As we noted in the proposed rule at 89 FR 99487, some States have implemented their own integrated HRA requirements to reduce burden and duplication. Other States, while not explicitly requiring integrated HRAs, have implemented requirements to improve integration and coordination across Medicare and Medicaid HRAs and services. In the proposed rule at 89 FR 99488, we proposed to require all D–SNPs that are AIPs to conduct a comprehensive HRA that meets all requirements at § 422.101(f)(1)(i) through (v) as well as any applicable Medicaid requirements, including those at § 438.208, such that enrollees in the AIP complete a single integrated HRA for Medicare and Medicaid. This proposal would not

[66] Based on CMS review of 2024 SMACs.

preclude deployment of assessments that are modular (such as a base level assessment that meets all Medicare and Medicaid requirements with optional additional sections that are specific to people for substance use or other factors) or include additional elements for people with special needs. For example, some States may require more expansive assessment questions to develop a service plan for 1915(c) waiver services, or plans may conduct additional assessment(s) for people who screen positive for substance use disorder or other conditions. Our proposal would not require that all enrollees complete any assessment, nor would it preclude plans from conducting such additional assessments separately from the HRA. Rather, our proposal would simply require that the base HRA and screening applies across both programs, such that enrollees are not asked to complete independent HRAs for Medicare and Medicaid. We believe that this proposal gives States the flexibility that the commenters are requesting.

Comment: Several commenters requested that, if this proposal is finalized, we issue specific technical assistance, such as which Medicaid assessments would be integrated with the D–SNP HRA, including in instances where States require multiple Medicaid MCO assessments, and how plans should proceed when there are Medicaid assessments that cannot be integrated due to misaligned timeframes and purposes. Further, a commenter suggested that we encourage States to align HRA requirements to Medicare requirements, ensuring that model of care domains are met.

Response: We thank the commenters and appreciate the request for more information. We note that, as discussed in our proposed rule at 89 FR 99488 and discussed earlier, this proposal would not change any specific Medicare or Medicaid requirements for the timing of or elements included in an HRA. This proposal does not preclude deployment of assessments that are modular or include additional elements for people with special needs. Our proposal would not preclude plans from conducting such additional assessments separately from the HRA. Our proposal simply requires that the base HRA and screening applies across both programs, such that enrollees are not asked to complete independent HRAs for Medicare and Medicaid. As is current practice, we plan to provide technical assistance to States and plans as needed. Lastly, we acknowledge that beyond the proposal specific to HRAs, model of care requirements at § 422.101(f) remain unchanged.

Comment: Many commenters requested general technical assistance or model materials to help plans facilitate implementation of an integrated HRA. Some commenters suggested that training should include strategies for maintaining patient confidentiality, and approaches to engaging enrollees in the HRA process. Commenters also requested clarification as to what specifically will be required within the integrated HRA. A commenter recommended that CMS create a core HRA with specific standardized elements across all States. The commenter stated that standardized requirements across States would greatly enhance Medicare-Medicaid integration efforts and build the ability to create benchmarks, assess performance, and capture best practices. Commenters further noted that in the absence of a common HRA, integrated HRAs could look different in every State.

Response: We thank commenters for their many suggestions and requests for technical guidance. Integrated HRAs may reflect State-specific requirements, leading to variation across States. However, our experience with States and HRAs leads us to believe that, in many cases, the MA organizations can meet both State and Federal requirements while using many standardized elements across States.

As discussed in the proposed rule at 89 FR 99488, this proposal would not change any specific Medicare or Medicaid requirements for the timing of or elements included in an HRA. We note that our proposal simply requires that the base HRA and screening applies across both programs, such that enrollees are not asked to complete independent HRAs for Medicare and Medicaid.

Creating or requiring a nationally standardized HRA (or standardized elements to include in an HRA) is beyond the scope of this rulemaking, but we will consider it for potential future rulemaking.

Comment: Several commenters expressed their support for our proposed requirement that plans combine only the initial base level assessment, allowing plans to provide follow-up assessments beyond Medicare requirements at another time.

Response: We appreciate the support for our proposal.

Comment: A few commenters suggested that CMS consider how to incentivize enrollees to more actively participate in their care and complete HRAs, as the commenters' expressed enrollees are becoming more reluctant to respond to outreach, which, they note, can affect HRA completion.

Response: We thank the commenters for raising this issue. We hope that using an integrated HRA (in contrast to entirely separate HRAs for Medicare and Medicaid) will reduce duplication and assessment burden for enrollees and, therefore, improve engagement. We note that plans can also use reward and incentive programs, as defined at § 422.134, to incentivize enrollee engagement with regard to HRAs.

Comment: Several commenters recommended that we hold plans accountable for compliance with our proposed requirements through audits or other oversight activities, and specifically monitor for their impact on care coordination, enrollee satisfaction, and overall health outcomes. Commenters further recommended that CMS engage stakeholders to better understand their experiences with integrated HRAs.

Response: We thank the commenters for their thoughts and suggestions. We plan to monitor implementation, in partnership with States. We encourage D–SNPs to consult with their enrollee advisory committees on use of or challenges with HRAs. Further, as described in § 422.101(f)(1), we have the ability to review HRA assessment tools during oversight activities to ensure that the results from the initial assessment and annual reassessment conducted for each individual enrolled in the D–SNP are addressed in the individuals' individualized care plan.

Comment: A few commenters offered suggestions for items to include in the HRA. A commenter suggested that we add a question on caregiver status, and another commenter suggested we include patient-centered metrics to account for the unique challenges faced by dually eligible enrollees, such as higher rates of chronic conditions.

Response: We thank the commenters. While these comments are out of scope—we noted at 89 FR 99488 that our proposal would not change any specific Medicare or Medicaid requirements for the timing of or elements included in an HRA—we encourage plans to consider these comments in developing their HRAs.

Comment: Several commenters expressed concern about the length of the HRAs. Commenters note that very long HRAs discourage participation and can be taxing for enrollees to complete leading to poor enrollee experience. Some commenters' concerns are largely related to the complexity and length of time an integrated HRA might take, depending on the number of

requirements a State imposes for the Medicaid HRA.

Response: We thank the commenters for their concern over the length of an integrated HRA. This proposal simply requires that the base HRA and screening applies across both programs, such that enrollees are not asked to complete independent HRAs for Medicare and Medicaid. This proposal would not preclude deployment of assessments that are modular (such as a base level assessment that meets all Medicare and Medicaid requirements with optional additional sections that are specific to people for substance use or other factors) or include additional elements for people with special needs. Further, our proposal would not require that all enrollees complete any assessment, nor would it preclude plans from conducting such additional assessments separately from the HRA. We believe that an integrated HRA would meaningfully reduce assessment burden for dually eligible individuals and improve their experience as managed care enrollees (where States are not already requiring something similar).

Our proposal stated the integrated HRA proposed at § 422.101(f)(1)(v) would require D–SNPs that are AIPs to meet applicable Medicare and Medicaid requirements, including those at § 438.208, such that enrollees in the AIP complete a single integrated HRA for Medicare and Medicaid. In this final rule, we are clarifying that the integrated HRA would need to satisfy the requirements at § 438.208(b)(3) but would not necessarily encompass the other requirements at § 438.208. We believe the more specific citation is more appropriate since § 438.208(b)(3) is the provision that requires that the Medicaid MCOs, PIHPs, or PAHPs make a best effort to conduct an initial screening of each enrollee's needs within 90 days of the effective date of enrollment for all new enrollees.

Comment: Many commenters supported our proposal that integrated HRAs be applicable to AIPs and agreed with our reasoning that it would be more feasible for D–SNPs whose enrollees are exclusively aligned with an affiliated Medicaid MCO to implement a fully integrated HRA. We received many comments expressing opposition to expanding this requirement to all HIDE SNPs, citing the administrative burden and complexity, resource constraint, and confusion that would result, as well as the complexity of aligning timing for State Medicaid agency contracts and MOC submissions. Some commenters supported an expansion to all HIDE SNPs and encouraged us to build a data sharing mechanism across Medicaid managed care, MA, and Medicaid fee-for-service programs for organizations to facilitate timely sharing of relevant data across plans.

Response: We appreciate the commenters' input on our proposal and comment solicitation. Based on the challenges described in the proposed rule at 89 FR 99488, we are not finalizing application of a requirement for an integrated HRA beyond what we proposed.

Comment: Several commenters suggested that we align Medicare and Medicaid HRA timelines to avoid beneficiary confusion and disruption.

Response: We thank commenters for their input. In the next section on Promoting Person-centeredness in SNP ICPs and Timeliness of HRAs and ICPs, we note that SNPs could conduct the comprehensive initial HRA within 90 days (before or after) of the effective date of enrollment for all new enrollees. But we also note that States could set more stringent timeframe requirements through their State Medicaid agency contracts for D–SNPs to conduct initial HRAs. The language we are finalizing at § 422.101(f)(1)(i) would establish a maximum timeframe, not a minimum.

Comment: A few commenters discussed potential misalignment between Medicare and Medicaid enrollment timelines and recommended that we finalize this proposal in a way that aligns Medicaid and Medicare enrollment timelines for dual eligible individuals and promotes consistency across States and the Federal Government.

Response: We appreciate the comments. We understand the operational considerations of potentially misaligned enrollment timelines for Medicare and Medicaid, but such a change would be out of scope for this final rule. Under our proposal on Promoting Person-centeredness in SNP ICPs and Timeliness of HRAs and ICPs, SNPs would need to conduct an HRA within 90 days (before or after) the enrollment effective date. As we discussed in the proposed rule at 89 FR 99488, we believe it would still be feasible to assess an enrollee using an integrated HRA in this scenario, given that the enrollee's Medicaid eligibility would already be verified through their enrollment in the D–SNP.

Comment: A handful of commenters suggested that we defer implementation of an integrated HRA to allow States and plans sufficient time to work through administrative complexities and train staff before implementation. Commenters also suggested that we be aware of the imposition that any major changes could have on States and plans and argued that sufficient time and coordination will be needed to develop streamlined and integrated HRAs that have the appropriate level of standardization to assess core clinical and social needs, while also maintaining the brevity and simplicity required to encourage member completion. A commenter suggested a new implementation date of January 1, 2027.

Response: We appreciate the comments. We are delaying the implementation date of this provision to January 1, 2027, to align with the implementation timeline of the provisions for integrated member ID cards and to allow States and plans more time to implement appropriate instrument redesigns and staff training. We note that since HRAs may be conducted within 90 days before or after the effective date of enrollment, this provision will be applicable beginning October 1, 2026.

After considering the comments and for the reasons described in the proposed rule, and our responses to comments, we are finalizing our proposal to require integrated HRAs for AIP D–SNPs with two modifications: (1) we are delaying the implementation date of this provision to January 1, 2027, with an applicability date of October 1, 2026 and (2) at § 422.101(f)(1)(v), for greater specificity, we are replacing the reference to § 438.208 with reference to § 438.208(b)(3).

3. Promoting Person-Centeredness in SNP ICPs and Timeliness of HRAs and ICPs

a. Medicare Context

Section 1859(f)(5)(A) of the Act requires SNPs to conduct an initial assessment and an annual reassessment of each enrollee's physical, psychosocial, and functional needs and ensure that the results are addressed in each enrollee's ICP. We codified this requirement at § 422.101(f)(1)(i), using the term ''health risk assessment,'' as a required component of the SNP MOC. Specifically, § 422.101(f)(1)(i) requires that MA organizations offering SNPs conduct a comprehensive initial HRA of the individual's physical, psychosocial, and functional needs as well as annual HRA, using a comprehensive risk assessment tool that CMS may review during oversight activities, and ensure that the results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individuals' ICP.

In addition, § 422.112(b)(4)(i) requires that MA organizations offering coordinated care plans make a ''best effort'' attempt to conduct an initial assessment of each enrollee's health care needs, including following up on unsuccessful attempts to contact an enrollee, within 90 days of the effective date of enrollment. In the CY 2024 Medicare Part C Reporting Requirements, as further defined by the Medicare Part C Technical Specifications Document Contract Year 2025,[67] CMS specifies that SNPs report to CMS the number of initial HRAs completed within 90 days of (before or after) the effective date of enrollment and annual HRAs performed within 365 days of the last HRA. As described in the Medicare Part C Technical Specification Document Contract Year 2025, SNPs may report an enrollee as unable to be reached if: the enrollee did not respond to at least three ''non-automated'' phone calls and a follow-up letter from the SNP where all the efforts were to solicit participation in the HRA, none of the efforts to solicit participation were automated calls (''robo'' or ''blast'' calls), and documentation of the enrollee's refusal and/or the SNP's inability to reach the enrollee is available at any time to CMS. The technical specifications include additional details regarding how to interpret the CY 2025 Medicare Part C Reporting Requirements.

In addition, § 422.101(f)(1)(ii) requires SNPs to develop and implement a comprehensive ICP through an interdisciplinary team in consultation with the beneficiary, as feasible, identifying goals and objectives including measurable outcomes as well as specific services and benefits to be provided. There are no timeframe requirements for developing ICPs in § 422.101(f).

b. Medicaid Context

Many D–SNPs have affiliated Medicaid managed care plans that deliver Medicaid services to D–SNP enrollees through their parent organization or another entity that is owned and controlled by the D–SNP's parent organization. For Medicaid managed care, § 438.208(b)(3) requires that MCOs, PIHPs, or PAHPs make a best effort to conduct an initial screening of each enrollee's needs, within 90 days of the effective date of enrollment for all new enrollees, including subsequent attempts if the initial attempt to contact the enrollee is unsuccessful.

For individuals enrolled in certain Medicaid home and community-based services (HCBS) programs, there are requirements for a person-centered care planning process. For section 1915(c) Medicaid HCBS waiver programs, these requirements are set forth at § 441.301(c)(1) through (3); for section 1915(k) Medicaid HCBS State plan amendments, these requirements are set forth at § 441.540; and for section 1915(i) Medicaid State plan HCBS benefits, these requirements are set forth at § 441.725. We refer readers to these regulations for more details.

Generally, these regulations require the State administering these Medicaid HCBS programs to ensure an individualized person-centered services plan, meeting certain minimum requirements, is developed for each individual beneficiary enrolled in a Medicaid HCBS program. A more in-depth discussion of the Medicaid HCBS care planning requirements can be found at 89 FR 99489.

c. Medicare-Medicaid Plan (MMP) Context

Like Medicaid managed care plans, MMPs are subject to more requirements than SNPs on person-centeredness and timeliness of HRAs and ICPs. The MMP care coordination requirements for HRAs and ICPs for the FAI are included in the three-way contracts between CMS, State Medicaid agencies, and MMPs. In several States, the three-way contracts apply requirements on the person-centeredness of ICPs beyond what is required for SNPs and specific requirements for the timing of HRAs and ICPs. Most States participating in the FAI (Illinois, Massachusetts, Michigan, Ohio, South Carolina, and Texas) require MMPs to develop HRAs and ICPs within 90 days or less of enrollment and include enrollees in the development of the ICPs.

4. Opportunities for Improvement

Over the years, we have identified opportunities to improve person-centeredness in care planning and the need to codify the timeline for development of HRAs and ICPs. For example, we have learned of instances in which SNPs did not complete initial or annual HRAs timely, or it took several months to develop an ICP for enrollees after an HRA. In addition, we have reviewed ICPs that were only loosely related to the needs and preferences of enrollees or did not contain measurable outcomes. We have identified some similarities in our review of MMP care plans, such as care plans that do not include goals that are meaningful to enrollees. We proposed regulatory updates to address these opportunities for improvement, better align requirements across Medicare and Medicaid, and build on our experiences in other programs and demonstrations.

We proposed amendments to § 422.101(f)(1) to codify timeliness standards, improve the organization of the various HRA and ICP requirements, and strengthen these requirements. First, in § 422.101(f)(1)(i), we proposed to specify that SNPs conduct the comprehensive initial HRA within 90 days (before or after) of the effective date of enrollment for all new enrollees. This would better align with the Medicaid requirement at § 438.208(b)(3) and, for Medicare, conform to § 422.112(b)(4)(i) and the standard currently described for reporting HRA completion in the Part C Reporting Requirements. We also noted that, as described in the Medicare Part C Technical Specifications, when a person enrolls, disenrolls, and re-enrolls into any SNP under the same contract number, the previous HRA is still considered valid and can continue to be used as long as it is not more than 365 days old. CMS will continue to provide guidance on these types of issues through the Medicare Part C Technical Specifications.

Second, we proposed to move the requirement for a comprehensive annual HRA from § 422.101(f)(1)(i) to § 422.101(f)(1)(ii) based on the updates and to improve the flow of the rule.

Third, we proposed to relocate the requirement for SNPs to use a comprehensive risk assessment tool that CMS may review during oversight activities that assesses the enrollee's physical, psychosocial, and functional needs and includes one or more questions from a list of screening instruments specified by CMS in subregulatory guidance, from § 422.101(f)(1)(i) to § 422.101(f)(1)(iii). This is a technical change to improve the organization of the rule. (This organizational change notwithstanding, we are planning to reassess these screening requirements in response to Executive Order 14192, ''Unleashing Prosperity Through Deregulation.'')

Fourth, we proposed a new § 422.101(f)(1)(iv)(A) through (C) to establish specific requirements for all SNPs related to outreach to enrollees regarding completion of the HRA. Consistent with the Medicare Part C Technical Specifications, we proposed to require that the SNP must make at least three non-automated phone call attempts, unless an enrollee agrees or declines to participate in the HRA before three attempts are made. We proposed to newly require that these

[67] *https://www.cms.gov/medicare/enrollment-renewal/health-plans/part-c.*

attempts be made on different days at different times of day. Also consistent with the Medicare Part C Technical Specifications, we proposed to require that, if the enrollee has not responded to these attempts, the SNP send a follow-up letter to conduct the initial or annual risk assessments. We also proposed that, for any enrollees who are unable to be reached or decline to participate in the HRA, the SNP must document the attempts to contact the enrollee and, if applicable, the enrollee's choice not to participate.

Fifth, in § 422.101(f)(1)(v), as discussed in the proposed rule at 89 FR 99490 and in section IV.A.2. of this final rule, we proposed to require D–SNPs that are AIPs conduct a comprehensive HRA that meets all requirements at § 422.101(f)(1)(i) through (iv) as well as any applicable Medicaid requirements, including those at § 438.208, such that enrollees complete a single integrated assessment for Medicare and Medicaid.

Sixth, we proposed to relocate the requirement to ensure that the results from the comprehensive initial and annual HRA conducted for each individual enrolled in the plan are addressed in the enrollee's ICP to § 422.101(f)(1)(vi).

Seventh, we proposed to add a new § 422.101(f)(1)(vii) that would require that SNPs within 30 days of conducting a comprehensive initial HRA or 30 days after the effective date of enrollment, whichever is later, develop and implement a comprehensive ICP that—

- Is person-centered and based on the enrollee's preferences, including for delivery of services and benefits, and needs identified in the HRA;
- Is developed through an interdisciplinary care team with the active participation of the enrollee (or the enrollee's representative, as applicable), as feasible;
- Identifies person-centered goals and objectives (as prioritized by the enrollee), including measurable outcomes as well as specific services and benefits to be provided; and
- Is updated as warranted by changes in the health status or care transitions of enrollees.

While section 1859(f)(5)(A) of the Act uses the term individual throughout, we have used the term enrollee to make it clear that the proposed requirements are for individuals who are enrolled in the SNP, consistent with how we have generally used the term enrollee in other recent rulemaking. For a more detailed discussion of the comprehensive ICP, please refer to 89 FR 99490.

Finally, we proposed to add § 422.101(f)(1)(viii) to require that, for any enrollees who are unable to be reached or decline to participate in the development or updates to the comprehensive ICP, the SNP must document the attempts to contact the enrollee or the enrollee's refusal to participate. While our goal is for SNPs to develop person-centered ICPs, if a SNP is unable to reach an enrollee (after the SNP has fulfilled its obligations as previously described to contact the enrollee for the HRA) or an enrollee declines to participate, then at a minimum the SNP should base the ICP on enrollee encounter data or other available data. We strongly encourage SNPs to continue to try to reach the enrollee even after satisfying the proposed regulatory requirement. We noted at 89 FR 99490 that Resources for Integrated Care (RIC) has developed a brief on Locating and Engaging Members: Key Considerations for Plans Serving Members Dually Eligible for Medicare and Medicaid, which SNPs may find helpful in bolstering their efforts to engage enrollees.[68]

In addition, as a result of these updates, we proposed to redesignate § 422.101(f)(1)(iii) as § 422.101(f)(1)(ix) and redesignate § 422.101(f)(1)(iv) as § 422.101(f)(1)(x) and change the term ''individual's'' to ''enrollee's''.

We posited in the proposed rule (89 FR 99491) that, collectively, our proposals would promote more timely and person-centered HRAs and ICPs for SNP enrollees. Our proposals at § 422.101(f)(1)(i) through (iv), (vi), and (viii) through (x), would codify elements of the CY 2024 Part C Reporting Requirements and Technical Specifications and restructure the current section for better flow. Our proposal at § 422.101(f)(1)(vii) would require that SNPs create and implement the ICP within 30 days of conducting an initial HRA or 30 days after the effective date of enrollment, whichever is later, although many SNPs already complete ICPs within such timeframes. We believe that the benefit gained by the ability for enrollees to quickly have an ICP in place which will assist with coordinating their care in a person-centered manner outweighs the associated burden. We solicited comment on several considerations, including whether to instead adopt alternative timelines for development and implementation of the ICP, whether to allow additional time for the development of the ICP, such as within 60 or 90 days of completion of the HRA, and whether the ICP should not be required when the enrollee is unable to be reached or declines to participate.

[68] *https://www.cms.gov/files/document/ricresource-locatingandengagingmembers-brief.pdf.*

Some States participating in the FAI—including Illinois, Michigan, South Carolina, and Texas—do not require the ICP in these circumstances. We also solicited comment on our consideration of whether text messaging could be useful for contacting enrollees to conduct HRAs in addition to phone calls and how follow-up to conduct the HRA would occur following the contact by text messages.

Finally, for § 422.101(f)(1)(vii) where we use the term ''person-centered,'' we solicited comment on whether to cross-reference the elements of the person-centered planning process at § 441.540(a) as written, a subset of those elements, or a different definition.

In the proposed rule at 89 FR 99508 we discussed our burden estimate for this proposal, stating that we did not expect any new burden to be associated with these requirements. We did not receive any comments on burden estimates for this proposal and are finalizing the proposed burden estimates without change. We received the following comments on this proposal and our responses are as follows:

Comment: Numerous commenters supported our proposals at § 422.101(f)(1)(i) through (x). Many commenters suggested that increased enrollee involvement in the development of the ICP as proposed would help to better ensure integrated care. Some commenters noted that engaging the enrollee and their representative is essential for developing more effective care plans, better reflecting the individual's unique circumstances and making it easier for providers to identify the type of care needed. A commenter stated that such requirements would provide enrollees a meaningful opportunity to offer input to improve the care they receive. Other commenters highlighted that consistent deadlines ensure that assessments and care plans are developed promptly, supporting a positive enrollee experience and relationship with a new health plan, and enabling early identification of health risks and barriers and faster implementation of interventions. A commenter applauded CMS for describing the person-centered ICP process, including goals not specific to medical diagnoses, noting that individualized, person-centered care coordination is the crux of integrated care that allows individuals to access appropriate, effective care in a way that works for their lives. The commenter noted that dually eligible enrollees experience confusion and conflicting information when attempting to navigate both Medicare and Medicaid

benefits and suggested that regulatory requirements on person-centered care, coupled with robust oversight to ensure their implementation, is critical to addressing these challenges. Another commenter noted that the HRA and ICP proposals are especially important for behavioral health treatment, believing that involvement of enrollees and their representatives will help create better care plans and lead to improved medication adherence. Another commenter indicated that generic ICPs that are not tailored to the individual hold little value for enrollees or the plan, while identifying and working towards meaningful life goals is critical to supporting the intended person-centered planning. A few commenters pointed out the value of updating ICPs after a change in health status or care transition to ensure ICPs are relevant and useful for individuals and their care teams. In addition, several commenters stated that these efforts would carry over best practices from the Medicare-Medicaid Plans (MMPs), which commenters described as a preeminent model for integrated care.

Response: We appreciate the support for our proposals to codify timeframes for SNPs to conduct HRAs and develop ICPs, prioritize the involvement of the enrollee or the enrollee's representative, as applicable, in the development of ICPs, and add MOCs to the topics SNPs discuss during their D–SNP EACs. Our proposals would promote more timely and person-centered HRAs and ICPs for SNP enrollees and build on the experience of MMPs. We believe these proposals will provide needed improvements, prompting SNPs to complete HRAs and ICPs timely and develop ICPs that are person-centered and based the enrollee's preferences, including for delivery of services and benefits, and needs identified in the HRA.

Comment: Numerous commenters supported our proposed requirement that SNPs conduct the comprehensive initial HRA within 90 days (before or after) of the effective date of enrollment for all new enrollees. Commenters noted that requiring completion of an HRA within 90 days of the effective date of enrollment would ensure timely identification of enrollee needs and consistency with MMP requirements, Medicare Part C Reporting Requirements, and Medicaid timeframes. A few commenters stated that they did not oppose establishing a 90-day standard given this timeline aligns with Medicaid screening requirements and with current Part C Reporting Requirements that have generally allowed D–SNPs to count Medicaid screenings performed during this timeline as meeting Medicare HRA requirements.

While supportive of CMS establishing a standard timeframe for completion of HRAs, a few commenters, including the Medicaid and CHIP Payment and Access Commission (MACPAC), suggested that CMS consider coordinating the proposed timeframe with State Medicaid requirements or requested clarification on how the proposed timeframe would interact with timeliness standards specified in SMACs. MACPAC recommended that CMS consider adding language that directs D–SNPs to defer to State requirements, as described in the SMAC, for these activities. MACPAC acknowledged that several States, such as Minnesota, recognize the need for more timely completion of the HRA and require a shorter timeline through the SMAC. MACPAC cited recent work on optimizing SMACs, which found States with mature integrated D–SNPs typically set requirements in their SMACs around HRA completion and including specific Medicaid services in the ICP. Another commenter indicated that States already require timely HRA completion within 60 days.

Response: We welcome these comments. Our proposal to require SNPs to conduct comprehensive initial HRAs within 90 days (before or after) the effective date of enrollment for all new enrollees would better align with the Medicaid requirement at § 438.208(b)(3) and, for Medicare, conform to § 422.112(b)(4)(i) and the standard currently described for reporting HRA completion in the Part C Reporting Requirements. We appreciate the request to clarify how the proposed timeframe for SNPs to conduct HRAs would interact with SMAC requirements. Our proposal would establish a maximum amount of time for SNPs to conduct HRAs but does not preclude a State from requiring a shorter timeframe for D–SNPs via the SMAC. We agree with the commenters that some States have already established shorter timeframes for D–SNPs to conduct HRAs. For CY 2025, these include Idaho, Massachusetts, and Minnesota. Also for CY 2025, other States, such as Oregon, Virginia, and Washington, set shorter timeframes for D–SNPs to conduct HRAs when enrollees are referred from a Medicaid managed care plan. Under our proposal, such States would be able to continue requiring (via the SMAC) initial HRAs be conducted in less than 90 days. This is also consistent with the Part C Technical Specifications Document Contract Year 2025, which specifies that SNPs report to CMS the number of initial HRAs completed within 90 days of (before or after) the effective date of enrollment. We do not believe modification to our proposed timeframe for initial HRAs is necessary.

Comment: A few commenters supported our proposal to establish a standard timeframe for conducting HRAs but recommended that CMS modify or clarify the proposal to ensure appropriate consideration for D–SNP-only contracts. Some of these commenters noted that when a State requires MA organizations to create D–SNP-only contracts with a new H contract number, the legacy plan's HRA should still be valid for the prior year; otherwise, this presents issue for States moving to D–SNP-only contracts and the enrollees served by these plans. These commenters requested that CMS consider replacing ''under the same contract number'' with ''under the same parent entity'' to address this issue. A few of these commenters recommended that CMS treat HRAs for enrollees transitioned into D–SNP-only contracts as valid the same way it treats HRAs conducted within the past year when a person enrolls, disenrolls, and re-enrolls into any SNP under the same contract number.

Response: We thank the commenters for their perspectives. As described in the Medicare Part C Technical Specifications, when a person enrolls, disenrolls, and re-enrolls into any SNP under the same contract number, the previous HRA is still considered valid and can continue to be used as long as it is not more than 365 days old. Per the Part C Technical Specifications, enrollees who received an initial HRA and remain continuously enrolled under a MA organization that was part of a consolidation or merger within the same MA organization or parent organization will not need to participate in a second initial HRA. This guidance also applies to enrollees who were crosswalked from a non-renewing D–SNP PBP under a broader MA contract to a D–SNP-only contract per § 422.107(e). We will continue to provide guidance on these types of issues through the Medicare Part C Technical Specifications.

Comment: A commenter suggested that CMS continue to allow SNPs to conduct HRAs before the effective date of enrollment, contingent on State regulations.

Response: We appreciate the opportunity for clarification. Under our proposal, SNPs could conduct the comprehensive initial HRA within 90 days (before or after) of the effective date of enrollment for all new enrollees. As discussed earlier in this section,

under language proposed at § 422.101(f)(1)(i), States could use their State Medicaid agency contracts under § 422.107 to set more stringent timeframe requirements for D–SNPs to conduct initial HRAs. The proposed language at § 422.101(f)(1)(i) would establish a maximum timeframe, not a minimum.

Comment: Numerous commenters, including MACPAC, supported our proposal at § 422.101(f)(1)(iv)(C) that SNPs document their attempts to contact enrollees who cannot be reached to conduct HRAs or develop ICPs, or who decline to participate. MACPAC viewed this effort as increasing transparency, which would assist CMS and States in conducting oversight of D–SNPs. A number of these commenters requested that SNPs be allowed flexibility to determine which methods of outreach work for their enrollees, as well as the timing of the outreach. Some of these commenters cited that engaging enrollees to actively participate in care management is a challenge, and digital literacy and adoption of digital technologies as a primary communications method continues to increase with the SNP population. Several of these commenters recommended that CMS expand the allowable outreach methods beyond non-automated phone calls to include electronic methods, such as text messaging, email, or electronic medical record messages. A commenter emphasized that text messaging has been shown to be an effective mode of communication, particularly among Medicaid enrollees and dually eligible individuals, and suggested that it may be a successful outreach method for the completion of HRAs. Other commenters recommended that CMS not require a specific method through which the enrollee outreach attempts are made. Another commenter requested that CMS specify through guidance whether the required letter can be combined with outreach that the plan currently does, such as sending a printed HRA form with a reminder mailing.

Another commenter asked whether sending a letter to an enrollee on the same day as a phone call attempt would meet the proposed requirement to conduct at least three non-automated attempts on different days, at different times of day.

Response: Consistent with the Medicare Part C Technical Specifications, we proposed to require that the SNP make at least three non-automated phone call attempts, unless an enrollee agrees or declines to participate in the HRA before three attempts are made. We proposed to newly require that these attempts be made on different days at different times of day. Also consistent with the Medicare Part C Technical Specifications, we proposed to require that, if the enrollee has not responded to these attempts, the SNP sends a follow-up letter to conduct the initial or annual risk assessments. We also proposed that, for any enrollees who are unable to be reached or decline to participate in the HRA, the SNP must document the attempts to contact the enrollee and, if applicable, the enrollee's choice not to participate. We appreciate the commenters' responses to our comment solicitation on whether text messaging could be useful for contacting enrollees to conduct HRAs in addition to phone calls. We note that the existing requirement to contact enrollees using non-automated phone calls only pertains to HRA outreach for Medicare Part C Reporting Requirement purposes. CMS does not otherwise prohibit use of alternative outreach for contacting enrollees to conduct HRAs and assumes SNPs use alternative modes of communication already. We acknowledge that use of electronic methods, such as text messaging, emails, and electronic medical records messaging, are widespread alternative uses of communication that could be useful in engaging enrollees to conduct HRAs. We are finalizing modifications to our proposed language at § 422.101(f)(1)(iv)(A) to replace ''at least three non-automated phone call attempts'' with ''at least three attempts to reach the enrollee (not including any automated phone calls).'' This change will allow SNPs to conduct at least three outreach attempts using any form other than automated calls, including but not limited to non-automated phone calls or written notifications, and it will allow SNPs flexibility in engaging enrollees in scheduling and conducting HRAs while prohibiting the opportunity to comply simply through automated calls. Also, we clarify that sending an enrollee a letter on the same day a SNP conducts another outreach attempt would be permissible under the requirement for conducting outreach attempts on different days at different times of day to schedule the initial or annual HRA. We will update the CY 2026 Part C Technical Specifications.

Comment: While numerous commenters supported establishing a standard timeframe for developing ICPs, many of these commenters requested more time to develop the comprehensive ICPs relative to our proposed requirement at § 422.101(f)(1)(vii) that SNPs develop and implement a comprehensive ICP within 30 days of conducting a comprehensive initial HRA or 30 days after the effective date of enrollment, whichever is later. We noted that many SNPs already complete ICPs within such timeframes. We solicited comment on several considerations, including whether to instead adopt alternative timelines for development and implementation of the ICP, such as within 60 or 90 days of completion of the HRA.

A few commenters requested that we extend the ICP development timeframe to within 45 days of HRA completion, and a few additional commenters suggested ICPs be developed within 60 or 90 days of HRA completion. A number of commenters suggested that ICPs be developed within 90 days of HRA completion. Commenters expressed similar rationales for needing the additional time. These included needing more time to reach and engage the enrollees; develop tailored, quality, comprehensive ICPs that meet enrollees' needs and preferences; provide time to coordinate and communicate with health care providers and specialists; allow care managers the ability to prioritize the creation and updating of care plans for enrollees at highest risk; and coordinate with Medicaid enrollment and eligibility dates. A commenter noted the additional time could be helpful in developing ICPs in rural areas with limited service availability. In support of a 90-day requirement, a commenter noted that 90 days is even more important for enrollees who do not respond to first, second, or third outreach attempts and to address various social risk factors of dually eligible enrollees, such as housing insecurity or lack of access to transportation, that create barriers to communication and access to care. Another commenter appreciated the existing practice of MMPs in several States requiring that HRAs and ICPs be conducted within 90 days of enrollment. In support of a 60-day requirement, another commenter noted that the amount of time it currently takes to complete ICPs differs by market with current completion rates ranging from within 45 days to within 60 days of completing an HRA.

Several commenters opined on the second part of the proposed ICP timeframe of ''or 30 days after the effective date of enrollment, whichever is later''. A few of these commenters emphasized that 30 days from the enrollment date, SNPs are still in the process of contacting enrollees to set up the HRA. A commenter noted that creating an ICP 30 days post enrollment

and then reaching out to create an HRA could trigger the need to create an additional ICP. Another commenter mentioned that an enrollee may experience a transition of care after enrollment or completion of an HRA, which may require additional time beyond 30 days to reach the enrollee and create a comprehensive ICP. A few commenters explained that at 30 days post enrollment, SNPs are not likely to have any claims data yet on which to base the ICP in lieu of the HRA. Another commenter stated that requiring real-time involvement of an enrollee in drafting an ICP can lead to delays in care and recommended that CMS allow the care team to draft the ICP based on the enrollee's health care goals and preferences, review the ICP with the enrollee, and then adjust the ICP based on the enrollee's feedback.

MACPAC supported codifying existing timelines for ICPs, including expectations around person-centeredness. Also, MACPAC cautioned that elongated timeframes can pose a risk for individuals in urgent need of LTSS—including home- and community-based services, behavioral health services, or other supports to delay or prevent institutionalization—who may need to seek institutional care if their home- and community-based needs are not addressed promptly. Another commenter emphasized that some States may wish to set shorter timelines for the completion of ICPs and recommended that CMS add language specifying that the Federal timeframe may be superseded by State requirements included in SMACs. Another commenter requested clarification on how the proposed timeliness standards for HRAs would interact with the timeliness standards that Medicaid agencies currently specify in their contracts with plans.

In addition, a commenter inquired about what CMS meant by ''implementation'' of the ICP, noting there are timing aspects to implementation of ICPs that are outside the control of a SNP (for example, obtaining provider signatures, performing home modifications) that may take longer than the timelines outlined in the proposed rule. The commenter explained further that if CMS intended implementation of the ICP to mean development of a care plan—understood to be the complete creation of the care plan that is acknowledged by the enrollee but not yet fully executed—then the timeline CMS proposed at § 422.101(f)(1)(vii) is reasonable.

Response: We thank commenters for sharing their perspectives on our proposal on the timeliness of ICPs.

We proposed that SNPs develop a comprehensive ICP within 30 days of conducting an initial HRA or 30 days after the effective date of enrollment, whichever is later. We clarify that we deliberately used the word ''develop'' rather than ''implement'' in our proposed language at § 422.101(f)(1)(vii) because we do not expect SNPs to have fully implemented an ICP within the timeframes proposed. ICPs generally include multiple goals and objectives, including measurable outcomes, and describe the specific services and benefits to be provided, as proposed at § 422.101(f)(1)(vii)(C). It often takes time to achieve goals and objectives.

We also clarify that in several States, the MMP three-way contracts include person-centered requirements for ICPs beyond what is required for SNPs and specific requirements for the timing of HRAs and ICPs. Most States participating in the FAI (Illinois, Massachusetts, Michigan, Ohio, South Carolina, and Texas) require MMPs to develop both HRAs and ICPs within 90 days or less of enrollment and include enrollees in the development of the ICPs. Under our proposal, SNPs would need to conduct an HRA within 90 days (before or after) of the enrollment effective date and have another 30 days (up to a total of 120 days after enrollment) to develop the ICPs.

Dually eligible individuals have a higher prevalence of many health conditions than their Medicare-only and Medicaid-only peers and are more likely than non-dually eligible Medicare beneficiaries to report being in poor health.[69] A comprehensive ICP, developed with the enrollee, is an important tool for helping SNP enrollees manage that complexity. We are persuaded by the comments articulating the need—in certain circumstances—for additional time to reach and engage an enrollee and their representative, if applicable, understand enrollee needs and preferences and any barriers, and coordinate and communicate with providers to develop a comprehensive ICP that truly coordinates care. We also appreciate concerns about ICP development potentially delaying access to care for enrollees in urgent need of services, such as LTSS.

Weighing these considerations, we are finalizing modifications to our proposed language at § 422.101(f)(1)(vii) to require SNPs to develop a comprehensive ICP within 90 days of conducting a comprehensive initial HRA or 90 days after the effective date of enrollment, whichever is later. We emphasize that 90 days is a regulatory maximum, not a goal or best practice. SNPs should not use the ICP process as a reason to delay provision of urgently needed services. We expect the vast majority of ICPs to be developed much sooner than the maximum allowable timeframe since in many cases using the maximum allowable time after an enrollee's effective date to complete and HRA and ICP would not yield the best outcome for enrollees. SNPs may also choose to develop the HRA and ICP during the same encounter, consistent with the experience of many MMPs. Yet we recognize that some enrollees are more difficult to reach or take more time to develop a relationship with a care coordinator before being ready to engage in an HRA or ICP. We do not want SNPs to sacrifice an enrollee's active involvement in the care planning process because of a shorter compliance timeframe. We will monitor HRA and ICP completion and consider whether changes are necessary through future rulemaking.

Based on review of CY 2025 SMACs, there are at least two States (Idaho and Minnesota) that have used their SMAC to set specific requirements for D–SNPs on the timing of ICP development. Like HRAs, the Federal standard establishes a maximum timeframe for developing the ICP. The language we are finalizing at § 422.101(f)(1)(vii) will require SNPs to develop a comprehensive ICP within 90 days of conducting a comprehensive initial HRA or 90 days after the effective date of enrollment, whichever is later. Nothing in our proposal, or the rule we are finalizing, precludes States from setting more restrictive requirements for D–SNPs as terms in their SMACs.

Comment: A few commenters expressed explicit support for our proposed criteria for comprehensive ICPs at § 422.101(f)(1)(vii)(A) through (D). These commenters encouraged CMS to ensure the enrollee and their representative, if applicable, lead the person-centered planning process, receive a timely copy of their ICP, have meaningful opportunities to amend it, receive plain language information about available care coordination, and have access to care coordination that effectively resolves any access issues. A commenter requested that CMS confirm that the ICP needs to be reviewed, and updated if necessary, when the interdisciplinary care team (ICT) becomes aware of changes in an enrollee's health status.

[69] *https://www.medpac.gov/wp-content/uploads/2024/01/Jan24_MedPAC_MACPAC_DualsDataBook-508_SEC.pdf.*

Response: We appreciate these comments and agree the proposals at § 422.101(f)(1)(vii)(A) through (D) promote active participation of enrollees (or the enrollee's representative, as applicable) in care planning, yielding a care plan based on enrollee's preferences, including for delivery of services and benefits, and their needs identified in the HRA. As proposed, the ICP would identify person-centered goals and objectives, as prioritized by the enrollee, and be updated, as warranted by changes in health status or care transitions. We expect the development of the ICP through the ICT will include plain language information about available care coordination and care coordinators/care managers will assist each enrollee in accessing services included in their ICP. We also confirm, per language we are finalizing at § 422.101(f)(1)(vii)(D), that SNPs will be required to update an ICP as warranted by changes in the health status or care transitions of enrollees.

Comment: A number of commenters expressed support for care coordination and care planning activities.

A commenter recommended that CMS ensure enrollees know who their care coordinator/care manager is and how they can file a grievance related to care coordination and require core competencies responsive to the needs of dually eligible individuals (for example, knowledge of community integration, person-centered planning, culturally competent and trauma informed care delivery practices, Medicaid home- and community-based services and Medicare home health benefits, health-related social needs, dignity of risk, and health equity). This commenter further recommended that an enrollee's care team be notified when they are admitted to a hospital or skilled nursing facility, and SNPs should be monitored for how well they implement notification requirements when an at-risk enrollee experiences a care transition.

A few commenters explained that while ICPs are intended to empower enrollees to have control over their health care, they may not address the full range of Medicare and Medicaid benefits. To make the ICP a meaningful tool, these commenters recommended that ICPs should be integrated and address all benefits for which an enrollee is eligible.

Response: We appreciate these comments. We consider sharing contact information for care coordinators/care managers with enrollees and establishing core competencies for care coordinators/care managers as best practices for care coordination. Some States, such as Massachusetts, New Jersey, and Virginia, include language in their CY 2025 SMACs requiring D–SNPs to provide enrollees with updated contract information for their care managers. We also expect ICTs to be notified of any enrollee hospital or skilled nursing facility admissions. We believe such notifications are common practice and many D–SNPs report hospital and SNF admissions to State Medicaid agencies or their designees per § 422.107(d)(1). Some States, such as Pennsylvania, include language in their SMACs, for D–SNPs to require contracted hospitals, nursing facilities, and skilled nursing facilities notify the D–SNP, including the D–SNP service coordinator, within 24 hours of any enrollee visits, admissions, and discharges. The service coordinator must follow-up to address care needs. Also, CMS audits of SNPs include review of enrollee care transitions.

Our proposed language at § 422.101(f)(1)(vii)(A) would require an ICP to be based on the enrollee's preferences, including for delivery of services and benefits, and their needs identified in the HRA. For D–SNPs, this includes describing coordination with Medicaid for any needed services at a minimum and for integrated D–SNPs providing Medicare and Medicaid services and benefits. We remind D–SNPs of the requirements at § 422.562(a)(5) that D–SNPs must offer to assist their enrollees in 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 a Medicaid fee-for-service program or a Medicaid managed care plan. We also emphasize that all MA plans, including SNPs, provide the Evidence of Coverage to enrollees each year. Chapter 9 of the Evidence of Coverage outlines steps for how enrollees can file appeals and grievances.

Comment: A commenter recognized the person-centered care plans being appropriate for certain populations (enrollees in D–SNPs or with well-controlled chronic conditions, for example) but suggested a medical focused care plan is often more appropriate for I–SNP and C–SNP enrollees. The commenter advised that education on medications, treatment adherence, and the importance of provider appointments are vital parts of managing chronic conditions and should be part of the care plan, when applicable.

Response: We thank the commenter for sharing this perspective. As stated in the proposed rule at 89 FR 99490, we intend for ICPs to engage and motivate enrollees by including goals that are meaningful to each enrollee. These may include goals that are not specific to a medical diagnosis, such as attending a child's graduation, pursuing higher education, or being able to attend religious services each week. The ICP should also outline steps for managing conditions, such as diabetes or high blood pressure, that may have been identified in the HRA and impact the enrollee's ability to meet their goals. The steps should also take account of the enrollee's preferences for delivery of any needed services or benefits. For example, an enrollee may have a goal of attending a child's graduation, but weight and mobility limitations are current barriers identified in the HRA. The care plan would include specific steps to help the enrollee lose weight and improve mobility, which would support the enrollee's efforts to attend the graduation. This personalized approach balances a medical focus with other goals that are meaningful to enrollees.

Comment: A few commenters shared their perspectives on whether ICPs should be required when the enrollee cannot be reached or declines to participate. Some of these commenters suggested that removing the ICP requirement when enrollees cannot be reached would remove the administrative burden and potential enrollee dissatisfaction caused by repeated attempts to reach these enrollees and allow plans to repurpose that time to managing care for enrollees who are willing to participate. Noting that SNPs continue to struggle with enrollees who are unable to reach or decline to participate in the HRA and ICP processes, another commenter indicated that there should not be a Federal requirement for ICPs in these cases but suggested that CMS consider allowing a separate timeframe for conducting these HRAs and ICPs for enrollees who eventually agree to participate. The commenter explained that a SNP could start a new clock for HRA completion and ICP development (which would override the effective date of enrollment) based on the date the enrollee expresses willingness to engage. To allow sufficient time for the enrollees to meaningfully participate in care planning, the commenter suggested that SNPs conduct an HRA within 90 days of the date an enrollee is willing to engage and develop an ICP within 60 days of conducting the HRA.

Another commenter noted that it works with States to encourage enrollee participation in HRAs and ICPs at the time of Medicaid enrollment and annually thereafter. This commenter surmised that primary care providers and care managers may have best practices to engage enrollees in HRAs and ICPs and recommended that CMS maintain a repository that shares this information.

Response: We appreciate these comments regarding our proposed language at § 422.101(f)(1)(viii), which would require SNPs to document the attempts to contact enrollees who they are unable to reach or refuse to participate. As we stated in the proposed rule (89 FR 99491), our goal is for SNPs to develop person-centered ICPs. But, if a SNP is unable to reach an enrollee (after the SNP has fulfilled its obligations as previously described to contact the enrollee for the HRA) or an enrollee declines to participate, then at a minimum the SNP should base the ICP on enrollee encounter data or other available data. We strongly encourage SNPs to continue to try to reach the enrollee even after satisfying the regulatory requirement but recognize the need to take a balanced approach to outreach to minimize enrollee abrasion.

We thank the commenter for the suggested alternative for enrollees who are hard to reach but ultimately agree to participate in HRA and ICP processes. We will take this suggestion as well as the recommendation to maintain a repository of best practices for engaging enrollees under consideration for future rulemaking.

Comment: A few commenters recommended that CMS modify the Star Ratings measure SNP Care Management to account for refusals and documented inability to reach enrollees.

Response: We thank the commenters for their input, but we do not believe the suggested change is needed. As articulated in the CY 2025 Part C Reporting Requirements, the SNP Care Management reporting section already includes elements to capture counts of enrollees that refused and enrollees that the SNP was unable to reach. However, as noted in the CY 2025 Medicare Part C and D Star Ratings Technical Notes, those elements are not included in the calculation of the SNP Care Management measure for Star Ratings purposes. This is so that MA organizations are incentivized to reach and engage enrollees for purposes of completing an HRA.

Comment: A commenter proposed that CMS allow SNPs to apply risk stratification methods for developing and updating ICPs and to focus higher touch ICP development efforts on higher-needs enrollees. The commenter explains that for enrollees at lower risk strata and/or with few needs or care plan changes, detailed engagement with their SNP plan to co-develop an ICP and to identify and track person-centered goals is a higher level of service than most enrollees require or want. Alternatively, the commenter suggests SNPs focus lower risk enrollees on ensuring engagement with a primary care provider and health screenings.

Response: We thank the commenter for sharing this perspective. Enrollment of dually eligible individuals is predominant in D–SNPs, I–SNPs, and some C–SNPs, and these individuals are navigating the complexity of Medicare and Medicaid programs. Dually eligible individuals have a higher prevalence of many health conditions than their Medicare-only and Medicaid-only peers and are more likely than non-dually eligible Medicare beneficiaries to report being in poor health.[70] A comprehensive ICP, developed with the enrollee, is an important tool for helping SNP enrollees manage that complexity regardless of risk strata. We also note that some States include more frequent requirements for care plan updates based on risk stratification levels. Nothing in our proposal would preclude SNPs from more frequent updates to the ICP or higher-touch approaches based on risk stratification.

Comment: A commenter recommended inclusion of family caregivers in conducting HRAs and developing ICPs and using caregiver assessments as ways to improve the success of the ICP for the enrollee. The commenter suggested that including caregivers in these discussions would help them understand the enrollee's care needs, effectively provide care, and highlight any necessary training. The commenter further explained that employing a caregiver assessment, such as the Caregiver Profiles©17 developed by The Rosalynn Carter Institute for Caregivers and Duke University, would inform the potential success of the care plan and whether it would place undue burden on the caregiver. The commenter emphasized the need for providers to understand social determinants of health factors that could impede successful outcomes coding to document SDOH data. Finally, the commenter advocated that MA organizations publicly provide information on available caregiver programs and supports.

Response: We welcome these comments and agree caregiver participation in HRA and ICP discussions can be valuable. Our proposed requirements at § 422.101(f)(1)(i) through (x) would promote development of a comprehensive ICP that is person-centered, based on the enrollee's preferences, and developed through an ICT with the active participation of the enrollee (or the enrollee's representative, as applicable). Nothing in our proposed requirements would preclude a caregiver from participating in the HRA or ICP processes if such participation is consistent with the enrollee's preferences.

Comment: A commenter noted that several SNPs are participating in an effort by the National Committee for Quality Assurance (NCQA) to develop and test person-centered outcome measures, which will not be ready for several years. The commenter suggested that more work be done before implementing requirements around person-centered care planning.

Response: We appreciate the commenter's perspective. We look forward to learning from these efforts as they progress but are not compelled to delay the requirements proposed at § 422.101(f)(1)(vii) through (viii). We will monitor the requirements finalized at § 422.101(f)(1)(vii) through (viii) and consider that experience as well as other information gained through efforts such as those described by the commenter in making any refinements in future rulemaking.

Comment: A commenter explained that it would be of great value to have States adopt the Federal model of care requirements since they are standardized and well-established in the field, D–SNPs already follow these requirements, and NCQA (under contract with CMS) already reviews them through a comprehensive MOC that is subject to CMS and oversight. As States consider how to modify their HRA, social risk screening, ICP, or ICT requirements to align with Federal MOC guidelines, the commenter suggested that CMS provide deemed status on a temporary basis for D–SNPs that meet all State care management requirements as a substitute for Federal MOC requirements. The commenter acknowledged that some States may already have State-specific requirements outlined in their SMACs, which do not align with Federal Medicare requirements, and these States may need some time to modify their requirements or may not be able to adopt the Federal standards due to State legislative language or policy governing

[70] *https://www.medpac.gov/wp-content/uploads/2024/01/Jan24_MedPAC_MACPAC_DualsDataBook-508_SEC.pdf.*

Medicaid. If CMS did not favor such deemed status, the commenter urged CMS to work with States to create a comprehensive crosswalk document showing each State's requirements and policy around HRA, social risk screening, care planning, care management, care teams, and oversight activities by State. Such a crosswalk would provide awareness of similarities and differences across care coordination elements.

Response: We appreciate these comments and will take them into consideration for future rulemaking. Based on our experience reviewing SMACs, we are not aware of any State-specific care coordination requirements that conflict with Federal MOC requirements. We reiterate that our proposals do not circumvent States' ability to establish—in their SMACs—requirements that are more restrictive than the Federal requirements we are finalizing here. Nor do our proposals affect the MOC review and approval processes.

Comment: A commenter advised that better care coordination between Medicare and Medicaid plans, such as through ICPs and improved communication, is needed for enrollees whose plans are aligned regardless of whether the D–SNPs are AIPs. This commenter gave the example of Pennsylvania having 52,000 dually eligible individuals enrolled in Medicaid plans aligned with D–SNPs, but none of the D–SNPs are AIPs. The commenter noted that while the State encourages individuals to enroll in Medicaid plans aligned with D–SNPs, aligned enrollees see little difference in access to and coordination of services compared to unaligned enrollees, citing problems related to poor coordination and communication related to motorized wheelchair repairs. The commenter also highlighted that D–SNPs should better educate their Medicare provider networks about coverage differences between Medicare and Medicaid. The commenter explained that this could help avoid instances where Medicare providers fail to submit a prior authorization request to the Medicaid managed care plan (on behalf of an enrollee) because they believe Medicaid can only cover services and benefits secondary to Medicare rather than Medicaid providing primary coverage in certain situations.

Response: We appreciate the commenter sharing this detailed perspective. The requirements we proposed at § 422.101(f)(1)(vii) would apply to all SNPs, including AIP and non-AIP D–SNPs, and, for D–SNPs, this includes describing coordination with Medicaid for any needed services at a minimum and for integrated D–SNPs providing Medicare and Medicaid services and benefits. We also remind D–SNPs of the requirements at § 422.562(a)(5) that D–SNPs must offer to assist their enrollees in 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 a Medicaid fee-for-service program or a Medicaid managed care plan. If the enrollee accepts the offer of assistance, the plan must provide the assistance. At § 422.562(a)(5)(i), we outline examples of the assistance D–SNPs can provide, which include explaining to an enrollee how to make a request for a Medicaid service authorization, how to file an appeal, and assisting the enrollee in contacting the enrollee's specific Medicaid fee-for-service program or Medicaid managed care plan, regardless of whether the Medicaid managed care plan is affiliated with the enrollee's D–SNP. Also, we agree with the commenter that it is worthwhile for D–SNPs to educate their providers about Medicaid coverage.

Comment: Several commenters expressed concern that SNPs, including AIP D–SNPs, may not be providing individualized planning and care delivery, in part due to lack of oversight. Another commenter stated that process requirements, like those related to conducting HRA and ICPs, are not sufficient to drive improvement in care outcomes for these enrollees and urged CMS to collect and publicly report data on how many individuals participate in assessments and care plans. These commenters also recommended that CMS conduct random audits to verify if ICPs reflect an individual's care objectives rather than standardized template language; analysis and action based on grievances specific to the person-centered planning processes; structured opportunities for enrollees to provide feedback on their person-centered planning experiences, including their ability to actively lead the drafting process, make changes to their care plans, and have care plans reflect their needs and goals; publication of outcomes from audits, enrollee feedback, and quality measures; and corrective action plans for SNPs that do not meet requirements. With additional requirements and oversight, these commenters indicated dually eligible individuals could have better access to quality care that meets their needs.

Response: We thank the commenters for their input and agree that process requirements, alone, do not guarantee good outcomes and experiences for enrollees. Currently, CMS audits HRA and ICP completion as well as care transitions. We expect these audits to continue and will update the CMS audit protocols, as necessary, for the requirements finalized in this section. We will also continue to monitor enrollee satisfaction and SNP reporting on HRA completion and consider other opportunities to improve enrollee outcomes and experiences.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the provisions as proposed at § 422.101(f)(1)(i) through (x), but with the following modifications: We are modifying the language at § 422.101(f)(1)(iv)(A) to read ''Make at least three attempts to reach the enrollee (not including any automated phone calls), unless an enrollee agrees or declines to participate in the HRA before three attempts are made, on different days at different times of day to reach the enrollee to schedule the comprehensive initial or annual HRA.'' We are also modifying the introductory language at § 422.101(f)(1)(vii) to read: ''Within 90 days of conducting a comprehensive initial HRA or 90 days after the effective date of enrollment, whichever is later, develop a comprehensive individualized plan of care that meets all of the following:''

5. Comment Solicitation—Making State Medicaid Agency Contracts Public

Section 164 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275) amended section 1859(f) of the Act to require that a D–SNP contract with the State Medicaid agency in each State in which the D–SNP operates. We refer to such contracts as State Medicaid agency contracts, or SMACs. As we have emphasized in rulemaking over the last several years, SMACs are important vehicles for integrating the delivery of Medicare and Medicaid services and improving experiences for dually eligible individuals. In many States, the provisions in the SMAC are of significant public policy interest, affecting the ways that many people experience the Medicare and Medicaid programs.

Some States, including Indiana, New Jersey, and Washington, have posted SMACs and any SMAC amendments—usually as a single model agreement,

rather than the individual signed copies with each D–SNP—on their websites. We encourage all States to post the content of the SMACs online. However, we have never done so on a CMS website.

We posited in the proposed rule (89 FR 99492) that posting SMACs would improve public transparency on the important requirements included in these agreements. This, in turn, would promote accountability in implementing the terms of the SMAC and make it easier for States, advocates, researchers, and others to identify promising practices or opportunities for improvement across States. However, while we review all SMACs for compliance with the requirements of § 422.107, CMS is not a signatory to the SMACs. And we have never systematically analyzed the extent to which SMACs may include confidential commercial or financial information that should not be shared publicly.

We solicited comments on whether and how CMS should post SMACs online. We are not responding to each specific comment submitted on this comment solicitation, but we appreciate all the comments and interest on this topic. We received overwhelming support for making the substantive content of SMACs publicly available. We intend to begin working through the operational process to make that possible. We will weigh all concerns, comments, and suggestions throughout. In the meantime, we continue to encourage States to post the content of their SMACs.

B. Clarifying Highly Integrated Dual Eligible Special Needs Plan Definition Relative to Oregon's Coordinated Care Organization Structure (§ 422.2)

The definition of HIDE SNPs is codified at § 422.2. According to this definition, a HIDE SNP, in addition to meeting other requirements, is a D–SNP offered by an MA organization that provides coverage of Medicaid benefits under a capitated contract between the State Medicaid agency and the MA organization itself, the MA organization's parent organization, or another entity that is owned and controlled by its parent organization. CMS defined this term in the final rule titled ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021,'' which appeared in the April 16, 2019, **Federal Register** (hereinafter referred to as the April 2019 final rule) (84 FR 15705), and further refined it in the final rule titled ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which appeared in the May 9, 2022, **Federal Register** (hereinafter referred to as the May 2022 final rule) (87 FR 27755).

The May 2022 final rule revised the HIDE SNP definition to outline more clearly the services HIDE SNPs must cover in their contracts with State Medicaid agencies to include LTSS or behavioral health services to the extent Medicaid coverage of those benefits is available to individuals eligible to enroll in a HIDE SNP, and required the capitated contract with the State Medicaid agency to cover the entire service area of the D–SNP beginning in 2025. The revisions facilitate HIDE SNP enrollees having access to both Medicare and Medicaid benefits from a single parent organization.

However, the definition of HIDE SNP at § 422.2 does not explicitly account for certain ownership arrangements of Medicaid managed care organizations that operate Medicaid health plans affiliated with D–SNPs that we believe should meet the definition of and be treated as a HIDE SNP. In Oregon, the State Medicaid managed care program utilizes community-governed organizations called coordinated care organizations (CCOs) to provide comprehensive Medicaid benefits, including physical, behavioral, and dental services.[71] These nonprofit community-governed organizations are locally based (rather than national organizations), and may be single corporate structures or networks of providers with contractual relationships, per Oregon law.[72]

In the Portland metro area that includes Clackamas, Multnomah, and Washington counties, one of the CCOs delivering Medicaid benefits to eligible residents is Health Share, a nonprofit public benefit corporation with 11 founding members that include providers, health systems, and county governments. A subset of these founding members includes organizations with which Health Share contracts to provide covered Medicaid physical, behavioral, and dental health services to beneficiaries assigned to them on a fully capitated basis through agreements called Integrated Delivery System (IDS) Participation Contracts. These founding members with IDS Participation Contracts administer Medicaid benefits on Health Share's behalf and assume full risk for their assigned beneficiaries' services.

Three of these Health Share founding members are organizations that also operate a D–SNP with a service area that includes the three-county Portland metro area. Dually eligible individuals in that three-county service area who are enrolled in one of these D–SNPs can therefore receive their Medicaid benefits from the same organization from which they receive their Medicare benefits, through the organization's IDS Participation Contract with Health Share to provide Medicaid benefits. Oregon estimates that between 80 and 91 percent of the Health Share enrollees who receive Medicare benefits through a D–SNP are assigned to the same organization for their Medicaid benefits, depending on which of the three organizations in which they are enrolled. We believe this arrangement is functionally similar to and should be treated as meeting the HIDE SNP definition because dually eligible individuals are receiving their Medicare and Medicaid benefits from the same organization or the parent organization of the entities that operate the D–SNP and the Medicaid managed care plan. While that organization does not *directly* hold a contract with the State Medicaid agency for Medicaid managed care services, it is responsible for the full obligations of the CCO contract with the State Medicaid agency through its IDS Participation Contract with Health Share. Furthermore, the current HIDE SNP definition requires the capitated contract to be between the State Medicaid agency and either the MA organization itself, the MA organization's parent organization, or another entity that is owned and controlled by its parent organization. While the founding members of Health Share do not meet the CMS definition of a parent organization,[73] founding members appoint representatives to Health Share's board of directors, vote on key leadership decisions, serve on standing committees of the board (including committees that oversee Health Share's contractual obligations), and financially support Health Share. We believe this is functionally an entity that is owned and controlled by the MA

[71] *https://www.oregon.gov/oha/HPA/Pages/CCOs-Oregon.aspx.*

[72] *https://oregon.public.law/statutes/ors_414.572.*

[73] CMS considers a parent organization to be the legal entity that owns a controlling interest in a contracting organization.

organization's parent organization as included in paragraph (1)(ii) of the HIDE SNP definition. For these reasons, we categorized these D–SNPs in the three-county Portland area as HIDE SNPs for CY 2025 as part of our review of Oregon's SMAC agreements with D–SNPs operating in the State. Nonetheless, given the foregoing ambiguity about the applicability of the existing HIDE SNP definition, we proposed to modify the HIDE definition at § 422.2 to make clear that it applies to this type of arrangement, whether in Oregon or elsewhere.

Under our authority at section 1859(f)(8)(D) of the Act to require that all D–SNPs meet certain minimum criteria for Medicare and Medicaid integration, and under section 1856(b) to establish requirements by regulation, we proposed to amend the definition of a HIDE SNP at § 422.2 to make minor edits to paragraph (1) and add a new paragraph (1)(iii) to the definition to explicitly describe a scenario in which there is a capitated contract between the State Medicaid agency and a local nonprofit public benefit corporation of which the MA organization is a founding member. The proposed change would clarify that D–SNPs with this ownership arrangement meet the HIDE SNP definition. (We did not propose any changes to paragraph (2) or (3) of the HIDE SNP definition.)

In developing this proposal, we considered other scenarios that have arisen related to the HIDE SNP definition as described at 89 FR 99493. In the proposed rule, we invited comments on our proposed clarifications to the HIDE SNP definition, including our use of the term ''founding member'' and whether the language we proposed was sufficiently narrow such that it does not unintentionally encompass additional delegation situations that are contrary to our goals of increasing the level of integration between D–SNPs and affiliated Medicaid managed care plans and facilitating D–SNP enrollees having access to Medicare and Medicaid benefits provided by the same parent organization. Additionally, we welcomed comment on whether there are existing scenarios like Health Share we may want to consider as we revise the HIDE SNP definition.

We do not believe that this provision adds any additional burden to the three D–SNPs in Oregon with affiliated Medicaid CCOs, which we have already classified as HIDE SNPs in recent years. We do not believe that any additional work from the three D–SNPs would amount to burden above and beyond what is routine, and as such, this work has already been accounted for in other burden estimates under OMB control number 0938–1410 (CMS–10796).

We did not receive any comments on burden estimates for this proposal and are finalizing the proposed burden estimates without change. We received the following comments on this proposal and our responses follow:

Comment: All of the commenters who commented on this topic supported our proposal to amend the definition of a HIDE SNP at § 422.2 to make minor edits to paragraph (1) and add a new paragraph (1)(iii) to the definition to explicitly describe a scenario in which there is a capitated contract between the State Medicaid agency and a local nonprofit public benefit corporation of which the MA organization is a founding member.

Response: We thank the commenters for their support.

Comment: A few commenters noted that this proposal, while highlighting Oregon's CCO structure, could allow States to pursue alternative structures for Medicaid managed care and could apply to other States that adopt a similar model.

Response: We thank the commenters for their interest in the application of this proposal to States outside of Oregon. We remind commenters that, as described at 89 FR 99493, we proposed a very narrow change to the HIDE definition at § 422.2, even though it is not regulatorily limited to Oregon.

Comment: A few commenters requested clarification as to how this proposed amendment to § 422.2 would affect policy at § 422.514(h), which, beginning in 2027, limits enrollment in certain D–SNPs to those individuals who are also enrolled in an affiliated Medicaid managed care organization (MCO), and limits 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, can offer in the same service area as an affiliated Medicaid MCO.

Response: We thank the commenters for the questions. The regulations at § 422.514(h)(1) are applicable where the 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 holds the Medicaid MCO contract with the State. In the scenario described by commenters, as we understand it, neither the MA organization offering the D–SNP, its parent organization, nor any entity that shares a parent organization with the MA organization holds the Medicaid MCO contract with the State. As such, the MA organization offering the D–SNP does not meet the condition set forth at § 422.514(h), and therefore the other requirement and limitations in § 422.514(h) would not apply. We will work with individual States and plans to assess specific situations and consider clarifications in sub-regulatory guidance or future rulemaking as necessary to clarify this and similar scenarios.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing revisions to § 422.2, as proposed.

We also note that some of the public comments received for the provisions related to the integration of Medicare and Medicaid were outside of the scope of the proposed rule. These comments covered topics such as: full integration standard for coverage and care for dually eligible individuals, C–SNPs with cost-sharing designed to attract dually eligible individuals, and concerns regarding a provision that CMS finalized in the April 2025 final rule at § 422.514(h). The following are our responses to these comments:

Comment: A commenter recommended that CMS establish a full integration standard for coverage and care for dually eligible individuals. This would include one benefit package with medical, behavioral health, dental, LTSS, fully aligned benefits and financing, and a single, streamlined set of quality and performance measures. Another commenter described that providers experience difficulty knowing when a secondary claim is paid appropriately or when to appeal for payment, especially for individuals enrolled in HIDE SNPs, FIDE SNPs, and AIPs. The commenter recommended that CMS require these plans to internally crossover or adjudicate claims without a provider having to submit a secondary claim. A commenter explained that many dually eligible individuals with mental health and substance use disorders inadvertently lose access to the Mental Health Parity and Addiction Equity Act of 2008 (Parity Act) protections associated with their Medicaid benefits when they enroll in D–SNPs that are not subject to the Parity Act. The commenter urged CMS to work with Congress to require D–SNPs be subject to the Parity Act.

Response: We appreciate these comments, but they are out of scope for this rulemaking. We will consider them for future rulemaking.

Comment: A commenter recommended that CMS leverage and facilitate access to PACE, which it described as a key part of any CMS

solution to achieve meaningful Medicare and Medicaid integration for dually eligible individuals. The commenter also advocated that CMS support enrollment in PACE at any point during the month and ensure that enrollment systems are designed to expedite enrollment in PACE for individuals who choose this option.

Response: We thank the commenter and agree that PACE is another option for dually eligible enrollees to receive integrated care. While this comment is out of scope for the current rulemaking, we will take it under consideration for future rulemaking.

Comment: A few commenters expressed concern about the increase in the number of C–SNPs with cost-sharing designed to attract dually eligible individuals and noted that C–SNPs are excluded from the D–SNP look-alike requirements at § 422.514(d). These commenters emphasized that the increase and presence of these C–SNPs may erode the effectiveness of CMS and State Medicare-Medicaid integration efforts and recommend that CMS assess this issue and apply the D–SNP look-alike threshold requirements to C–SNPs.

Response: We appreciate these comments. They are out of scope for the current rulemaking, but we will consider for future rulemaking.

Comment: A commenter indicated mandating MA organizations to hold Medicaid contracts for non-senior populations dilutes senior-focused expertise and limits choice. The commenter recommended that Federal policies prioritize integration programs that preserve a senior-first focus without requiring non-senior services.

Response: We appreciate the commenter's perspective. We note that States have broad flexibility to establish parameters for their D–SNPs through State Medicaid agency contract authority under MIPPA, including enrollee eligibility.

Comment: A commenter described a recent survey of State Health Insurance Assistance Program (SHIP) counselors, which found that many individuals are unaware of D–SNPs or the benefits they provide, States and plans do not provide education to potentially eligible individuals, and SHIP counselors have difficulty obtaining information from States and plans regarding individual eligibility for AIP D–SNPs.

Response: We appreciate this comment and will consider ways to better empower and inform SHIP counselors about D–SNPs, eligibility for D–SNPs and the benefits they provide. We do have a resource available on the Special Enrollment Periods (SEPs) for dually eligible and low-income subsidy eligible individuals available at *https://www.cms.gov/files/document/duals-lissepsjobaid01012025.pdf.* We designed the resource to provide an overview of the SEPs and help anyone who assists dually eligible and LIS-only eligible individuals with their Medicare coverage choices-including SHIP counselors.

Comment: A few commenters expressed concerns regarding a provision that CMS finalized in the April 2025 final rule at § 422.514(h). A commenter suggested that CMS amend § 422.514(h) to allow MA organizations to offer multiple D–SNPs if they are fully integrated and have exclusively aligned enrollment. Another commenter supported CMS's overall goals of increased integration and alignment for D–SNPs but expressed concerns about the complexity of determining eligibility for D–SNPs under § 422.514(h), State burden, and State autonomy in crafting programs for their dually eligible individuals. The commenter also raised the potential misalignment in timing between State Medicaid competitive bid cycles and Medicare Advantage timelines for bids, networks, and service area expansions or reductions that might result in D–SNPs disenrolling individuals to Medicare FFS when an affiliated Medicaid contract expires. The commenter further suggested that the exception provided at § 422.514(h)(3)(i)—which allows for parent organizations to provide multiple D–SNPs in the same service area for full-benefit dually eligible when the State Medicaid agency's contract differentiates enrollment into D–SNPs by age group, eligibility or benefit design—will result in a confusing collection of plans that require navigation and support from agents, SHIP counselors, and others.

Response: We appreciate comments on § 422.514(h), but adjustments to § 422.514(h) are outside the scope of this rulemaking. We are continuing to provide technical assistance to States and MA organizations on § 422.514(h). For example, CMS developed a frequently asked questions (FAQ) document to help MA organizations, States, and other interested parties prepare for the implementation of § 422.514(h). The FAQs are located on our website at *https://www.cms.gov/medicare/medicaid-coordination/about/dsnps* under the 2025 Integrated D–SNPs section. We look forward to working with States and MA organizations on successfully implementation.

V. Technical Changes

A. Technical Change to the Specific Rights to Which a PACE Participant Is Entitled (§ 460.112)

In the Medicare Program: Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE) (hereinafter referred to as the April 2024 final rule), we finalized changes to the regulations impacting the specific rights to which a participant is entitled (89 FR 30756). Specifically, we added a new paragraph (a) which was entitled ''right to treatment,'' and redesignated existing § 460.112(a) through (c) as § 460.112(b) through (d). In the new paragraph (a), we finalized that each participant has the right to appropriate and timely treatment for their health conditions.

On May 6, 2024, we issued the Nondiscrimination in Health Programs and Activities final rule (hereinafter referred to as the Nondiscrimination 2024 final rule) (89 FR 37522), with the intention of adding language to the respect and nondiscrimination paragraph (which had been redesignated from § 460.112(a) to § 460.112(b) in the April 2024 final rule). Because the respect and nondiscrimination paragraph had only been redesignated a few weeks prior to the issuance of the Nondiscrimination 2024 final rule, the updated language was added in error to the newly added paragraph (a) instead of the redesignated paragraph (b); thereby replacing the right to treatment language provision added to paragraph (a) through the April 2024 final rule. As a result of this error, the current regulation text has two identically titled paragraphs (§ 460.112(a) and (b)). To avoid any further confusion and for the reasons explained in the April 2024 final rule (89 FR 30756), we proposed to make a technical change to reinstate the language that each participant has the right to appropriate and timely treatment for their health conditions in § 460.112(b) instead of in § 460.112(a).

We also finalized two paragraphs under § 460.112(a) in the April 2024 final rule. Paragraph (a)(1) related to the right to receive all care and services needed to improve or maintain the participant's health condition and attain the highest practicable physical, emotional, and social well-being. Paragraph (a)(2) related to the participants' rights to access emergency

health care services when and where the need arises without prior authorization by the PACE interdisciplinary team. Since the two paragraphs under § 460.112(a), paragraphs (a)(1) and (2), more appropriately align with the requirement in the ''right to treatment'' paragraph, we proposed to redesignate § 460.112(a)(1) and (2) as § 460.112(b)(1) and (2). The paragraphs under § 460.112(b) more appropriately align with the ''respect and nondiscrimination'' paragraph. Therefore, we proposed to redesignate the paragraphs under § 460.112(b)(1) through (8) as § 460.112(a)(1) through (8).

Finally, we note that two courts, in *Tennessee* v. *Becerra,* No. 1:24–cv–161–LG–BWR (S.D. Miss.), and *Texas* v. *Becerra,* 6:24–cv–211–JDK (E.D. Tex.), have issued orders that, in relevant part, stay nationwide the effective date of, respectively, § 460.112 to the extent it ''extend[s] discrimination on the basis of sex to include discrimination on the basis of gender identity'' and § 460.112(a). Nothing in this technical change is intended to affect the scope of those orders or CMS's compliance with those orders as long as they remain in effect.

This provision is technical and is therefore not expected to have economic impact beyond current operating expenses.

We solicited comments on these proposals. A summary of the comments received, and our responses follow.

Comment: A commenter supported our technical change and requested that we expeditiously issue an updated PACE Participant Rights template to reflect the correction. Another commenter expressed agreement with the purpose of the change, but noted their concern about the impact on PACE organizations that would need to update materials. The commenter requested that CMS adopt a regular schedule for implementing technical and other necessary updates and suggested that schedule could be every four years to minimize the impact to PACE organizations' administrative processes.

Response: We thank the commenter for their support, and we are finalizing this technical change as proposed. While we understand the commenter's concern regarding the impact of regulatory changes on PACE organizations, it is important that CMS move quickly to address and correct errors in regulatory text to minimize any potentially negative impact to beneficiaries. The PACE Participant Rights template was updated in June 2024 to incorporate regulatory requirements from the April 2024 final rule and this technical change would not impact the template.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the technical change to § 460.112 as proposed.

B. Technical Change to PACE Contracted Services (§ 460.70(e)(2))

In the April 2024 final rule, we finalized changes to the PACE service delivery requirements at § 460.98. Specifically, we removed paragraph (b)(4), added a new paragraph at § 460.98(c), and redesignated paragraphs (b)(5) and (c) through (e) as paragraphs (b)(4) and (d) through (f), respectively (89 FR 30845). As part of these changes, the paragraph titled ''Minimum services furnished at each PACE center'' was redesignated from § 460.98(c) to § 460.98(d). However, the April 2024 final rule did not include a correction to the cross-reference at § 460.70(e)(2) to reflect the redesignation of ''Minimum services furnished at each PACE center'' requirements from § 460.98(c) to § 460.98(d).

Therefore, we proposed a technical change at § 460.70(e)(2) to update the cross-reference from § 460.98(c) to § 460.98(d), which would affirm the connection between § 460.70(e)(2) and the ''Minimum services furnished at each PACE center'' requirements at the redesignated § 460.98(d).

This technical change would not impose any new requirements or burden on PACE organizations. Additionally, we expect no cost impact to the Medicare Trust Funds.

We solicited comment on the proposed technical change. A summary of the comment received, and our response, follows.

Comment: A commenter expressed support for our proposal to amend the cross-reference at § 460.70(e)(2) from § 460.98(c) to § 460.98(d) as a clarifying change.

Response: We thank the commenter for their support. We agree that this technical change provides clarification to the requirement at § 460.70(e)(2).

After consideration of the public comment we received, we are finalizing the technical change at § 460.70(e)(2) as proposed.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information,'' as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the proposed rule (89 FR 99340), 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 Medicare Prescription Payment Plan Pharmacy POS Notification Process and Clarifying MA Organization Determinations to Enhance Enrollee Protections in Inpatient Settings. A summary of the comments and our response follows under section VI.B.5. and 7. of this final rule, respectively.

This final rule is only finalizing some of the proposed provisions. The remaining provisions may be finalized in subsequent rulemaking, as appropriate. See table 4 for a list of those provisions.

TABLE 4—PRA-RELATED PROVISIONS OF PROPOSED RULE THAT A DECISION TO BE FINALIZED IS DEFERRED FOR SUBSEQUENT RULEMAKING

ICR No.	Provision description	Regulatory citation
8	Part D Medication Therapy Management (MTM) Program Eligibility Criteria	423.153(d).
10	Ensuring Equitable Access to Behavioral Health Benefits Through Section 1876 Cost Plan and MA Cost Sharing Limits.	417.454 and 422.100.
12	Format Medicare Advantage (MA) Organizations' Provider Directories for Medicare Plan Finder	422.111 and 422.2265.
13	Promoting Informed Choice—Enhancing Review of Marketing & Communications	422.2260 and 423.2260.
III.U	Enhancing Rules on Internal Coverage Criteria	422.101.

A. Wage Data

1. Private Sector

To derive average (mean) costs, we are using data from the most current U.S. Bureau of Labor Statistics' (BLS's) National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/2023/may/oes_nat.htm*), which, at the time of publication of this final rule, provides May 2023 wages. In this regard, table 5 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 5—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupational title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and other indirect costs ($/hr)	Adjusted hourly wage ($/hr)
Business Operations Specialists (All Others)	13–1199	42.85	42.85	85.70
Computer Programmer	15–1251	51.80	51.80	103.60
Computer Systems Analyst	1–1211	53.27	53.27	106.54
Database Administrators	15–1242	50.39	50.39	100.78
Medical and Health Service Managers	11–9111	64.64	64.64	129.28
Software Developer	15–1252	66.40	66.40	132.80
Software Quality Assurance Analysts and Testers	15–1253	52.15	52.15	104.30
Web Developer	15–1254	45.95	45.95	91.90

Adjusting our employee hourly wage estimates by a factor of 100 percent is a rough adjustment that is being used since fringe benefits and other indirect costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. In this regard, we believe that doubling the hourly wage to estimate costs is a reasonably accurate estimation method.

2. Beneficiaries

We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $24.73/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $1,192, divided by 40 hours to calculate an hourly pre-tax wage rate of $29.80/hr.[74] This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of $24.73/hr. Unlike our private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

For valuing time spent outside of work, there is logic to this approach but also to using a fully loaded wage. In the past we have used BLS occupational code 00–0000, the average of all occupational codes, which currently is $31.48/hr. Thus, we proposed a range for enrollees of $24.73/hr to $31.48/hr. Nevertheless, the upper limit is based on an average over all occupations while the lower limit reflects a detailed analysis by the Assistant Secretary for Planning and Evaluation (ASPE) targeted at enrollees, many of whom are over 65 and unemployed; consequently, in our estimates we will use the lower limit as we consider it more accurate.

B. Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble of this final rule.

1. ICRs Regarding Medicare Prescription Payment Plan Calculation of the Maximum Monthly Cap on Cost-Sharing Payments (§ 423.137(c))

The following finalized changes will be submitted to OMB for approval under control number 0938–1475 (CMS–10882) using the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. The initial 60-day notice will publish sometime after the publication date of this final rule. This rule finalizes proposals to implement the requirements in section 1860D–2(b)(2)(E)(iv) of the Act related to the calculation of the monthly caps on out-of-pocket (OOP) cost sharing payments. The burden related to these new requirements for Part D sponsors reflects the time and effort needed to correctly calculate the monthly caps based on the statutory formulas, determine the amount to be billed, and send monthly bills to program participants. The average number of Part D contracts per year is 840 (based on 2021, 2022, and

[74] ''Usual Weekly Earnings of Wage and Salary Worders, Fourth Quarter 2024,'' Bureau of Labor Statistics, January 22, 2025, accessed on February 20, 2025 <*https://www.bls.gov/news.release/pdf/wkyeng.pdf*>.

2023 data). This average number of Part D contracts per year excludes contracts with Program of All-Inclusive Care for the Elderly (PACE) organizations that exclusively charge $0 cost sharing, which we do not expect to offer enrollees the option to pay their OOP costs through monthly payments over the course of the plan year or otherwise comply with the Medicare Prescription Payment Plan requirements set forth in this final rule and at § 423.137.

As outlined in the proposed rule the burden associated with sponsors sending monthly bills to program participants is a function of the number of enrollees likely to enroll in the program. CMS conducted internal analyses of CY 2021 Prescription Drug Event (PDE) data to identify the number of enrollees likely to be identified as likely to benefit from the program and estimates that between 435,000 and 3,200,000 individuals will elect to participate in the Medicare Prescription Payment Plan. Because of the prior to plan year and during the plan year targeted outreach required for individuals identified as likely to benefit, we assume that the majority of enrollees who participate will pick up a high-cost prescription early in the year, for which they will be billed over all 12 months of the plan year.

Assuming 3,200,000 enrollees participate, and they all incur drug costs in January for which they are billed over the course of 12 months, the projected number of bills sent per year is 38,400,000 (3,200,000 * 12). Billing statements may be provided via mail or electronically; consistent with existing estimates for other required Part D materials, we estimate that approximately one-third or 12,800,000 (⅓ * 38,400,000) will be sent electronically since we estimate that one third of enrollees will opt to receive billing statements electronically. We estimate that the remaining two-thirds of enrollees or 25,600,000 (⅔ * 38,400,000) will receive hard copy billing statements.

We assume the following costs include paper, toner, envelopes, and postage (envelope weight is normally considered negligible when citing these rates and is not included) for hard-copy mailings:

- *Paper:* $3.50 for a ream of 500 sheets. The cost for one page is $0.007 ($3.50/500 sheets).
- *Toner:* $70 for 10,000 pages. The toner cost per page is $0.007 ($70/10,000 pages).
- *Envelope:* Bulk envelope costs are $440 for 10,000 envelopes or $0.044 per envelope.
- *Postage:* The cost of first-class metered mail is $0.73 per letter up to 1 ounce. We estimate that a sheet of paper weighs 0.16 ounces, and do not anticipate additional postage for mailings in excess of 1 ounce.

We estimate the aggregate cost per mailed billing statement is $0.802 ([$0.007 for paper * 2 pages] + [$0.007 for toner * 2 pages] + $0.73 for postage + $0.044 per envelope). We assume a maximum of 2 double-sided pages (generally, weighing less than 1 ounce) will be needed for a billing statement, based on the required content for billing statements. Because preparing and generating a hard-copy billing statement is automated once the systems have been developed, we do not estimate any labor costs. Therefore, we estimate a total annual mailing cost by sponsors to enrollees of $20,531,200 (25,600,000 mailings * $0.802/mailing).

We also estimate annual burden associated with maintenance of associated systems. On average, we expect that for each Part D contract, a two-person team consisting of one database administrator at $100.78/hr and one computer systems analyst at $106.54/hr will each spend 50 hours per year performing system maintenance. In aggregate, we estimated an annual burden of 84,000 hours (840 Part D contracts * 100 hr/contract) at a cost of $8,707,440 (840 contracts × [($100.78/hr × 50 hr) + ($106.54/hr × 50 hr)]).

Therefore, the total burden for all Part D contracts associated with the aforementioned provisions is 84,000 hours at an ongoing annual cost of $29,238,640 (see table 6).

When compared to our proposed rule, this is a decrease of 388,095 hours (from 472,095 hr to 84,000 hr) and $38,977,908 (from $68,216,548 to $29,238,640) despite an increase in the number of Part D contracts that we expect to comply with the requirements in the rule (an increase of 33 from 807 to 840 contracts) due to the inadvertent inclusion of previously incurred one-time burden.

TABLE 6—BURDEN FOR CALCULATION PROVISIONS

Requirement	Total time (hr)	Total cost (year 1)	Total cost (subsequent years)	Labor (L) vs non-labor (NL)
Mailing Billing Statements	0	20,531,200	20,531,200	NL
System Maintenance	84,000	8,707,440	8,707,440	L
Total	84,000	29,238,640	29,238,640	n/a

While we received no comments on our proposed changes, CMS notes that the requirements and burden (89 FR 99495 and 99497) are active and were approved by OMB under CMS's program instruction authority for the first year of the program. Although we had accounted for such requirements/burden in our proposed rule (391,395 hours at a cost of $39,319,986), we are not carrying them over into this final rule's COI section because they are one-time payment system development burden previously incurred in 2025.

2. ICRs Regarding Medicare Prescription Payment Plan Eligibility and Election Requirements (§ 423.137(d))

Except where noted, the following finalized changes will be submitted to OMB for review and approval under control number 0938–1475 (CMS–10882) using the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. While the use of the standard non-rule PRA update process was not indicated in the proposed rule, we are correcting that inadvertent omission in this final rule. The initial 60-day notice will publish sometime after the publication date of this final rule.

This rule's finalized amendments to § 423.137(d) requires that Part D sponsors offer the Medicare Prescription Payment Program to all Part D enrollees and set forth requirements for how Part D sponsors must process program election requests.

The finalized amendments to § 423.137(d) also requires Part D sponsors to send a notice alerting the Part D enrollee that their participation in the Medicare Prescription Payment Plan will continue into the next year

unless they indicate that they choose to opt out.

We estimate a one-time burden for Part D sponsors to develop a standard auto-renewal notice alerting the Part D enrollee that their participation in the Medicare Prescription Payment Plan will continue into the next year unless they indicate that they choose to opt out. On average, we expect that for each Part D contract, a team of one medical and health services manager will spend 2 hours at $129.28/hr and one business operations specialist will spend 10 hours at $85.70/hr to implement the requirements. In aggregate, we estimate a one-time burden of 10,080 hours (12 hr/contract * 840 Part D contracts) at a cost of $937,070 (840 contracts × [($129.28/hr × 2 hr) + ($85.70/hr × 10 hr)]).

We estimate annual burden for Part D sponsors to provide these auto-renewal notices to all enrollees participating in the Medicare Prescription Payment Plan at the end of the plan year. Assuming 3,200,000 individuals participating in the Medicare Prescription Payment Plan, we estimate a total of 3,200,000 auto-renewal notices sent each year. We assume that one-third or 1,065,600 enrollees (3,200,000 * ⅓) will receive this notice electronically and the remaining two-thirds or 2,133,333 enrollees (3,200,000 * ⅔) will receive hard copy notices.

We estimate the aggregate cost per mailed auto-renewal notice to be $0.802 ([$0.007 for paper * 2 pages] + [$0.007 for toner * 2 pages] + $0.73 for postage + $0.044/envelope). We assume a maximum of 2 double-sided pages (generally, weighing less than 1 ounce) will be needed for this notice. Because preparing and generating hard copy notices is automated once the systems have been developed, we do not estimate any labor costs. Therefore, we estimate total annual mailing costs to sponsors of $1,710,933 (2,133,333 hard copy notices * $0.802/notice).

To estimate the information collection burden for beneficiaries, we estimate that approximately 160,000 enrollees will voluntarily terminate their participation in the program in CY2026. We estimate that 99,200 will opt out of the program electronically, and the remaining 60,800 will opt out via telephone. We also estimate that it would take approximately 5 minutes (0.083 hr) to voluntarily terminate (by phone or electronically) participation in the Medicare Prescription Payment Plan. We estimate an annual recurring burden of 13,280 hours (160,000 enrollees * 0.083 hr) at a cost of $328,414 ($24.73/hr * 13,280 hr) for beneficiaries who choose to opt out of the program to complete a voluntary termination request.

The total burden for all Part D contracts associated with the aforementioned requirements (developing standard auto-renewal notice and mailing standard auto-renewal notice) is 10,080 hours with a one-time first year cost of $2,648,003 and a cost of $1,710,933 in subsequent years. When compared to our proposed rule, this is an decrease of 114,198 hours (from 124,278 hr to 10,080 hr) and $11,896,918 (from $14,544,921 to $2,648,003) despite an increase in the number of Part D contracts that we expect to comply with the requirements in the rule (an increase of 33 from 807 to 840 contracts) due to the inadvertent inclusion of burden associated with developing and mailing a standard request for additional information and the inadvertent inclusion of previously incurred one-time burden (see table 7).

The total burden for Part D beneficiaries with the aforementioned requirements is 13,280 hours with an ongoing annual cost of $328,414 (see table 7). When compared to our proposed rule, this is a decrease of 80,000 hours (from 93,280 hr to 13,280 hr) and $1,603,415 (from $1,931,829 to $328,414) due to the inadvertent inclusion of burden associated with completing incomplete election requests and the inadvertent use of $20.71/hr instead of $24.73/hr to calculate beneficiary cost.

TABLE 7—BURDEN FOR ELECTION REQUIREMENTS

Requirement	Total time (hr)	Total cost (year 1)	Total cost (subsequent years)	Labor (L) vs non-labor (NL)
Part D Contracts				
Develop Standard Auto-Renewal Notice	10,080	937,070	0	L
Mail Standard Auto-Renewal Notice	0	1,710,933	1,710,933	NL
Subtotal: Part D Contracts	10,080	2,648,003	1,710,933	N/A
Part D Beneficiaries				
Complete Program Opt-Out Process	13,280	328,414	328,414	L
Subtotal: Part D Beneficiaries	13,280	328,414	328,414	N/A
Total	23,360	2,976,417	2,039,347	N/A

While we did not receive comments on our proposed changes, CMS notes that the proposed requirements and burden related to systems programming (89 FR 99497 and 99498) are active and were approved by OMB (CMS–10882, OMB 0938–1475) under CMS's program instruction authority for the first year of the program. Although we had accounted for such requirements/burden in our proposed rule (104,910 hours at a cost of $10,862,381), we are not carrying it over into this final rule's COI section because it represents one-time burden previously incurred in 2025. The burden associated with developing the standard auto-renewal notices (one-time), mailing the standard auto-renewal notices (annual), and the beneficiary opt-out process (annual) is new burden for 2026 and subsequent years and will be submitted to OMB for approval as indicated previously.

3. ICRs Regarding Medicare Prescription Payment Plan Part D Enrollee Targeted Outreach (§ 423.137(e))

The following finalized changes will be submitted to OMB for approval under control number 0938–1475 (CMS–10882) using the standard non-rule PRA process which includes the publication

of 60- and 30-day **Federal Register** notices. The initial 60-day notice will publish sometime after the publication date of this final rule.

This rule finalizes proposals to require Part D sponsors to undertake targeted outreach to enrollees who are likely to benefit from making an election into the Medicare Prescription Payment Plan, including notifying a pharmacy when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the enrollee may benefit from participating in the program, and directly outreaching to enrollees likely to benefit prior to the plan year and on an ongoing basis during the plan year.

We estimate annual burden for Part D sponsors to review annual updates to the ''likely to benefit'' identification criteria and update their systems accordingly. On average, we expect that for each Part D contract, one business operations specialist will spend 2 hours at $85.70/hr to review annual updates and make corresponding systems changes. In aggregate, we estimate an annual burden of 1,680 hours (840 Part D contracts * 2 hr/contract) at a cost of $143,976 (1,680 hr * $85.70/hr).

We are also including annual burden associated with the cost of providing the ''Medicare Prescription Payment Plan Likely to Benefit Notice,'' as well as the program's election request form, notice of election approval, notice of failure to pay, notice of involuntary termination, and notice of voluntary termination to enrollees. As of January 2023, there were 50,657,397 Part D enrollees. We estimate that approximately 3,200,000 enrollees will elect to participate in the Medicare Prescription Payment Plan program. This estimate is predicated on internal CMS data analysis regarding the number of enrollees who may be identified as likely to benefit from participating in the program, new enrollees to the Part D plan, and enrollees that elect to participate in the program. Our analysis also takes into account the number of enrollees who may receive one or more notices from their Part D plan regarding the program.

To estimate the cost associated with providing beneficiaries and prospective beneficiaries model notices regarding the Medicare Prescription Payment Plan program, we note that all Part D plans and MA organizations must provide education and outreach materials to enrollees likely to benefit, to new enrollees to the Part D plan, and to enrollees participating in the Medicare Prescription Payment Plan program.

We estimate that plans will furnish a total of 16,080,000 notices regarding the program. This estimate includes both electronic and hard-copy mailings. Because electronic preparation and delivery is automated, we do not estimate any burden for the preparation and delivery of the electronic model notices. Instead, these costs are included in our systems programing estimate discussed previously.

We estimate that a total of 10,725,360 hard-copy Medicare Prescription Payment Plan notices will be mailed annually (see table 8). This total does not include the auto-renewal notice addressed in ICR 2. A description of each model notice and a detailed breakdown of our estimation for each is also provided under control number 0938–1475 (CMS–10882).

TABLE 8—BURDEN FOR MAILING NOTICES

Requirement	Total time (hr)	Total mailings	Total cost (year 1)	Total cost (subsequent years)	Labor (L) vs non-labor (NL)
Likely to Benefit Notice	0	2,134,400	1,711,789	1,711,789	NL
Election Request Form	0	5,709,520	4,579,035	4,579,035	NL
Notice of Election Approval	0	2,134,400	1,711,789	1,711,789	NL
Notice of Failure to Pay	0	426,880	342,358	342,358	NL
Notice of Involuntary Termination	0	213,440	171,179	171,179	NL
Notice of Voluntary Termination	0	106,720	85,589	85,376	NL
Total	0	10,725,360	8,601,739	8,601,739	N/A

We assume the following costs include paper, toner, envelopes, and postage (envelope weight is normally considered negligible when citing these rates and is not included) for hard-copy mailings:

- *Paper:* $3.50 for a ream of 500 sheets. The cost for one page is $0.007 ($3.50/500 sheets).
- *Toner:* $70 for 10,000 pages. The toner cost per page is $0.007 ($70/10,000 pages).
- *Envelope:* Bulk envelope costs are $440 for 10,000 envelopes or $0.044 per envelope.
- *Postage:* The cost of first-class metered mail is $0.73 per letter up to 1 ounce. We estimate that a sheet of paper weighs 0.16 ounces, and do not anticipate additional postage for mailings in excess of 1 ounce.

We estimate the aggregate cost per mailing is $0.802 ([$0.007 for paper × 2 pages] + [$0.007 for toner × 2 pages] + $0.044 per envelope + $0.73 for postage). We assume 3 pages on average will be needed for each model notice, based on the content included in the model notices. The notices are assumed to be printed double sided to save on printing costs, yielding 2 pages of double-sided print, generally weighing less than 1 ounce. Because preparing and generating a hard-copy model is automated once the template is loaded, we do not estimate any labor costs. Thus, we estimate a total annual mailing cost to sponsors of $8,601,739 (10,725,360 model notices × $0.802). The total burden for all Part D contracts associated with the aforementioned requirements is 1,680 hours at an ongoing annual cost of $8,745,715 (see 9). When compared to our proposed rule, this is a decrease of 48,254 hours (from 50,034 hr to 1,680 hr) and an increase of $13,110,088 (from $5,148,176 to $18,258,264) despite an increase in the number of Part D contracts that we expect to comply with the requirements in the rule (an increase of 33 from 807 to 840 contracts) and the inadvertent exclusion of burden associated with mailing notices due to the inadvertent inclusion of previously incurred one-time burden. The proposed rule did not include the burden associated with the cost of programming model notices into existing systems and providing model notices to enrollees because the burden is active and unchanged by the proposed rule and this final rule.

TABLE 9—BURDEN FOR PART D ENROLLEE TARGETED OUTREACH

Requirement	Total time (hr)	Total cost (year 1)	Total cost (subsequent years)	Labor (L) vs non-labor (NL)
Review/Update	1,680	143,976	143,976	L
Mailing Notices	0	8,601,739	8,601,739	NL
Total	1,680	8,745,715	8,745,715	n/a

While we received no comments on this proposal, CMS notes that the burden activities outlined (50,034 hours at a cost of $5,148,176) in the proposed rule (89 FR 99340) were approved by OMB (CMS–10882, OMB 0938–1475) under CMS's program instruction authority for the first year of the program. Although we had accounted for the requirements/burden related to systems development in our proposed rule, we are not carrying it over into this final rule's COI section because it represents one-time burden previously incurred in 2025. The burden associated with the cost of providing Medicare Prescription Payment Plan model notices to enrollees is accounted for under control number 0938–1475 (CMS–10882) as an annual burden.

4. ICRs Regarding Medicare Prescription Payment Plan Termination of Election, Reinstatement, and Preclusion (§ 423.137(f))

This rule finalizes our proposal to require Part D sponsors to have a process to allow a participant who has opted into the Medicare Prescription Payment Plan to opt out during the plan year. Part D sponsors are also required to terminate an individual's Medicare Prescription Payment Plan participation if that individual fails to pay their monthly billed amount. CMS received no comments on our proposal. The proposed requirements and burden (51,648 hours at a cost of $5,362,515) (89 FR 99340) were implemented in 2025 under CMS's program instruction authority for the first year of the program. Although we had accounted for the requirements/burden related to systems development in our proposed rule, we are not carrying it over into this final rule's COI because it represents one-time burden previously incurred in 2025.

5. ICRs Regarding Medicare Prescription Payment Plan Pharmacy POS Notification Process (§ 423.137(i))

This rule finalizes our proposal to require Part D sponsors to ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that they are likely to benefit from the Medicare Prescription Payment Plan. The provision also outlines the required claims processing methodology for applicable Medicare Prescription Payment Plan transactions.

The system development burden activities outlined (1,467,940 hours at a cost of $164,923,059) in the proposed rule (89 FR 99340) were implemented in 2025 under CMS's program instruction authority for the first year of the program. Although we had accounted for these requirements/burden in our proposed rule, we are not carrying it over into this final rule's COI because it represents one-time burden previously incurred in 2025.

As indicated previously, PRA-related public comments were received and are summarized along with our responses.

Comment: A commenter stated that the ICRs Regarding Medicare Prescription Payment Plan Pharmacy POS Notification Process (§ 423.137(i)) should also include the time that pharmacies have invested in educating and training their employees, additional transaction fees that pharmacies will incur due to having to reverse, resubmit, and send secondary claims to effectuate Medicare Prescription Payment Plan processing, and the cost of paper to print the ''Medicare Prescription Payment Plan Likely to Benefit Notice.''

Response: CMS appreciates the commenter's feedback. As noted, the requirements and burden were approved by OMB under CMS's program instruction authority for the first year of the program and will be submitted to OMB for review and approval under control number 0938–1475 (CMS–10882) using the standard non-rule PRA process.

6. ICRs Regarding Medicare Prescription Payment Plan Pharmacy Claims Processing (§ 423.137(j))

The electronic claims processing methodology outlined in our proposed rule is utilized today by Part D sponsors and pharmacies and therefore the addition of the BIN/PCN that is unique to the Medicare Prescription Payment Plan does not require new or revised burden.

CMS is finalizing as proposed the requirement that Part D sponsors report their program-specific PCN starting with ''MPPP'' to CMS. We estimate that this will require 1 hour at $85.70/hr for a business operations specialist to report their identifier to CMS. In aggregate, we estimate an annual ongoing burden of 840 hours (840 Part D contracts * 1 hr/response) at a cost of $71,988 (840 Part D contracts * $85.70/hr). When compared to our proposed rule, this is an increase of $2,828 (from $69,160 to $71,988) due to an increase in the number of Part D contracts that we expect to comply with the requirements in the rule (an increase of 33 from 807 to 840 contracts).

7. ICRs Regarding Medicare Transaction Facilitator for 2026 and 2027 Under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)

The following changes will be submitted to OMB for review and approval under control number 0938–TBD (CMS–10912) using the standard non-rule PRA process which includes the publication of 60-day and 30-day **Federal Register** notices. The initial 60-day notice was published on October 28, 2024, and the initial 60-day comment period closed on December 27, 2024. The tentative date for the publication of the 30-day notice will be on or around April 1, 2025, making the tentative closing date for the comment period on or around May 1, 2025.

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117–169), CMS is implementing the Medicare Drug Price Negotiation Program (''the Negotiation Program''), codified in sections 1191 through 1198 of the Social Security Act (''the Act''). The Act establishes the Negotiation Program to negotiate a maximum fair price (''MFP''), defined at section 1191(c)(3) of the Act, for certain high expenditure, single source drugs covered under Medicare Part B and Part D (''selected drugs''). In accordance with section 1193(a) of the Act, any Primary Manufacturer of a selected drug that continues to participate in the Negotiation Program and reaches agreement upon an MFP must provide

access to the MFP to MFP-eligible individuals, defined in section 1191(c)(2)(A) of the Act, and to pharmacies, mail order services, other dispensing entities, providers and suppliers with respect to such MFP-eligible individuals who are dispensed that selected drug during a price applicability period.

The purpose of the information collection request (CMS–10912, OMB 0938 NEW) is for CMS to collect information from manufacturers of drugs covered under Part D selected for negotiation under the Inflation Reduction Act for the initial price applicability years 2026 and 2027 and the dispensing entities that dispense the selected drugs to MFP-eligible individuals. To facilitate the effectuation of the MFP, CMS will engage a Medicare Transaction Facilitator (MTF). The ICR includes the following forms:

- Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Entity Enrollment Form (Appendix A)
- Drug Price Negotiation Program MTF DM Primary Manufacturer Maximum Fair Price (MFP) Effectuation Plan Form (Appendix B)
- Drug Price Negotiation Program MTF DM Primary Manufacturer Payment Elements Form (Appendix C)
- Drug Price Negotiation Program Complaint and Dispute Intake Form (Appendix D)

By virtue of this rulemaking, Part D sponsors will require dispensing entities in their network to complete Appendix A. CMS expects approximately up to 95,000 pharmacies, including both chain and non-chain pharmacies to enroll in the MTF DM; this assumption represents CMS' maximum expectation for participation. CMS expects chain pharmacies to enroll individual stores through a central office. There are an estimated 760 chain pharmacies representing approximately 39,000 stores. In the burden estimate, CMS uses 760 chain pharmacy respondents. An estimated 56,000 non-chain pharmacies will individually enroll in the MTF DM. CMS believes collection of these data will be a one-time cost for each submitting dispensing entity enrolling in the MTF and that a significant majority of pharmacies will enroll before January 1, 2026. The MTF will not charge dispensing entities any fees to use the system.

CMS expects 56,000 non-chain pharmacies to individually enroll in the MTF DM. For a non-chain pharmacy completing the one-time enrollment form for initial price applicability year 2026, we estimate it will take a financial manager (2 hours at $173.08/hour, a business operations specialist (2 hours at $89.88/hour), a pharmacist (2 hours at $129.62/hour), and lawyer (2 hours at $140.16/hour). In this regard, we estimate each respondent would spend 8 hours at a total cost of $1,065.48 ($346.16 + $179.76 + $259.24 + $280.32). In aggregate, we estimate the total annual burden hours across all 56,000 non-chain dispensing entities would be approximately 448,000 hours (8 hours × 56,000 respondents), with a total cost of $59,666,880.00 ($1,065.48 × 56,0000 respondents).

For a chain pharmacy, we expect the chain home office to enroll once on behalf of the associated store locations. For the chain office to complete the one-time enrollment form (for initial price applicability year 2026), we estimate it will take a financial manager (4 hours at $173.08/hour), a business operations specialist (4 hours at $89.88/hour), a pharmacist (4 hours at $129.62/hour), and a lawyer (4 hours at $140.16/hour). In this regard, we estimate each respondent would spend a burden of 16 hours at a total cost of $2,130.96 ($692.32 + $359.52 + $519.48 + $560.64). In aggregate, we estimate the total annual burden hours across all 760 respondents representing 39,000 pharmacies would be approximately 12,160 hours (16 hours × 760 respondents), with a total cost of $1,619,529.60 ($2,130.96 × 760 respondents).

8. ICRs Regarding Clarifying MA Organization Determinations To Enhance Enrollee Protections in Inpatient Settings (§§ 422.138, 422.562, 422.566, 422.568, and 422.616)

The following changes will be submitted to OMB for reinstatement 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.

The revision to clarify the definition of ''organization determinations'' is intended to enhance enrollee protections in inpatient settings. This will be accomplished by clarifying in this final rule that an MA organization's refusal, pre- or post-service or in connection with a decision made concurrently with an enrollee's receipt of services, to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization is an organization determination subject to the requirements under 42 CFR part 422, subpart M, including, but not limited to, adjudication timeframes and the form and content of decision notifications. We are also finalizing a corresponding change at § 422.138(c), to include concurrent reviews as a type of determination subject to the rules at § 422.138(c). Per § 422.138(c), if the MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, or, as finalized in this rule, a concurrent determination made during the enrollee's receipt of inpatient or outpatient services, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at § 405.986) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616.

As discussed in section III.A. of this final rule, we are finalizing our proposals with the following modifications:

- At § 422.562(c)(2), we are revising the language to state that if a contract provider's request for payment has been adjudicated and the enrollee is determined to have no further liability to pay for the services furnished by the MA organization, the claim payment determination is not subject to the appeal process in this subpart.
- At § 422.616(e), we are omitting the unitalicized heading that was included in the proposed rule.
- At § 422.138(c), we are making a minor modification to fix an editorial error that was inadvertently made in the proposed regulation text revision at 89 FR 99560 (specifically, reinstating ''or'' between ''prior authorization'' and ''pre-service determination'').

When making an organization determination, the plan must issue a coverage determination notice. The clarification to the definition of an organization determination means that when an MA organization downgrades an enrollee from receiving inpatient to outpatient services or when an MA organization denies payment for services after such services were rendered but before a request for payment is submitted, the MA organization will be required to provide proper notice of the decision to the enrollee. The revision we are finalizing strengthens requirements related to

notifying providers. The existing notice requirements for standard organization determinations at § 422.568 specify that MA organizations must provide the enrollee with notice of its decisions. Under existing rules, MA organizations are required to use CMS–10003 (OMB control number: 0938–0829, titled ''Notice of Denial of Medical Coverage (or Payment) (NDMCP)'') to notify enrollees of adverse decisions. (The NDMCP is not being modified at this time.)

In this final rule, we are amending requirements related to notice of a standard organization determination at § 422.568(b)(1) for MA organizations to notify an enrollee's physician or provider, as appropriate, as well as the enrollee. We continue to believe strengthening notice requirements will not have a measurable impact on the practices of MA organizations. The final rule codifies longstanding requirements and guidance that we believed the majority of plans already implement based on the few complaints we receive on this issue from providers and enrollees. In addition, we also understand that due to the contractual relationship MA organizations have with their providers, most contracted providers should already receive notice of relevant organization determinations, including those that the provider submitted on behalf of the enrollee. The burden for issuing notices is captured under control number 0938–0753 (CMS–R–267) which, as noted earlier, will be submitted to OMB for reinstatement.

In terms of our clarification of the definition of an organization determination, we acknowledged that some plans were complying with the existing regulations in a manner that is consistent with this clarification, but we do not have the data on the number of plans that are not complying. In this final rule we continue to estimate that annually 60,000 inpatient admissions are downgraded to an outpatient level of care at the time the enrollee is receiving hospital services.

We estimated that of those 60,000 cases, approximately 10 percent of those cases were being handled appropriately (that is, plans are complying with the existing regulations). We do not have definitive data sources that indicate the number of plans that may not be in compliance and, therefore, invited stakeholder comment on our assumptions.

Due to lack of data on the number of plans that may not be in compliance under the current rules, we cannot precisely quantify all burden that may result from finalizing this provision. However, we can quantify some and perform qualitative estimates for: (1) additional notices to enrollees and providers not currently receiving them, and (2) an increase in the number of appeals received.

a. Additional Notices

We continue to anticipate there will be an increase in the number of notices to providers and enrollees regarding downgrading inpatient stays to observation status. Because the issuance of these notices is typically automated, there could be a one-time first year cost to update systems in addition to a potential annual mailing cost. We estimated that, per plan, it may take a programmer 4 to 8 hours to update systems. In aggregate we estimate a one-time, first year burden of 5,816 hours (8 hr/plan * 727 plans) at a cost of $602,538 (5,816 hr * $103.60/hr).

By examining risk-adjustment data for MA plan use of Condition Code 44, the code used in Traditional Medicare for a downgrade of an inpatient stay to observation, we estimate there are 60,000 downgrades annually. We continue to believe that MA plans are using Condition Code 44 to indicate downgrades, and that most downgrades are being captured. Since the information in the notice is confidential, they must be mailed via first class at a rate of $0.802/notice. We assume the following costs include paper, toner, and postage (envelope weight is normally considered negligible when citing these rates and is not included), and envelope (supplies) for hard-copy mailings:

- *Paper:* $3.50 for a ream of 500 sheets. The cost for one page is $0.007 ($3.50/500 sheets).
- *Toner:* $70 for 10,000 pages. The toner cost per page is $0.007 ($70/10,000 pages).
- *Postage:* The cost of first-class metered mail is $0.73 per letter up to 1 ounce. We estimate that a sheet of paper weighs 0.16 ounces, and do not anticipate additional postage for mailings in excess of 1 ounce.
- *Envelope:* Bulk envelope costs are $440 for 10,000 envelopes or $0.044 per envelope.

We estimate the 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).

In addition, we believe there will be a new burden for approximately 90 percent of plans. This assumption is based on complaints, correspondence with plans, and other anecdotal evidence, but we acknowledged that it is speculative since we do not collect related data. Based on our assumptions, the cost of mailing notices would be a non-labor cost of $43,308 annually (60,000 downgrades * 90 percent that are not currently complying * $0.802/notice). Besides the other assumptions detailed previously, this estimate is an over-estimate since some enrollees will receive their NDMCP (CMS–10003) in the hospital and hence incur no mailing costs.

b. Increased Appeals

While we expect an increase in the number of organization determinations reported, as well as the number of appeals received, we did not have data to confirm this assumption. Appeals data available to CMS is not currently broken out by the type of service; therefore, we did not know how many MA organizations fail to provide proper notification and how many inpatient approvals being downgraded to outpatient are appealed. There is no applicable appeals data at the Independent Review Entity (IRE) level. We were unable to estimate: (1) how many cases of the overall universe of 60,000 will now receive notices; (2) how many appeals would arise; (3) how many are overturned; and (4) how many will go to the IRE. Thus, we could not quantify this, but we could qualitatively identify this as a cost.

We also noted that amending the reopening rules at § 422.616 would not add to existing plan processes or requirements, so we believed any overall burden associated with processing a reopening of an organization determination related to inpatient hospital admissions will remain unchanged or will possibly be reduced (given that we proposed to eliminate the discretion of an MA organization to reopen an approved authorization for an inpatient hospital admission based on new and material evidence), including a concurrent review decision per the change to § 422.138(c). The decision to reopen an organization determination is at the discretion of an MA organization. Curtailing an MA organization's authority to reopen and modify an approved authorization for an inpatient hospital admission on the basis of good cause for new and material evidence does not impose any new burden in the decision-making process related to prior authorization and concurrent review for inpatient hospital admissions. Consequently, we continue to believe this provision will not have added impact on enrollees, MA organizations, or the Medicare Trust Funds.

Likewise, we noted our clarification to § 422.562(c)(2) would not add to

existing plan processes or requirements., We continue to believe the overall estimated burden on MA organizations associated with processing organization determinations and appeals will be unchanged and this provision will not have added impact and will not adversely impact enrollees or MA organizations. Further, we continue to believe that most MA organizations are already properly excluding provider payment appeals from the subpart M administrative appeals process when a dispute no longer involves enrollee financial liability for furnished services. Similarly, we did not believe the proposed changes would have any impact to the Medicare Trust Funds.

c. Public Comments

As indicated previously, we received PRA-related public comments, the summation of the comments and our responses follow.

Comment: A commenter disagreed with our assumption that our changes would result in an increase in the number of notices that MA organizations would need to deliver to providers. They believed that we were broadening the scope of those allowed to file appeals on behalf of beneficiaries and noted that this was not necessary since this has been a long-standing flexibility. They also believed that any increase in costs related to delivery of notices would be negated by the reduction in the number of ''unwarranted denials'' and that CMS should execute corrective action to eliminate *inappropriate* denials.

Response: We appreciate the commenter's feedback. As the commenter did not provide further context or detail on how our estimates should be adjusted, we have no basis to revise our estimates. Upon further consideration and review of our estimates we are finalizing our assumption and estimates as proposed.

Comment: A few commenters encouraged CMS to carefully evaluate the increased complexity, risk of member and provider confusion, and significant resource investments, including increases in clinical and administrative staffing to manage the additional workload thoroughly before finalizing the proposal to ensure the policy achieves its intended goals. A commenter also suggested that CMS reflect these additional significant costs in its cost projections.

Response: We appreciate the commenters' suggestions. We acknowledged in the proposed rule (89 FR 99463) that MA organizations are already making decisions on the appropriateness of inpatient hospital services before and during the course of treatment. While some MA organizations consider concurrent review decisions as organization determinations, others utilize internal dispute resolution processes. Notably, in both cases, the MA organizations are already expending resources on evaluating the medically necessity for the services being requested or rendered, providing notice to the providers, and permitting appeals (albeit through the MA organization's internal processes). Our change merely clarifies that these decisions, which are already being widely made, must adhere to the existing requirements for organization determinations. Therefore, we disagree with the commenter that our estimate failed to fully evaluate for costs to MA organizations related to staffing and workload increases.

Upon further consideration and review of our estimates, we believe the assumption that 10 percent of these cases are being handled appropriately is fair and we intend to leave this estimate as is. Further, we also noted in the proposed rule (89 FR 99507) that our estimated burden related to increased notices was an overestimate and we continue to believe this is an accurate statement. We have adjusted our estimates related to notices to include paper and toner.

9. ICRs Regarding Clarifying the Obligation of PACE Organizations To Submit Risk Adjustment Data § 460.180(b)

The following requirements and burden are active and approved by OMB under control number 0938–1152 (CMS–10340) and 0938–0878 (CMS–10662).

Medicare requirements at § 460.180(b) clarify the obligation of PACE organizations to submit risk adjustment data to CMS. Section 1894(d)(1) of the Act provides that CMS makes payments to PACE organizations in the same manner as MA organizations. To do so, PACE organizations must submit data in accordance with the risk adjustment data requirements for MA organizations at § 422.310. Codified at § 460.200, PACE organizations are required to collect data, maintain records, and submit reports as required by CMS to establish payment rates. CMS finalized the longstanding practice of requiring the collection and mandatory submission of risk adjustment data by PACE organizations by adding a new paragraph (b)(3) to § 460.180 that requires the data PACE organizations submit be in accordance with risk adjustment data submission requirements in § 422.310. As stated in the proposed rule (89 FR 99395), this change does not set forth any new reporting requirements or changes to reporting requirements to PACE organizations. As such, we do not anticipate any additional costs associated with continued submission of data under this longstanding practice. We are providing cost estimates had these organizations not been submitting data under the longstanding requirements noted previously.

The estimated total burden for all PACE organizations associated with the current submission of encounter data is 156,510 hours (4,700,000 × 0.03 hr) with a yearly recurring cost of $8,695,000 (4,700,000 × $1.85). The number of active PACE contracts for CY 2025 is approximately 189. For 2023 dates of service, PACE organizations submitted approximately 4,700,000 risk adjustment encounter data records. The estimated annual electronic processing cost per encounter data record is $1.85 according to the 2022 Council for Affordable Quality Healthcare (CAQH) and the estimated time required to process an electronic record based on the CAQH Index Report is 2 minutes.

The estimated total burden for all PACE organizations associated with the current submission of encounter data through RAPS is 333,000 hours (10,000,000 × 0.03 hr) with a yearly recurring cost of $18,500,000 (10,000,000 × $1.85). For 2023 dates of service, PACE organizations submitted approximately 10,000,000 diagnosis codes through RAPS. The estimated annual electronic processing cost per encounter data record is $1.85 according to the 2022 Council for Affordable Quality Healthcare (CAQH) and the estimated time required to process an electronic record based on the CAQH Index Report is 2 minutes.

The aforementioned reporting requirements would total a yearly recurring estimated burden of 489,510 hours (156,510 hr + 333,000 hr) and yearly recurring cost of $27,195,000 ($8,695,000 + $18,500,000) for organizations that are not currently submitting in accordance with longstanding practice. As indicated, the requirements and burden are active and approved by OMB. This final rule does not set out any new or revised requirements or burden.

10. ICRs Regarding Clarifying the Obligation of Cost Plans To Submit Risk Adjustment Data (§ 460.180(b))

The following requirements and burden are active and approved by OMB under control number 0938–1152 (CMS–10340).

Medicare requirements at § 460.180(b) clarify the obligation of Cost plans to submit risk adjustment data to CMS. CMS will finalize § 417.486(a) by adding a new paragraph (§ 417.486(a)(3)) to codify the longstanding practice of requiring the collection and mandatory submission of risk adjustment data as specified in § 422.310 by Cost plans. As stated in the proposed rule (89 FR 99395), this change to § 417.486(a) codifies longstanding practice and does not set forth any new reporting requirements to changes to reporting requirements to Cost plans. As such, we do not anticipate any additional costs associated with continued submission of data under this longstanding practice. We provide cost estimates had these organizations not been submitting data under the longstanding requirements noted previously.

Currently, CMS requires the submission of risk adjustment data from organizations that operate Cost plans under section 1876 of the Act in the same manner as MA organizations. Codified at § 417.486(a), the contract of section 1876 Cost plans must provide that the plan agrees to submit to CMS: (1) all financial information required under subpart O of part 417 and for final settlement; and (2) any other information necessary for the administration or evaluation of the Medicare program.

The estimated total burden for all Cost plans associated with the current submission of encounter data is 186,480 hours (5,800,000 × 0.03 hr) with a yearly recurring cost of $10,360,000 (5,800,000 × $1.85). The number of active Cost plan contracts for CY 2025 is approximately 11. For 2023 dates of service, Cost plans submitted approximately 5,800,000 risk adjustment encounter data records. The estimated annual electronic processing cost per encounter data record is $1.85 according to the 2022 Council for Affordable Quality Healthcare (CAQH) and the estimated time required to process an electronic record based on the CAQH Index Report is 2 minutes.

This final rule does not set out and new or revised requirements or burden.

11. ICRs Regarding Promoting Person-Centeredness in SNP ICPs and Timeliness of HRAs and ICPs (§ 422.101(f))

In section IV.A.4. of this final rule, we discuss our amendments to § 422.101(f)(1) to codify timeliness standards, improve the organization of the various HRA and ICP requirements, and strengthen these requirements. The amendments will require that—

- SNPs conduct the comprehensive initial HRA within 90 days (before or after) of the effective date of enrollment for all new enrollees. This would better align with the Medicaid requirement at § 438.208(b)(3) and codify the standard currently described for reporting HRA completion in the Part C reporting requirements.
- Consistent with the Medicare Part C Technical Specifications, SNPs make at least three attempts to reach the enrollee (not including any automated phone calls), unless an enrollee agrees or declines to participate in the HRA before three attempts are made, on different days at different times of day. We are also finalizing that for any enrollees that are unable to be reached or decline to participate in the HRA, the SNP must document the attempts to contact the enrollee or the enrollee's choice not to participate. These updates would better conform to the standard currently described for reporting HRA completion in the Part C reporting requirements. We will update the CY 2026 Part C Technical Specifications consistent with these changes.
- Within 90 days of conducting a comprehensive initial HRA or 90 days after the effective date of enrollment, whichever is later, SNPs to develop and implement a comprehensive ICP that—

++ Is person-centered and based on the enrollee's preferences, including for delivery of services and benefits, and needs identified in the HRA;

++ Is developed through an interdisciplinary care team with the active participation of the enrollee (or the enrollee's representative, as applicable) as feasible;

++ Identifies person-centered goals and objectives (as prioritized by the enrollee), including measurable outcomes as well as specific services and benefits to be provided; and

++ Is updated as warranted by changes in the health status or care transitions of enrollees.

Since SNPs are already required to conduct HRAs and ICPs, we did not anticipate that the changes to § 422.101(f) would impose any new burden on MA organizations offering SNPs. However, we would need to revise language on allowable methods of plan outreach to enrollees for conducting HRAs in the Part C Technical Specifications, which is part of the Part C Reporting Requirements submitted annually and currently approved by OMB under control number 0938–0154 (CMS–10261). We received no comments on these assumptions.

We received non-PRA related comments on the proposals, which we summarize and respond to in section IV.A.4. of this final rule. As indicated, we are finalizing the provisions as proposed at § 422.101(f)(1)(i) through (x), but with the following modifications: We are modifying the language at § 422.101(f)(1)(iv)(A) to read ''Make at least three attempts to reach the enrollee (not including any automated phone calls), unless an enrollee agrees or declines to participate in the HRA before three attempts are made, on different days at different times of day to reach the enrollee to schedule the comprehensive initial or annual HRA.'' We are also modifying the introductory language at § 422.101(f)(1)(vii) to specify that within 90 days of conducting a comprehensive initial HRA or 90 days after the effective date of enrollment, whichever is later, develop a comprehensive individualized plan of care that meets all of the following.

12. ICRs Regarding Integrating Member ID Cards for Dually Eligible Enrollees in Certain Integrated D–SNPs (§§ 422.2267(e)(30) and 423.2267(e)(32))

Consistent with our Contract Year 2023 final rule (87 FR 27860) and our Contract Year 2026 proposed rule (89 FR 99486), we noted that the Member Identification Card burden is exempt from the requirements of the PRA since the issuance of such cards is a normal and customary practice throughout the insurance industry, citing the fact that health plans, whether commercial, through Medicare or Medicaid, or Original Fee-for-Service issue cards that inform providers of the enrollee's insurance. The MA requirements were previously described in the May 2022 final rule, and we are simply combining these requirements with Medicaid requirements for one ID card. Sections 422.2267(e)(30) and 423.2267(e)(32) require D–SNPs to provide member ID cards to enrollees. Medicaid managed care plans also send member ID cards to enrollees. However, when a dually eligible individual is enrolled in both an MA plan and a Medicaid managed care plan, the plans currently may issue the enrollee separate member ID cards—one for their MA plan and one for their Medicaid managed care plan—to access services for each program. The change we are finalizing requires that applicable integrated plans (AIPs), as defined in § 422.561, provide one integrated member ID card to serve as the ID card for both the Medicare and Medicaid plans in which the enrollee is enrolled. Given that issuance of member ID cards is a usual and customary practice throughout the insurance industry and most States with AIPs currently require integrated member ID cards in their SMACs, we do not

estimate any PRA-related burden for the requirement.

We did not receive any comments on these burden assumptions.

We received non-PRA related comments on our proposal, which we summarize and respond to in section IV.A.1. of this final rule. As indicated, we are finalizing without modification our proposal to require integrated member ID cards for AIP D–SNPs.

13. ICRs Regarding Integrating Health Risk Assessments for Dually Eligible Enrollees in Certain Integrated D–SNPs (§ 422.101(f)(1)(v))

The following changes will be submitted to OMB for approval under control number 0938–1446 (CMS–10825).

Medicare requirements at § 422.101(f)(1) require D–SNPs to conduct a comprehensive HRA for each enrollee, both at the time of enrollment and annually thereafter. Separately, Medicaid managed care regulations at § 438.208(b)(3) require Medicaid managed care plans to make a best effort to conduct an initial screening of enrollee needs within 90 days of their effective enrollment date, and State requirements may include additional assessments such as long-term services and supports (LTSS) and home and community-based services eligibility screenings. While some States have implemented their own requirements, through SMACs, to reduce burden and duplication, not all States have done so. In this rule, we are finalizing a requirement that D–SNPs that are AIPs conduct a comprehensive HRA that meets all Medicare and Medicaid requirements, rather than two separate HRAs, beginning no later than contract year 2027, which is one year later than we proposed.

AIPs in seven States (DC, FL, ID, NJ, PR, VA, and WI) that do not currently combine their HRAs will be required to adhere to this new provision. We believe that a business operation specialist associated with each contract that has an AIP in these seven states would spend an average of 2 hours at $85.70/hr to determine whether the HRA tool currently in use meets State requirements and make any necessary system updates in preparation for implementation in plan year 2027. With 26 unique contracts in the seven States that would be required to meet this provision, we estimate that half of the contracts or 13 contracts (26 contracts * ½) will only need to make minor administrative changes to comply with this provision. This would be a one-time burden of 26 hours (13 contracts* 2 hr) at a cost of $2,228 (26 hr * $85.70/hr) (see table 10). We estimate that the other half of the contracts (13 contracts) would require more extensive updating and merging of two separate HRAs (at 40 hr/response) to comply with this provision. We estimate such MA organizations would need to merge two separate HRAs and implement systems updates to operationalize the integrated HRA. We estimate that these activities would take 40 hours per contract. This would be a one-time burden of 520 hours (13 contracts * 40 hr) at a cost of $44,564 (520 hr * $85.70/hr).

After initial implementation, the requirement would reduce burden for AIPs in the seven states listed earlier with HRAs that are not already integrated, as plans would be conducting one integrated HRA instead of two. As discussed in the prior paragraph, we estimate that half of the contracts that would be affected by this rule currently administer some form of a consolidated HRA. Conversely, we estimate that the other half of the contracts are currently conducting two HRAs. Based on this assumption, we are estimating that half of the contracts that would be required to adhere to this provision will see a reduction of burden by half. We expect some long-term burden reduction from the 13 contracts that currently administer two HRAs for their enrollees but would only administer one HRA under this final rule.

We did not receive any comments on these burden assumptions and are finalizing our estimates as proposed.

We received non-PRA related comments on our proposal, which we summarize and respond to in section IV.A.2. of this final rule. As indicated, we are finalizing our proposal to require integrated HRAs for AIP D–SNPs with two modifications: (1) we are delaying the implementation date of this provision from the proposed timeframe of January 1, 2026 to January 1, 2027 with an applicability date of October 1, 2026; and (2) at § 422.101(f)(1)(v), we are changing the specificity of the Medicaid requirements cited to clarify that the integrated HRA would necessarily satisfy the requirements at § 438.208(b)(3) but would not necessarily encompass the other requirements at § 438.208.

C. Summary of Information Collection Requirements and Associated Burden

TABLE 10—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 ($/hr)	Total cost, 1st yr ($)	Total cost, subsequent years ($)
423.137(c)	Medicare Prescription Payment Plan Calculation of the Maximum Monthly Cap on Cost-Sharing Payments: Calculations: Mailing bills.	0938–1475 CMS–10882	25,600,000 Beneficiaries.	N/A	N/A	N/A	N/A	20,531,200	20,531,200
423.137(c)	Medicare Prescription Payment Plan Calculation of the Maximum Monthly Cap on Cost-Sharing Payments: Calculations: Maintenance.	0938–1475 CMS–10882	840 Part D Contracts.	840	100	84,000	Varies	8,707,440	8,707,440
423.137(d)	Medicare Prescription Payment Plan: Eligibility and Election Requirements: Auto renewal notice development.	0938–1475 CMS–10882	840 Part D Contracts.	840	12	10,080	Varies	937,070	.....
423.137(d)	Medicare Prescription Payment Plan: Eligibility and Election Requirements: Auto renewal mailings.	0938–1475 CMS–10882	840 Part D Contracts.	2,133,333	N/A	N/A	N/A	1,710,933	1,710,933

TABLE 10—SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN—Continued

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 ($/hr)	Total cost, 1st yr ($)	Total cost, subsequent years ($)
423.137(d)	Medicare Prescription Payment Plan: Eligibility and Election Requirements: Beneficiary: Opt out.	0938–1475 CMS–10882	160,000 Beneficiaries.	160,000	0	13,280	25	328,414	328,414
423.137(e)	Medicare Prescription Payment Plan Part D Enrollee Targeted Outreach: System Updates.	0938–1475 CMS–10882	840 Part D Contracts.	840	2	1,680	86	143,976	143,976
423.137(e)	Medicare Prescription Payment Plan Part D Enrollee Targeted Outreach: Mailings.	0938–1475 CMS–10882	840 Part D Contracts.	N/A	N/A	N/A	N/A	8,601,739	8,601,739
423.137(j)	Medicare Prescription Payment Plan Pharmacy Claims Processing.	0938–1475 CMS–10882	840 Part D Contracts.	840	1	840	Varies	71,988	71,988
423.505(q)	Medicare Transaction Facilitator: Independent Pharmacies.	OMB 0938 NEW CMS–10912	56,000 Non-Chain Pharmacies.	56,000	8	448,000	Varies	59,666,880	
423.505(q)	Medicare Transaction Facilitator: Chain Pharmacies.	OMB 0938 NEW CMS–10912	760 Chain Pharmacies.	760	16	12,160	Varies	1,619,530	
422.138, 422.562, 422.566, 422.568, 422.572, 422.616, and 422.631.	Enhance enrollee protections in inpatient settings—system update.	0938–0753 CMS–R–267	727 MA Contracts.	727	8	5,816	104	605,538	

VII. Regulatory Impact Analysis

A. Statement of Need

The primary purpose of this final rule is to amend the regulations for the Medicare Advantage (Part C) and Medicare Prescription Drug Benefit (Part D) programs, and Programs of All-Inclusive Care for the Elderly (PACE). It is necessary to codify our implementation of policies laid out in acts of Congress and to improve access and transparency for beneficiaries enrolled in MA and Part D plans. The rule includes provisions implementing requirements or improving processes initiated by the Inflation Reduction Act of 2022 (IRA). The IRA directed CMS to implement the Medicare Prescription Payment Plan program as well as the IRA's insulin and vaccine cost-sharing requirements through the end of calendar year 2025 through program instruction or other forms of program guidance. For 2026 and subsequent years, CMS must codify the policies implementing these aspects of the IRA through rulemaking. Similarly, CMS must also enact regulations related to manufacturer effectuation of the ''maximum fair prices'' negotiated under the Medicare Drug Price Negotiation Program established by the IRA to the extent that such regulations involve exercising authorities under the Act that are not subject to the IRA's program instruction requirement. For that purpose, this rule will finalize provisions to shorten the PDE submission window for selected drugs and to require plan sponsors to require their network pharmacies to be enrolled in the Medicare Transaction Facilitator Data Module. Other major provisions of this rule will clarify or enhance plan requirements pertaining to supplemental benefits for the chronically ill, approved inpatient admissions decisions, and risk adjustment.

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; section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4); and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 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, the President's priorities, or the principles set forth in E.O. 12866.

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, the Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant under section 3(f)(1) of E.O. 12866. Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has determined that this rule meets the criteria set forth in 5 U.S.C. 804(2).

C. Detailed Economic Analysis

Many provisions of this final rule have negligible impact either because they are technical provision 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 VI. of this final rule and in this RIA. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this RIA cross-references impacts from section VI. of this final rule in order to arrive at the total impact. Table 11 provides a summary of the estimated transfers and costs associated with the various provisions in this final rule over a 10-year period. Further detail is provided later in this RIA.

TABLE 11—SUMMARY OF THE TRANSFERS AND COSTS OF THE FINAL RULE BY PROVISION AND YEAR

[In $ millions]

Category of provisions	Year(s)										
TRANSFERS	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2025–2034
Cost Sharing for Insulin Products: Federal Spending	.....	$110	$120	$120	$130	$140	$110	$110	$120	$120	$1,080
Cost Sharing for Insulin Products: Premium Offsets	.....	.....	.....	.....	.....	.....	$30	$30	$30	$40	$130
COSTS *	2026	2026	2027	2028	2029	2030	2031	2032	2033	2034	2026–2035
Medicare Prescription Payment Plan Provisions (ICR)	† $270.4	$40.9	$40	$40	$40	$40	$40	$40	$40	$40	$631.4
Medicare Transaction Facilitator	.....	$61.3	.....	.....	.....	.....	.....	.....	.....	.....	$61.3
Risk Adjustment Provisions (ICR)	0	$37.6	$37.6	$37.6	$37.6	.....	$37.6	$37.6	$37.6	$37.6	$338
Other Provisions **	.....	$0.6	$0.1	0	0	0	0	0	0	0	$1
Total Costs	$270.4.4	$140.5	$77.7	$77.7	$77.7	$77.7	$77.7	$77.7	$77.7	$77.7	$1,032.5

† The Medicare Prescription Payment Plan impacts for 2025 originate from ICRs authorized through program instruction authority granted by the IRA.

* Figures in the Costs section of table 11 have been rounded to the nearest tenth of one million. For that reason, numbers in the 2025–2034 column may not equal the sum of columns 2025 through 2034.

** The Other Provisions row includes estimated first-year and annually recurring impacts for the Information Collection Requirements of the following provisions: Clarifying MA Organization Determinations to Enhance Enrollee Protections in Inpatient Settings ($648,846 for the first year and $43,308 per year thereafter), and Integrating Health Risk Assessments for Dually Eligible Enrollees in Certain Integrated D–SNPs ($46,792), costs for which will only be incurred in 2027.

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

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

The cost-sharing limits for ACIP-recommended adult vaccines outlined in this final rule have been in place since CMS implemented the limits in 2023 through program instruction authority. We annually review cost sharing in plan benefit package submissions and expect our codification of these requirements to have minimal impact on Part D sponsors and beneficiaries. All Part D enrollees have had zero cost sharing for ACIP-recommended adult vaccines since 2023.

Shortly after the IRA was enacted, the Congressional Budget Office (CBO) scored the $0 cost-sharing requirement for ACIP-recommended adult vaccines as a Federal cost of $4.4 billion from FY 2022 to FY 2031 and, therefore, the estimates are not a result of this rule.[75]

2. Effects of Cost Sharing for Covered Insulin Products Under Medicare Part D (§§ 423.100 and 423.120)

This provision implements section 11406 of the IRA, which amends section 1860D–2 of the Act to require that, effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible shall not apply to covered insulin products, and the Part D cost-sharing amount for a 1-month supply of each covered insulin product must not exceed the statutorily defined ''applicable copayment amount'' for all enrollees. The applicable copayment amount for 2023, 2024, and 2025 was $35. For 2026 and each subsequent year, in accordance with the statute, we are finalizing that, with respect to a covered insulin product covered under a PDP or an MA–PD plan prior to an enrollee reaching the annual out-of-pocket threshold, the ''covered insulin product applicable cost-sharing amount'' is the lesser of—

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

The requirement to provide enrollees with an applicable cost-sharing amount equal to the lesser of $35, 25 percent of the MFP, or 25 percent of the negotiated price, has not yet been implemented. As described in Part E of title XI of the Act, the Secretary must establish a Medicare Drug Price Negotiation Program and negotiate MFPs for selected drugs that will go into effect beginning in initial price applicability year 2026. The selected drug list for initial price applicability year 2026 includes a selected drug that will be subject to the cost-sharing requirements outlined in this final rule.[76] The selected drug list under the Medicare Drug Price Negotiation Program in future years may also include additional insulin products. As defined in § 423.100, the negotiated price is the price for a

[75] *https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.*

[76] *https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.*

covered Part D drug that the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug. A negotiated price must meet all of the following: (1) includes all price concessions from network pharmacies or other network providers; (2) includes any dispensing fees; and (3) excludes additional contingent amounts, such as incentive fees, if these amounts increase prices. Finally, a negotiated price is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor passes through to Part D enrollees at the point of sale.

Beginning in 2026, the applicable cost-sharing amount for a 1-month supply of a covered insulin product will depend on which of the following is the lowest amount: $35, an amount equal to 25 percent of the insulin product's MFP (if the insulin product is a selected drug), or an amount equal to 25 percent of the negotiated price of the insulin product. If 25 percent of the MFP or 25 percent of the negotiated price is not less than $35, the impact on Part D sponsors will be minimal as this $35 applicable copayment amount has been in place since 2023. However, if either 25 percent of the MFP or 25 percent of the negotiated price is less than $35, the impact on Part D sponsors will depend on: (1) the magnitude of difference between 25 percent of the MFP or 25 percent of the negotiated price and $35; and (2) the number of beneficiaries affected. In other words, the greater the difference in 25 percent of the MFP or 25 percent of the negotiated price and $35, the greater the impact on Part D sponsors.

We estimated the impact of the change in Part D insulin coverage for years 2026 through 2034 using a claim-level simulation model under the defined standard benefit before and after the application of the change. As the beneficiary cost sharing is reduced, the net effect is an increase in benefit costs. Additionally, because of the premium stabilization provisions of the IRA, beneficiary premiums are not impacted until 2031. In 2031 and subsequent years, we expect beneficiaries will see small increase in premiums to account for the richer benefit structure. Overall, we expect Federal costs to increase by approximately $1.1 billion from 2026 to 2034.

TABLE 12—FINANCIAL IMPACT OF COST–SHARING FOR COVERED INSULIN PRODUCTS UNDER MEDICARE PART D

CY incurred: in millions	2026	2027	2028	2029	2030	2031	2032	2033	2034
Net Medicare	$110	$120	$120	$130	$140	$110	$110	$120	$120
Premium Offset	0	0	0	0	0	30	30	30	40
Gross Impact	110	120	120	130	140	140	140	150	160

3. Effects of Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements

The codification of the ''Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements'' provision applies to Part D sponsors. It requires Part D sponsors to include a provision in their network agreements with contracting pharmacies that requires such pharmacies, mail order services, and dispensing entities be enrolled in the Medicare Transaction Facilitator (MTF) Data Module. Therefore, the entities directly affected by the codification of the ''Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements'' provision are Part D sponsors. Hence, CMS notes that this provision in the final rule will have a negligible direct economic impact on -Part D sponsors (associated with adding language to their network agreements) and will not have a direct significant economic impact on a substantial number of small entities. CMS recognizes that dispensing entities (including those that are ''small entities'' under the meaning of the RFA) are indirectly involved in the downstream impacts of this provision as they fulfill the requirements of their network agreement(s) with Part D sponsors and will enroll in the MTF Data Module. This one-time enrollment activity among dispensing entities is expected to have a nominal economic cost per entity associated with completing a brief web-based enrollment form, which CMS has described in the Medicare Transaction Facilitator Information Collection Request (CMS–10912, OMB 0938–NEW).

CMS expects that enrollment in the MTF Data Module by dispensing entities will be necessary and beneficial to such dispensing entities as they dispense prescription drugs with negotiated maximum fair prices (MFPs) under the Part D program. As discussed in the preamble of this final rule, the MTF is designed to provide an efficient, timely, and unified data exchange and payment flow where none currently exists between Primary Manufacturers and dispensing entities. Further, by enrolling in the MTF Data Module, dispensing entities can self-identify whether they are a dispensing entity that anticipates having material cashflow concerns at the start of a price applicability period with respect to selected drugs as a result of potential delays created by reliance on retrospective MFP refund payments within the 14-day prompt MFP payment window. CMS will provide information about dispensing entities' self-identification in the MTF Data Module to Primary Manufacturers to assist in development of Primary Manufacturers' mitigation approach for dispensing entity material cashflow concerns as part of their MFP Effectuation Plans, consistent with section 1193(a)(5) of the Act and as mentioned in the preamble of this final rule. CMS recognizes that some commenters requested that—separate from the requirement on Part D sponsors at issue in this rulemaking—CMS revisit the design of the MTF and establish an alternative approach to processing MFP refund payments (for example, a pre-funded model). As mentioned in our response in this rule, CMS appreciates this feedback but considers such comments out of scope as those comments are beyond the intent of the provision being codified in this rule. CMS reiterates that it is aware of such concerns regarding the Negotiation Program and addressed similar comments in the ''Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027'' (final guidance).

4. Clarifying MA Organization Determinations To Enhance Enrollee Protections in Inpatient Settings (§§ 422.138, 422.562, 422.566, 422.568, and 422.616)

We proposed modifications to existing regulations at 42 CFR part 422, subpart M, to clarify and strengthen existing rules related to organization determinations. The intent of this provision is to clarify the definition of an organization determination to enhance enrollee protection in inpatient settings. We wanted to ensure enrollees and providers acting on their behalf receive notice of an inpatient/outpatient downgrade and are aware of their appeal rights. The intent of this provision was also to increase awareness when inpatient stays are downgraded with the expectation that there would be more appeals and some overturns. Thus, qualitatively, we expected this proposal to generate increased costs to the MA organizations and ultimately to the Medicare Trust Funds since inpatient stays are generally more expensive than services billed in an outpatient setting.

In section VI.B.8. of this rule, we estimated that there are annually 60,000 downgrades of inpatient to observation. Although we could estimate 60,000 affected enrollees, we did not have any way to estimate the following: (1) what percent of the enrollees are already receiving required written notification and what percent of them will receive a notice due to change in the provision; (2) of those receiving the notice, what percent will appeal; (3) of those appealing the downgrade, what percent will be overturned by the plan; (4) of those appeals upheld by the plan, what percent will be overturned by the Independent Review Entity (IRE) (given that 100 percent of upheld plan decisions are forwarded to IRE). If this data was available, we could obtain average costs of inpatient stays and observation days and estimate the cost to the trust fund. In the absence of this data, we estimated this as a non-quantified cost to the plans that is passed on to the Trust Fund. We received no comments on our assumption and are therefore finalizing without modification.

D. Alternatives Considered

In this section, CMS includes discussions of alternatives considered. Several provisions of this rule reflect a codification of existing policy where we have evidence, as discussed in the appropriate preamble sections, that the codification of this existing policy would not affect compliance. In such cases, the preamble typically discusses the effectiveness metrics of these provisions for public health.

1. Proposal for Medicare Prescription Payment Plan (§ 423.137(d), (e), (f), (i), and (j))

a. Auto Renewal

In the proposed rule, CMS considered how to address year-over-year program participation because the IRA limited CMS's program instruction authority to a single year of the program (that is, CY 2025). We proposed an automatic election renewal process that requires a Part D sponsor to automatically renew a Part D enrollee's participation in the Medicare Prescription Payment Plan, provided the participant remains in the same Plan Benefit Package (PBP) in the upcoming year, unless the program participant indicates otherwise. This option would minimize burden for Part D enrollees, who would not need to complete additional paperwork to remain in the program, and Part D sponsors, which would not be required to process new election forms for active program participants or conduct ''likely to benefit'' analyses for the upcoming plan year for those participants. Alternatively, we considered requiring Part D enrollees to re-elect into the program each plan year, which would allow Part D enrollees to actively choose to participate in the program each year but would place additional burden on both enrollees and Part D sponsors. While some commenters opposed the automatic renewal requirement and asked that it be optional for plans in the early years of the program, many commenters expressed support for the proposed automatic election renewal process because of the reduced burden on beneficiaries. For the reasons set forth in the proposed rule and our responses to the related comments summarized in section II.C.2. of this final rule, we are finalizing the automatic renewal process at § 423.137(d)(9).

b. Point-of-Sale Enrollment

Timely effectuation of election requests is important to prevent dispensing delays and potential prescription abandonment. For enrollees who trigger the likely to benefit threshold with a new high-cost prescription and receive the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' informing them about the Medicare Prescription Payment Plan at the point of sale, a real-time or point of sale election mechanism could allow them to pay $0 at the point of sale and still leave the pharmacy with their medication. We considered the three options for point-of-sale enrollment: permit point of sale enrollment by establishing a new value in an existing NCPDP data field for the Medicare Prescription Payment Plan, permit real-time enrollment by telephone or mobile or web-based application, and require Part D sponsors to process election requests within 24 hours.

CMS proposed to codify the 24-hour timeframe for election requests made during the plan year, as required in 2025, and requested comment on real-time election. We believe that the 24-hour timeframe, paired with the required process to retroactively apply the program to those meeting criteria for a retroactive election, reduces the likelihood of dispensing delays and prescription abandonment while avoiding the operational burden that would be required for Part D sponsors, PBMs, and pharmacies to develop and implement mechanisms to support real-time or POS election. While many commenters expressed support for real-time election due to the reduced burden on enrollees, many commenters opposed requirements for real-time election and expressed concern about the technological and operational challenges for plans and pharmacies. For the reasons set forth in the proposed rule and our responses to the related comments summarized in section II.C.2. of this final rule, we are finalizing the 24-hour timeframe for election requests made during the plan year as proposed.

c. Pharmacy Processes

Section 1860D–2(b)(2)(E)(v)(III)(ff) of the Act states that an individual's participation in the Medicare Prescription Payment Plan does not affect the amount paid (or the timing of such payments) to pharmacies. Accordingly, we proposed that the Part D sponsor must pay the pharmacy for the final amount the individual would have otherwise paid at the POS. Because an individual's OOP costs are net of any contributions made by supplemental payers to Part D to which the individual may be entitled and that reduce the OOP amount due, this requires the Medicare Prescription Payment Plan to be integrated into current coordination of benefits (COB) transactions for program participants.

We proposed to require pharmacies and Part D sponsors to utilize an additional BIN/PCN that is unique to the Medicare Prescription Payment Plan to facilitate electronic processing of supplemental COB transactions for program participants.

We also considered the use of a pre-funded card, which would keep the

pharmacy whole and could allow for COB with other payers supplemental to Part D. However, this approach does not provide the same level of Part D sponsor oversight, there are other concerns surrounding timeliness of issuing payment cards and participants needing to present a physical card at the POS, and not all organizations have the financial capabilities established to enable a prefunded payment card system. Moreover, interested parties have also expressed a desire to have a single, uniform method of adjudicating and managing the patient liability for the Medicare Prescription Payment Plan at the POS; we determined the use of unique BIN/PCNs for the final transaction to the Medicare Prescription Payment Plan best accomplishes that objective. CMS received a comment in response to the proposed rule recommending that CMS instead require a pre-funded card system for processing Medicare Prescription Payment Plan claims. For the reasons set forth in the proposed rule, we are finalizing the requirement that pharmacies and Part D sponsors utilize an additional BIN/PCN that is unique to the Medicare Prescription Payment Plan as proposed.

E. Regulatory Review Costs

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret the proposed rule, then we should estimate the cost associated with regulatory review. We received approximately 2,000 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 $106.42 per hour, including fringe benefits, overhead, and other indirect costs (*https://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 $1,064 (10 hours × $106.42). Therefore, we estimated that the maximum total cost of reviewing the final rule is $ 2.1 million ($1,064 × 2,000 reviewers). However, we expected that many reviewers, for example pharmaceutical companies and PBMs, will not review the entire rule but review just the sections that are relevant to them. We expected that on average (with fluctuations) 10 percent of the proposed rule will be reviewed by an individual reviewer; we therefore estimated the total cost of reviewing to be $ 0.2 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 13, we have prepared an accounting statement showing the transfers and costs associated with the provisions of this rule over a 10-year period or for contract years 2025 through 2034.

TABLE 13—ACCOUNTING STATEMENT-CLASSIFICATIONS OF ESTIMATED TRANSFERS AND COSTS, CONTRACT YEARS 2025–2034

[Millions]

Category	3% Discount rate	7% Discount rate
TRANSFERS:		
Annualized monetized Federal budgetary transfers	$107.4	$105.1
From Federal Government to MA–PDs & PDPs:		
Annualized monetized budgetary transfers	14.1	15.6
From Beneficiaries to MA–PDs & PDPs:		
COSTS:		
Annualized monetized costs	106.6	111.2

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 proposed a wide range of policies to codify, modify, and update current guidance governing MA organization bid requirements. We believe this final rule will have a direct economic impact on beneficiaries, health insurance plans, and pharmacies. Based on the size standards set by the Small Business Administration 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 North American Industry Classification System (NAICS) code 524114, have a $47 million threshold for ''small size.'' Several Medicare Advantage plans (about 30 to 40 percent) are not-for-profit, automatically classing them as ''small entities'' by the definitions found in the RFA. Pharmacies and Drug Retailers, classified under NAICS code 456110, have a $37.5 million threshold to qualify as a small business. According to the United States Census Bureau's survey of retail businesses, firms classified with this NAICS code had an average revenue of over $27.6 million in 2022; on a per establishment basis, retail pharmacies averaged nearly $12.4 million in revenue.[77] We believe most retail pharmacies qualify as small businesses.

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

[77] US Census Bureau, ''Retail Trade: Summary Statistics for the U.S.: 2022,'' All Sectors: Summary Statistics for the U.S., States, and Selected Geographies: 2022, EC2200BASIC, <*https://data.census.gov/table/ECNBASIC2022.EC2200BASIC?q=456110*>, accessed on February 5, 2025.

provisions, identifies the final policies, and presents rationales for our decisions and, where relevant, alternatives that were considered. The analyses discussed in this section and throughout the preamble of this final rule constitutes our RFA analysis. The RFA does not define the terms ''significant economic impact'' or ''substantial number.'' The Small Business Administration (SBA) advises that this absence of statutory specificity allows what is significant'' or ''substantial'' to vary, depending on the problem that is to be addressed in the rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. Nevertheless, HHS typically considers a ''significant'' impact to be 3 to 5 percent or more of the affected entities' costs or revenues. To explain our position, we note certain operational aspects of the Medicare program.

Each year, MA organizations, submit a bid for each plan for furnishing Parts A and B (and sometimes Part D) benefits and the entire bid amount is paid by the government through the Medicare Trust Funds to the plan, if the plan's bid is below an administratively set benchmark. If the plan's bid exceeds that benchmark, the beneficiary pays the difference in the form of a basic premium (note that a small percentage of plans bid above the benchmark, whereby enrollees pay a basic premium, thus this percentage of plans is not ''significant'' as defined by the RFA and as justified in this section of this rule). Part D sponsors also submit a bid for each plan, and the payments made to stand-alone Part D plans (PDPs) are covered by the Supplementary Medical Insurance Medicare Trust Fund. PACE organizations are paid a capitation amount that is funded by both the Medicare Trust Funds (the Hospital Insurance and Supplementary Medical Insurance trust funds) as well as the State Medicaid programs they contract with.

MA plans can also offer enhanced benefits—that is—benefits not covered under Traditional Medicare. These enhanced benefits are paid for through enrollee premiums, rebates or a combination. Under the statutory payment formula, if the plan bid submitted by an MA organization for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a rebate. The rebate must be used to provide supplemental benefits (that is, benefits not covered under Traditional Medicare) and/or to lower beneficiary 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.

Small entities that must comply with MA regulations, such as those in this final rule, are expected to include the costs of compliance in their bids, thus avoiding additional burden, since the cost of complying with any proposed or final rule is funded by payments from the government and, if applicable, enrollee premiums.

For Direct Health and Medical Insurance Carriers, NAICS 524114, plans estimate their costs for the upcoming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to paying the plan either (1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from Traditional Medicare data; or (2) the benchmark, if the bid amount is greater than the benchmark.

Theoretically, there is additional burden if plans bid above the benchmark. However, consistent with the RFA, the number of these plans is not substantial. Historically, only 2 percent of plans bid above the benchmark, and they contain roughly 1 percent of all plan enrollees. Since the HHS criterion for a ''substantial'' number of small entities is 3 to 5 percent, the number of plans bidding above the benchmark is not substantial.

The preceding analysis shows that meeting the direct cost of 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 above, are certain indirect consequences of these provisions which also create impact. We have already explained that 98 percent of MA plans (including MA–PD plans) bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal Government, given that as previously noted, under the statutory payment formula, if a bid submitted by a MA plan for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a beneficiary rebate, which must be used to provide supplemental benefits and/or lower beneficiary Part B or Part D premiums. If the plan's bid exceeds the administratively set benchmark, the beneficiary pays the difference in the form of a basic premium. However, as also noted previously, the number of MA plans bidding above the benchmark to whom this burden applies does not meet the RFA criteria of a significant number of plans. If the provisions of the rule were to cause bids to increase and if the benchmark remains unchanged or increases by less than the bid does, the result could be a reduced rebate. Plans have different ways to address this in the short-term, such as reducing administrative costs, modifying benefit structures, and/or adjusting profit margins. These decisions may be driven by market forces. Part of the challenge in pinpointing the indirect effects is that there are many other factors combining with the effects of the rule, making it effectively impossible to determine whether a particular policy had a long-term effect on bids, administrative costs, margins, or supplemental benefits.

As indicated in table 11, the total costs imposed by this rule and the guidance that it codifies amount to approximately $270.4 million in 2025, $140.5 million in 2026, and $77.7 million in subsequent years. Most of those costs will be faced by insurers, such as Part D sponsors and Medicare Advantage Organizations. Provisions implementing the Medicare Prescription Payment Plan are expected to result in $84.9 million in costs for all affected plans in 2025, $20.1 million for 2026, and an additional $19.2 million incurred every year thereafter. Of those amounts, $92,162 are expected to be incurred by each Part D Plan sponsor in 2025 to perform software updates, develop notices, and perform other duties necessary to operationalize aspects of the Medicare Prescription Payment Plan, dropping to $21,893 in 2026, and $20,778 in subsequent years. The remaining costs, amounting to $7.5 million in 2025 and $1.7 million annually thereafter, are primarily the cost to mail notices and will most affect plans with higher enrollment.

The provisions we have titled ''Clarifying MA Organization Determinations to Enhance Enrollee Protections in Inpatient Settings'' are expected to result in additional expenses of $605,538 spread across all affected plans in the first year (amounting to $833 per plan), with an additional $43,308 incurred every year to send notices to beneficiaries, again with costs likely most affecting those plans with higher enrollments.

The cost of the Risk Adjustment data submission provisions will result in an annual cost of $37.6 million. Of that, the PACE organizations will incur $27.2 million a year, likely to be borne more heavily by those with more enrollees and those that will have a higher volume of data to submit. Similarly, Cost plans will likely have increased expenses of $10.4 million annually, likewise falling most heavily on those plans with higher enrollment.

As noted previously, plans are expected to include the costs of compliance in their bids. For that reason, we do not believe these costs result in a significant economic impact on the affected plans.

This rule will also affect pharmacies. As noted earlier in this section, we believe most of the pharmacies affected by this rule are small entities, as indicated by Census data on businesses classified with the appropriate NAICS code (456110). While not all pharmacies are captured using this code—those pharmacies that are a part of larger non-pharmacy retailers or other entities are likely included under the code for those entities—many of the excluded businesses are also likely to have sources of income that are not impacted by this regulation and may also have higher revenues than an average pharmacy. However, even among pharmacies correctly identified by the NAICS code, there is reason to believe that there is a high degree of variability in revenue from one pharmacy to another. Independent pharmacies are believed to be smaller on average than their peers that are part of large pharmacy chains. Widely available figures published by industry sources indicate that independent retail pharmacies have averaged gross revenues between $3.4 and nearly $5 million over the last several years. Given the high degree of variation in revenue over a relatively short amount of time, we will make our estimates based on total revenues of $3.4 million for small pharmacies.

Two provisions of this rule were expected to create burden for pharmacies. Under program instruction authority, the Medicare Prescription Payment Plan was expected to impose costs of $164,923,059 for 2025, spread across all participating pharmacies. This would amount to costs of $2,247 per pharmacy. Of the $59,666,880 of total costs for 2026 faced by independent pharmacies due to the requirements of the Medicare Transaction Facilitator provision, each pharmacy could be expected to bear $1,065.48. For both 2025 and 2026, these amounts are well below the 3 to 5 percent threshold that HHS typically uses when determining if a rule will have a significant impact. For 2026, the chain pharmacy home offices are expected to incur a total of $1,619,530 in costs due to Medicare Transaction Facilitator provision, equaling $2,130.96 per chain.

We requested comment on the assessment of this outcome in association with this rule.

Comment: A commenter requested a more detailed breakdown of the costs to be borne by small entities, with an emphasis on pharmacies. The commenter noted that our previous analysis did not provide adequate data to determine if the rule would have a ''significant economic impact'' on pharmacies.

Response: We thank the commenter for reviewing the proposed rule and providing feedback on the analysis that it contained. We have included more detail in our analysis to help clarify the costs imposed on affected entities. Additionally, we would like to highlight some of the steps taken to reduce burden on pharmacies in particular. Section VII.D.1 of this rule, discussing alternatives considered for enrollment into the Medicare Prescription Payment Plan, explains how CMS is opting to finalize the 24-hour enrollment timeframe with retroactive election into the program, selecting this method in part because it will reduce operational burden on pharmacies and other entities. Other sections such as sections II.E and VII.C.3. of this rule, covering the Medicare Transaction Facilitator, describe CMS' attention to the requirements of pharmacy operations in the development of this rule.

As noted, the costs for pharmacies that we have identified in this RFA fall below HHS' threshold for a significant burden. These costs can also be found listed in the Summary of Annual Information Collection Requirements and Burden (table 10) in section VI.C. of this rule. Several of the other notable costs faced by pharmacies that were highlighted by the commenter are not the result of this rule and are considered out of scope.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. This 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 $187 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. 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 final 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 considered an E.O. 14192 regulatory action. We estimate that this rule generates $95 million in annualized costs 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 transfers, from the Medicare Trust Fund, of between $107.4 and 105.1 million for calendar years 2025–2034. These transfers are entirely attributable to the insulin cost-sharing

requirements of the Inflation Reduction Act. In addition, this final rule will result in net annualized costs of between $106.6 and $111.2 million for calendar years 2025 to 2034, which are primarily attributable to provisions for the information collection requirements of the Medicare Prescription Payment Plan. These provisions implement requirements created by the Inflation Reduction Act. This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

Stephanie Carlton, Acting Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 2, 2025.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health Insurance, Health maintenance organizations (HMO), Loan programs-health Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Citizenship and naturalization, Civil rights, Health, Health care, Health records, Individuals with disabilities, Medicaid, Medicare, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority for part 417 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 300e, 300e–5, and 300e–9, and 31 U.S.C. 9701.

■ 2. Section 417.486 is amended by:

■ a. Removing the word ''and'' at the end of paragraph (a)(1);

■ b. Removing the period and adding in its place ''; and'' at the end of paragraph (a)(2); and

■ c. Adding paragraph (a)(3).

The addition reads as follows:

§ 417.486 Disclosure of information and confidentiality.

* * * * *

(a) * * *

(3) Risk adjustment data as specified in § 422.310 of this chapter for the purposes of determining an individual's health status. In applying this paragraph (a)(3), references to Medicare Advantage (MA) organizations in § 422.310 must be read to mean HMOs and CMPs.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 3. The authority for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–21 through 1395w–28, and 1395hh.

■ 4. Section 422.2 is amended by revising the definition of ''Hierarchical condition categories (HCC)'', paragraph (1) of the definition of ''Highly integrated dual eligible special needs plan'', and the introductory text of the definition of ''Service area'' to read as follows:

§ 422.2 Definitions.

* * * * *

Hierarchical condition categories (HCC) mean diagnosis groupings that predict average healthcare spending. HCCs consist of International Classification of Diseases, Clinical Modification (ICD–CM) diagnosis codes and represent the disease component of the enrollee risk score that are applied to MA payments.

Highly integrated dual eligible special needs plan * * *

(1) The capitated contract is between the State Medicaid agency and one of the following:

(i) The MA organization.

(ii) The MA organization's parent organization, or another entity that is owned and controlled by its parent organization.

(iii) A local nonprofit public benefit corporation of which the MA organization, MA organization's parent organization, or another entity that is owned and controlled by its parent organization is a founding member where the local nonprofit public benefit corporation is responsible for the delivery of physical, behavioral, and dental health services.

* * * * *

Service area means a geographic area that for local MA plans is one or more counties, as defined in § 422.116, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Facilities in which individuals are incarcerated are not included in the service area of an MA plan. Each MA plan must be available to all MA-eligible individuals within the plan's service area. In deciding whether to approve an MA plan's proposed service area, CMS considers the following criteria:

* * * * *

■ 5. Section 422.101 is amended by revising paragraph (f)(1) to read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(f) * * *

(1) MA organizations offering special needs plans (SNP) must implement an evidence-based model of care with appropriate networks of providers and specialists designed to meet the specialized needs of the plan's targeted enrollees. The MA organization must, with respect to each individual enrolled, do all of the following:

(i) Within 90 days (before or after) of the effective date of enrollment for all new enrollees, conduct a comprehensive initial health risk assessment (HRA).

(ii) Conduct a comprehensive annual HRA.

(iii) Use a comprehensive risk assessment tool that CMS may review during oversight activities that meet both of the following:

(A) Assesses the enrollee's physical, psychosocial, and functional needs.

(B) Includes one or more questions from a list of screening instruments specified by CMS in subregulatory guidance on each of the following domains:

(*1*) Housing stability.

(*2*) Food security.

(*3*) Access to transportation.

(iv) Must do all of the following:

(A) Make at least three attempts to reach the enrollee (not including any automated phone calls), unless an enrollee agrees or declines to participate in the HRA before three attempts are made, on different days at different times of day to reach the enrollee to schedule the comprehensive initial or annual HRA.

(B) If the enrollee has not responded, send a follow-up letter to conduct the initial or annual HRA.

(C) For any enrollees who are unable to be reached or decline to participate in the HRA, document the attempts to contact the enrollee and, if applicable, the enrollee's choice not to participate.

(v) For D–SNPs that are applicable integrated plans (as defined in § 422.561), conduct a comprehensive HRA that meets all requirements at paragraphs (f)(1)(i) through (iv) of this section and Medicaid requirements at § 438.208(b)(3) of this chapter, such that enrollees complete a single integrated assessment for Medicare and Medicaid, beginning no later than contract year 2027.

(vi) Ensure that the results from the comprehensive initial and annual HRA conducted for each enrollee are addressed in the enrollee's individualized care plan as required under paragraph (f)(1)(vii) of this section.

(vii) Within 90 days of conducting a comprehensive initial HRA or 90 days after the effective date of enrollment, whichever is later, develop a comprehensive individualized plan of care that meets all of the following:

(A) Is person-centered and based on the enrollee's preferences, including for delivery of services and benefits, and their needs identified in the HRA.

(B) Is developed through an interdisciplinary care team with the active participation of the enrollee (or the enrollee's representative, as applicable), as feasible.

(C) Identifies person-centered goals and objectives (as prioritized by the enrollee), including measurable outcomes as well as specific services and benefits to be provided.

(D) Is updated as warranted by changes in the health status or care transitions of enrollees.

(viii) For any enrollees who are unable to be reached or decline to participate in the development or updates to the comprehensive individualized plan of care, document the attempts to contact the enrollee or the enrollee's refusal to participate.

(ix) In the management of care, use an interdisciplinary team that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

(x) Provide, on at least an annual basis, beginning within the first 12 months of enrollment, as feasible and with the enrollee's consent, for face-to-face encounters for the delivery of health care or care management or care coordination services and be between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff, or contracted plan healthcare providers. A face-for-face encounter must be either in person or through a visual, real-time, interactive telehealth encounter.

* * * * *

■ 6. Section § 422.102 is amended by adding paragraph (f)(1)(iii) to read as follows:

§ 422.102 Supplemental benefits.

* * * * *

(f) * * *

(1) * * *

(iii) *Non-allowable SSBCI.* Examples of items or services that may not be offered as SSBCI include all of the following:

(A) Procedures that are solely cosmetic in nature and do not extend upon Traditional Medicare coverage (for example, cosmetic surgery, such as facelifts, or cosmetic treatments for facial lines, atrophy of collagen and fat, and bone loss due to aging).

(B) Hospital indemnity insurance.

(C) Funeral planning and expenses.

(D) Life insurance.

(E) Alcohol.

(F) Tobacco.

(G) Cannabis products.

(H) Broad membership programs inclusive of multiple unrelated services and discounts.

(I) Non-healthy food.

* * * * *

■ 7. Section 422.116 is amended by—

■ a. Redesignating paragraphs (a)(1) through (4) as paragraphs (a)(2) through (5);

■ b. Adding a new paragraph (a)(1);

■ c. Removing ''(a)(2)'' and adding in its place ''(a)(3)'' in newly redesignated paragraph (a)(2)(i); and

■ d. Removing ''(a)(4)(i)'' and adding in its place ''(a)(5)(i)'' in paragraph (b)(2)(xiv)(A).

The addition reads as follows:

§ 422.116 Network adequacy.

(a) * * *

(1) *Definition of county. County,* for purposes of this section, is defined as the primary political and administrative division of most States and includes functionally equivalent divisions called ''county equivalents'' as recognized by the United States Census Bureau (for economic census purposes).

* * * * *

■ 8. Section 422.138 is amended by revising paragraph (c) to read as follows:

§ 422.138 Prior authorization.

* * * * *

(c) *Effect of prior authorization, pre-service, or concurrent approval.* If the MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, or a concurrent determination made during the enrollee's receipt of inpatient or outpatient services, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at § 405.986 of this chapter and § 422.616) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. The definitions of the terms ''reliable evidence'' and ''similar fault'' in § 405.902 of this chapter apply to this paragraph (c).

■ 9. Section 422.562 is amended by revising paragraph (c)(2) to read as follows:

§ 422.562 General provisions.

* * * * *

(c) * * *

(2) If a contract provider's request for payment has been adjudicated and the enrollee is determined to have no further liability to pay for the services furnished by the MA organization, the claim payment determination is not subject to the appeal process in this subpart.

* * * * *

■ 10. Section 422.566 is amended by revising paragraph (b)(3) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(b) * * *

(3) The MA organization's refusal, pre- or post-service or in connection with a decision made concurrently with an enrollee's receipt of services, to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization.

* * * * *

■ 11. Section 422.568 is amended by revising paragraphs (b)(1) introductory text, (d) introductory text, and (f) to read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

* * * * *

(b) * * *

(1) *Requests for service or item.* Except as provided in paragraph (b)(2) of this section, when a party has made

a request for an item or service, the MA organization must notify the enrollee (and the physician or provider involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires but no later than either of the following:

* * * * *

(d) *Written notice for MA organization denials.* The MA organization must give the enrollee and the physician or provider involved, as appropriate, a written notice if—

* * * * *

(f) *Effect of failure to provide timely notice.* If the MA organization fails to provide the enrollee and the physician or provider involved, as appropriate, with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

* * * * *

■ 12. Section 422.572 is amended by revising paragraph (f) to read as follows:

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

* * * * *

(f) *Effect of failure to provide a timely notice.* If the MA organization fails to provide the enrollee and the physician or prescriber involved, as appropriate, with timely notice of an expedited organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

■ 13. Section 422.616 is amended by revising paragraph (a) and adding paragraph (e) to read as follows:

§ 422.616 Reopening and revising determinations and decisions.

(a) Subject to paragraph (e) of this section and the rules at § 422.138(c), an organization or reconsidered determination made by an MA organization, a reconsidered determination made by the independent entity described in § 422.592, or the decision of an Administrative Law Judge (ALJ) or attorney adjudicator or the Council that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 405 of this chapter.

* * * * *

(e) If the MA organization approved an inpatient hospital admission under the rules at § 412.3(d)(1) and (3) of this chapter, any additional clinical information obtained after the initial organization determination cannot be used as new and material evidence to establish good cause for reopening the determination.

■ 14. Section 422.631 is amended by revising paragraphs (a) and (d)(1)(i) and (ii) to read as follows:

§ 422.631 Integrated organization determinations.

(a) *General rule.* An applicable integrated plan must adopt and implement a process for enrollees to request that the plan make an integrated organization determination. The process for requesting that the applicable integrated plan make an integrated organization determination must be the same for all covered benefits. Timeframes and notice requirements for integrated organization determinations for Part B drugs are governed by the provisions for Part B drugs in §§ 422.568(b)(3), 422.570(d)(2), and 422.572(a)(2).

* * * * *

(d) * * *

(1) * * *

(i) The applicable integrated plan must send an enrollee a written notice (and notify the physician or provider involved, as appropriate) of any adverse decision on an integrated organization determination (including a determination to authorize a service or item in an amount, duration, or scope that is less than the amount previously requested or authorized for an ongoing course of treatment) within the timeframes set forth in this section.

(ii) For an integrated organization determination not reached within the timeframes specified in this section (which constitutes a denial and is thus an adverse decision), the applicable integrated plan must send a notice to the enrollee (and notify the physician or provider involved, as appropriate) on the date that the timeframes expire. Such notice must describe all applicable Medicare and Medicaid appeal rights.

* * * * *

■ 15. Section 422.2267 is amended by:

■ a. Removing the word ''and'' at the end of paragraph (e)(30)(vi);

■ b. Removing the period and adding in its place ''; and'' at the end of paragraph (e)(30)(vii); and

■ c. Adding paragraph (e)(30)(viii).

The addition reads as follows:

§ 422.2267 Required materials and content.

* * * * *

(e) * * *

(30) * * *

(viii) For dual eligible special needs plans that are applicable integrated plans, as defined in § 422.561, must be an integrated member ID card that serves as the ID card for both the Medicare and Medicaid plans in which the enrollee is enrolled, beginning no later than contract year 2027.

* * * * *

■ 16. Section 422.2420 is amended by adding paragraph (b)(4)(i)(D) to read as follows:

§ 422.2420 Calculation of medical loss ratio.

* * * * *

(b) * * *

(4) * * *

(i) * * *

(D) Unsettled balances from the Medicare Prescription Payment Plan.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 17. The authority for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 18. Section 423.100 is amended by adding in alphabetical order definitions for ''ACIP-recommended adult vaccine'', ''Covered insulin product'', ''Covered insulin product applicable cost-sharing amount'', and ''Effective date of the ACIP recommendation'' to read as follows:

§ 423.100 Definitions.

* * * * *

ACIP-recommended adult vaccine means a covered Part D drug, as defined in this section, that is a vaccine licensed by the U.S. Food and Drug Administration (FDA) under section 351 of the Public Health Service Act for use by adult populations and administered in accordance with recommendations of the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) as adopted by the CDC Director.

* * * * *

Covered insulin product means, for purposes of § 423.120(h), an insulin product, including a product that is a combination of more than one type of insulin or a product that is a combination of both insulin and a non-insulin drug or biological product, that—

(1) Is a covered Part D drug covered under a PDP or MA–PD plan—

(i) Is licensed under section 351 of the Public Health Service Act; and

(ii) Is marketed under the license described in paragraph (1)(i) of this definition.

(2) Is not a compounded drug product that contains insulin (as described in § 423.120(d)).

Covered insulin product applicable cost-sharing amount means, with respect to a covered insulin product, as defined in this section, covered under a PDP or an MA–PD plan prior to an enrollee reaching the annual out-of-pocket threshold during plan year 2026 and each subsequent plan year, the lesser of the following:

(1) $35.

(2) An amount equal to 25 percent of the maximum fair price established for the covered insulin product in accordance with Part E of title XI of the Act.

(3) An amount equal to 25 percent of the negotiated price (as defined in this section) of the covered insulin product under the PDP or MA–PD plan.

* * * * *

Effective date of the ACIP recommendation means the date specified on the CDC website noting the date the CDC Director adopted the ACIP recommendation.

* * * * *

■ 19. Section 423.120 is amended by adding paragraphs (g) and (h) to read as follows:

§ 423.120 Access to covered Part D drugs

* * * * *

(g) *Coverage of ACIP-recommended adult vaccines.* With respect to an ACIP-recommended adult vaccine, a Part D sponsor must—

(1) Not apply any deductible nor charge any cost sharing; and

(2) Once a new or revised recommendation is posted on the CDC website, provide coverage consistent with paragraph (g)(1) of this section for dates of service on or after the effective date of the ACIP recommendation, as defined at § 423.100.

(3) Apply the requirements in paragraphs (g)(1) and (2) of this section to ACIP-recommended adult vaccines obtained from either an in-network or out-of-network pharmacy or provider in accordance with § 423.124(a) and (c).

(h) *Cost sharing for covered insulin products.* With respect to a covered insulin product, as defined at § 423.100, covered under a PDP or an MA–PD plan prior to an enrollee reaching the annual out-of-pocket threshold, a Part D sponsor must do all of the following:

(1) Not apply a deductible.

(2) Ensure any enrollee cost sharing for each prescription fill up to a one-month supply does not exceed the covered insulin product applicable cost-sharing amount defined at § 423.100.

(3) Ensure any enrollee cost sharing for each prescription fill greater than a 1-month supply does not exceed the cumulative covered insulin product applicable cost-sharing amount (as defined in § 423.100) that would apply if the same days' supply was dispensed in the fewest number of 1-month supply increments necessary.

(4) Apply the requirements in paragraphs (h)(1) through (3) of this section to covered insulin products obtained from either an in-network or out-of-network pharmacy or provider.

■ 20. Section 423.137 is added to subpart C to read as follows:

§ 423.137 Medicare Prescription Payment Plan.

(a) *General.* For plan years beginning on or after January 1, 2026, or, in the case of a plan operating on a non-calendar year basis, for the portion of the plan year starting on January 1, 2026, each PDP sponsor offering a prescription drug plan and each MA organization offering an MA–PD plan must provide to any enrollee of such plan, including an enrollee who is a subsidy eligible individual (as defined at § 423.4), the option to elect with respect to a plan year to pay $0 cost sharing at the point of sale and pay cost sharing under the plan in monthly amounts that are capped in accordance with this section.

(b) *Definitions.* For the purposes of this section, the following definitions apply:

(1) *OOP costs for the Medicare Prescription Payment Plan* means the out-of-pocket (OOP) cost sharing amount the Part D enrollee is directly responsible for paying.

(i) For the subsequent month calculation of the Part D cost sharing incurred by the Part D enrollee, it includes those Part D cost sharing amounts that the enrollee is responsible for paying after taking into account amounts paid by third-party payers.

(ii) It does not include the covered plan pay amount or other costs defined under section 1860D–2(b)(4)(C) of the Act.

(2) *Remaining OOP costs owed by the participant* means the sum of out-of-pocket costs for the Medicare Prescription Payment Plan that have not yet billed to the program participant. For example, if a Medicare Prescription Payment Plan participant incurs $2,000 in January 2025 and is billed $166.67, the remaining OOP costs for the Medicare Prescription Payment Plan are $2,000 − $166.67 = $1,833.33.

(c) *Calculation of the maximum monthly cap on cost-sharing payments.* For each month in the plan year for which an enrollee in a PDP or an MA–PD plan has made an election to participate in the Medicare Prescription Payment Plan, the PDP sponsor or MA organization must determine a maximum monthly cap (as defined in paragraph (c)(1) of this section) for such enrollee.

(1) *Enrollee monthly payments.* For each month an enrollee is participating in the Medicare Prescription Payment Plan, the PDP sponsor or MA organization shall bill such enrollee an amount (not to exceed the maximum monthly cap) for the out-of-pocket costs of such enrollee in such month.

(i) *First month maximum monthly cap calculation.* For the first month for which the enrollee has made an election to participate in the Medicare Prescription Payment Plan, the maximum monthly cap is an amount determined by calculating the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) of the Act minus the incurred costs of the enrollee as described in section 1860D–2(b)(4)(C) of the Act; divided by the number of months remaining in the plan year.

(A) When the out-of-pocket costs incurred in the first month of program participation are less than the maximum monthly cap defined in this paragraph (c)(1)(i), the PDP sponsor or MA organization must bill the participant the lesser of the participant's actual out-of-pocket costs or the first month's maximum monthly cap.

(B) When an enrollee opts into the Medicare Prescription Payment Plan prior to the start of the plan year, the calculation described in this paragraph (c)(1)(i) applies to their first month of active coverage within the plan year.

(ii) *Calculation of maximum monthly cap in subsequent months.* For subsequent months in the plan year, the maximum monthly cap is an amount determined by calculating the sum of any remaining out-of-pocket costs owed by the enrollee from a previous month that have not yet been billed to the enrollee and any additional out-of-pocket costs incurred by the enrollee; divided by the number of months remaining in the plan year.

(2) *Eligible out-of-pocket costs.* The calculations described in paragraphs (c)(1)(i) and (ii) of this section apply only to covered Part D drugs, as defined at § 423.100.

(3) *Months remaining in the plan year.* For the calculations described in paragraphs (c)(1)(i) and (ii) of this section, the number of months remaining in the plan year includes the month for which the cap is being calculated.

(4) *Impact on true out-of-pocket cost accumulation.* Participation in the Medicare Prescription Payment Plan must have no impact on true out-of-pocket cost accumulation. Costs defined

under section 1860D–2(b)(4)(C) of the Act incurred under the Medicare Prescription Payment Plan must still be treated as incurred based on the date each Part D claim is adjudicated.

(5) *Prescriptions for an extended day supply.* For participants who fill prescriptions for an extended day supply, their OOP costs for the Medicare Prescription Payment Plan for those prescriptions must be attributed to the month the prescription was filled and not be pro-rated over the months covered by the prescription.

(6) *Mid-year plan switching.* When an individual opts into the Medicare Prescription Payment Plan after switching plans midyear, the new Part D sponsor must calculate the individual's monthly cap for the first month of participation under the new plan using the formula for the calculation of the maximum monthly cap in the first month.

(d) *Eligibility and election.* An individual is eligible for the Medicare Prescription Payment Plan if they are enrolled in a Part D plan and have not been precluded from participation due to failure to pay, as described in paragraphs (f)(2)(ii) and (f)(5) of this section. LIS-eligible Part D enrollees are eligible to participate in the program. The requirements described in this paragraph (d) are applicable beginning October 1, 2025, with respect to eligibility and election in the Medicare Prescription Payment Plan for 2026.

(1) *Election.* A Part D sponsor must allow any Part D enrollee, including those who are LIS-eligible, to opt into the program prior to the beginning of the plan year or at any point during the plan year. A Part D enrollee must also be allowed to opt into the program in advance of a new plan enrollment effective date, including during any of the following:

(i) The annual coordinated election period for the subsequent plan year.

(ii) The Part D initial enrollment period.

(iii) Part D special election periods.

(2) *Format of election requests.* A Part D sponsor must allow any Part D enrollee or a Part D enrollee's authorized legal representative acting on behalf of the enrollee to opt into the program using a paper or electronic election request form or through a telephone call. Part D sponsors must process any election request regardless of format.

(i) *Paper election requests.* Paper election requests are considered received on the date and time:

(A) The Part D sponsor initially stamps a document received by regular mail (that is, U.S. Postal Service); or

(B) A delivery service that has the ability to track when a shipment is delivered (for example, U.S. Postal Service, UPS, FedEx, or DHL) delivers the document.

(ii) *Telephonic election requests.* Telephonic election requests are considered received on the date and time that either of the following occurs:

(A) The verbal request is made by telephone with a customer service representative.

(B) A message is left on the Part D sponsor's voicemail system if the Part D sponsor utilizes a voicemail system to accept requests or supporting statements after normal business hours.

(iii) *Electronic election requests.* An electronic election request is considered received on the date and time a request is received through the Part D sponsor's website. This is true regardless of when a Part D sponsor ultimately retrieves or downloads the request.

(3) *Completion of election request.* For an election request to be considered complete, the Part D sponsor must receive all of the following:

(i) The name of the Part D enrollee.

(ii) The Medicare ID number of the Part D enrollee.

(iii) The Part D enrollee's or their authorized legal representative's agreement to the Part D sponsor's terms and conditions for the program (signature or, in the case of telephonic requests, verbal attestation).

(4) *Processing an election request*—(i) *Prior to plan year.* Part D sponsors must process election requests received prior to the plan year within the following timeframes:

(A) Within 10 calendar days of receipt, process a complete election request as specified in paragraph (d)(3) of this section.

(B) Within 10 calendar days of receipt of an incomplete election request, contact the Part D enrollee to request the necessary information to process the request as specified in paragraph (d)(3) of this section.

(C) If information necessary to consider the request complete, as required at paragraph (d)(3) of this section, is not received within 21 calendar days of the request for information, the Part D sponsor may deny the request.

(ii) *During a plan year.* Part D sponsors must process election requests received during a plan year within the following timeframes:

(A) Within 24 hours of receipt, process a complete election request, as specified in paragraph (d)(3) of this section.

(B) Within 24 hours of receipt of an incomplete election request, contact the Part D enrollee to request the necessary information to process the request, as required in paragraph (d)(3) of this section.

(C) If information necessary to consider the request complete, as required at paragraph (d)(3) of this section, is not received within 21 calendar days of the request for information, the Part D sponsor may deny the request.

(D) In the event a Part D sponsor fails to process the request within 24 hours due to no fault of the Part D enrollee, the Part D sponsor must—

(*1*) Process a retroactive election effective on the date on which the enrollee should have been admitted into the program; and

(*2*) Reimburse the enrollee for any cost-sharing paid on or after that date within 45 calendar days and include those amounts, as appropriate, in the program calculations.

(5) *Inclusion of all covered Part D drugs once in the program.* Once a participant has opted into the program, cost sharing for all covered Part D drugs must be included in the program.

(6) *Retroactive election.* (i) A Part D sponsor must have in place a process to effectuate a retroactive election into the Medicare Prescription Payment Plan if both of the following conditions are met:

(A) The Part D enrollee believes that any delay in filling the prescription(s) due to the 24-hour timeframe required to process their request to opt in may seriously jeopardize their life, health, or ability to regain maximum function.

(B) The Part D enrollee requests retroactive election within 72 hours of the date and time the claim(s) were adjudicated.

(ii) The Part D sponsor must process the reimbursement for all cost sharing paid by the enrollee for the prescription and any covered Part D prescription filled between the date of adjudication of the claim and the date that the enrollee's election is effectuated within 45 calendar days of the election date.

(iii) If the Part D sponsor determines that an enrollee failed to request retroactive election within the required timeframe, it must promptly notify the individual of its determination and provide instructions on how the individual may file a grievance, as required under paragraph (h)(2) of this section.

(7) *Retroactive LIS eligibility.* A Part D sponsor must develop standardized procedures for determining and processing reimbursements for excess Medicare Prescription Payment Plan payments made by program participants who become LIS eligible and that meet

requirements specified at §§ 423.800(c) and (e) and 423.466(a).

(8) *Mid-year plan switching.* When a Part D enrollee switches Part D plans, whether offered by the same or a different Part D sponsor, during the plan year or is reassigned by CMS, the Part D sponsor of the new Part D plan is not permitted to automatically sign up the individual for the Medicare Prescription Payment Plan under the new plan but must allow the individual to opt into the program. Part D plan has the definition established at § 423.4.

(i) The Part D sponsor of the prior Part D plan must offer the participant the option to repay the full outstanding amount in a lump sum. If the individual chooses to continue paying monthly, the Part D sponsor must continue to bill the participant monthly based on the participant's accrued OOP costs for the Medicare Prescription Payment Plan while in the program under that sponsor's Part D plan. The Part D sponsor cannot require full immediate repayment.

(ii) Part D enrollees may only be precluded from opting into the program under a new Part D plan if both of the following conditions are met:

(A) Both the former and new plans are offered by the same Part D sponsor.

(B) The enrollee was involuntarily terminated from the program under the former plan, as described in paragraph (f)(2)(ii) of this section, for failure to pay and still owes an overdue balance.

(9) *Automatic renewal.* A Part D sponsor is required to automatically renew a Part D enrollee's participation in the Medicare Prescription Payment Plan for subsequent plan years. The Part D sponsor must notify the enrollee of the renewal and remind enrollees that they may opt out of the program at any time, in accordance with paragraph (f)(2)(i) of this section.

(10) *Election communications*—(i) *Election request form.* A Part D sponsor must make available throughout the plan year and during the Part D plan enrollment periods described at paragraph (d)(4)(i)(A) of this section an election request form in the formats specified in paragraph (d)(2) of this section.

(A) *Timing.* A Part D sponsor must send a paper election request form within the same timeframe as the membership ID card mailing specified at § 423.2267(e)(32)(i). The election form may be sent in the membership ID card mailing itself or in a separate mailing.

(B) *Contents.* The election request form must include or provide all of the following:

(*1*) Fields for all of the following Part D enrollee information:

(*i*) First and last name.

(*ii*) Medicare Number.

(*iii*) Birth date.

(*iv*) Phone number.

(*v*) Permanent residence street address, and mailing address, if different from permanent residence street address.

(*vi*) Signature field, allowing the enrollee to attest that they understand that form is a request to participate in the Medicare Prescription Payment Plan and the Part D sponsor will contact them if more information is needed to complete the request; their signature indicates they have read and understood the Part D sponsor's terms and conditions; and the Part D sponsor will inform the individual when their participation in the program is active, and, until the individual receives that notification, they are not a participant in the program.

(*2*) Instructions for how to submit the form to the Part D sponsor.

(*3*) Instructions for how the Part D enrollee can contact the Part D sponsor for questions or assistance.

(C) *Additional information.* Additional educational information about the Medicare Prescription Payment Plan must accompany the election request form when provided in hard copy or on the web. The additional information requirement may be fulfilled by including with the election request form the CMS-developed fact sheet about the program. If the Part D sponsor develops and uses alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this paragraph (d)(10)(i)(C), they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at subpart V of this part.

(D) *Terms and conditions.* A Part D sponsor may include their program terms and conditions on the election request form or may include them on a separate attachment.

(ii) *Notice of election approval.* Upon accepting an election request, the Part D sponsor must send a notice of election approval.

(A) *Timing.* (*1*) For requests received prior to the plan year, the notice of election approval must be sent within 10 calendar days of receipt of the election request.

(*2*) For requests received during the plan year, the notice of election approval must be sent within 24 hours of receipt of the election request.

(*3*) The initial notice must be delivered via telephone, to be followed by a written notice delivered to the participant within 3 calendar days of delivering the initial telephone notice. If a Part D plan sponsor is processing an election request over the phone or electronically and at that same time provides the enrollee with the effective date of their program effectuation and other notice of election requirements as outlined at this paragraph (d)(10)(ii), then a second telephonic notification of election acceptance is not required.

(B) *Contents.* The notice of election approval must include all of the following:

(*1*) The effective date of the individual's participation.

(*2*) A description of how payments for covered Part D drugs under the program will work.

(*3*) An overview of how the monthly bill is calculated.

(*4*) Information about procedures for involuntary termination due to failure to pay and how to submit an inquiry or file a grievance.

(*5*) A statement that leaving the program will not affect the individual's Part D plan enrollment.

(*6*) A description of how individuals may still owe a program balance if they leave the program, and they can choose to pay their balance all at once or be billed monthly.

(*7*) An overview of other Medicare programs that can help lower costs and how to learn more about these programs. These programs include all of the following:

(*i*) Extra Help.

(*ii*) The Medicare Savings Program.

(*iii*) The State Pharmaceutical Assistance Program.

(*iv*) A manufacturer's Pharmaceutical Assistance Program.

(C) *Additional information.* Additional educational information about the Medicare Prescription Payment Plan must accompany the notice of election approval. The additional information requirement may be fulfilled by including with the notice the CMS-developed fact sheet about the program. If the Part D sponsor develops and uses alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this paragraph (d)(10)(ii)(C), they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at subpart V of this part.

(iii) *Notification of denial.* Upon denial of an election request, the Part D sponsor must send a notice of denial.

(A) *Timing.* (*1*) For requests received prior to the plan year, the notice of denial must be sent within 10 calendar days of receipt of the election request.

(*2*) For requests received during the plan year, the notice of denial must be

sent within 24 hours of receipt of the election request.

(*3*) For incomplete election requests, within 10 calendar days of the expiration of the timeframe for submission of additional information.

(B) *Contents.* The notice of denial must explain the reason for denial and a description of the grievance process available to the individual.

(iv) *Renewal notice.* A Part D sponsor must send a notice alerting program participants that their participation in the program will automatically renew for the subsequent plan year.

(A) *Timing.* The notice must be sent after the end of the annual coordinated election period, as described at § 422.62(a)(2) of this chapter, but prior to the end of the plan year.

(B) *Contents.* The notice must include all of the following:

(*1*) Notification to the participant that their participation will automatically renew for the upcoming year.

(*2*) Reminder that the participant may opt out of the program at any time, including for the upcoming plan year.

(*3*) Terms and conditions. A Part D sponsor must include their program terms and conditions for the upcoming year as part of the renewal notice or as a separate attachment.

(e) *Part D enrollee targeted outreach.* A Part D sponsor must undertake targeted outreach to enrollees who are likely to benefit from making an election into the Medicare Prescription Payment Plan. The requirements described in this paragraph (e) are applicable beginning October 1, 2025, with respect to targeted outreach for the Medicare Prescription Payment Plan for 2026.

(1) *Identification criteria.* An enrollee deemed to be ''likely to benefit'' from the Medicare Prescription Payment Plan is identified by the Part D sponsor based on the following criteria.

(i) For 2026 and subsequent years, the targeted outreach criteria are as follows:

(A) A Part D enrollee is likely to benefit from participating in the program if the enrollee incurs $600 or more in out-of-pocket costs for a single covered Part D drug.

(B) A Part D enrollee is likely to benefit from participating in the program if the enrollee incurred $2,000 in out-of-pocket costs for covered Part D drugs in the first nine months of the year prior to the upcoming plan year.

(ii) A Part D sponsor may develop supplemental strategies for identification of additional Part D enrollees likely to benefit. If supplemental strategies are implemented, then the Part D sponsor must apply any additional identification criteria to every enrollee of each plan equally.

(2) *Point of sale notification.* (i) A Part D sponsor must have a mechanism to notify a pharmacy when a Part D enrollee incurs out-of-pocket costs with respect to covered Part D drugs that make it likely the enrollee may benefit from participating in the program using the identification criteria set forth in paragraphs (e)(1)(i)(A) and (e)(1)(ii) of this section.

(ii) A Part D sponsor must ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that it is likely that the Part D enrollee may benefit from the Medicare Prescription Payment Plan.

(3) *Part D sponsor notification.* A Part D sponsor must directly outreach to enrollees identified as likely to benefit from the program during either of the following timeframes:

(i) *Prior to the plan year.* Prior to the plan year, a Part D sponsor must notify current enrollees that they are likely to benefit from the program during the fourth quarter of the year, and no later than the end of the annual coordinated election period, as described at § 422.62(a)(2) of this chapter, using the identification criteria set forth in paragraphs (e)(1)(i)(B) and (e)(1)(ii) of this section.

(ii) *On an ongoing basis during the plan year.* Part D sponsors must put in place reasonable guidelines for ongoing identification and notification of enrollees that are likely to benefit from the program on an ongoing basis during the plan year.

(4) *Targeted outreach notification requirements.* When an enrollee is identified as likely to benefit from the program, using the identification criteria set forth in paragraphs (e)(1)(i) and (ii) of this section or based on Part D sponsor-developed guidelines set forth at paragraph (e)(3)(ii) of this section, the Part D sponsor must provide to the enrollee the standardized ''Medicare Prescription Payment Plan Likely to Benefit Notice'' consistent with the requirements at § 423.2267(b).

(i) When the enrollee is identified as likely to benefit directly by the Part D sponsor, either prior to or during the plan year, the notification may be done via mail or electronically (based on the Part D enrollee's preferred and authorized communication methods).

(A) The outreach must include a program election request form and additional information about the Medicare Prescription Payment Plan. The additional information requirement may be fulfilled by including with the notice the CMS-developed fact sheet about the program. If the Part D sponsor develops and uses alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this paragraph (e)(4)(i)(A), they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at subpart V of this part.

(B) During the plan year, the initial notice may be provided via telephone, so long as the written ''Medicare Prescription Payment Plan Likely to Benefit Notice,'' election request form, and additional information are sent within 3 calendar days of the telephone notification.

(ii) When the enrollee is identified as likely to benefit during the plan year at the pharmacy point of sale, the notice must be provided as described in paragraph (i)(2) of this section.

(5) *Targeted outreach exclusions.* A Part D sponsor does not have to notify enrollees that they are likely to benefit from the program under any of the following circumstances:

(i) For the current year during the final month of the plan year (December).

(ii) When the enrollee is currently participating in the program, including—

(A) For the current year; and

(B) For the upcoming year.

(iii) When the enrollee is precluded from opting into the program.

(iv) When the PDP is non-renewing its contract or individual plan benefit package. This exclusion only applies to the requirements at paragraph (e)(3)(i) of this section related to prior to plan year targeted outreach.

(f) *Termination of election, reinstatement, and preclusion*—(1) *General rule.* Except as provided in paragraph (f)(2) of this section, a Part D sponsor may not do any of the following:

(i) Terminate an individual from the Medicare Prescription Payment Plan.

(ii) Orally or in writing, or by any action or inaction, request or encourage an individual to disenroll.

(2) *Basis for termination*—(i) *Voluntary terminations.* A Part D sponsor must have a process to allow participants who have opted into the Medicare Prescription Payment Plan to opt out during the plan year.

(A) When a participant opts out of the Medicare Prescription Payment Plan, a Part D sponsor must—

(*1*) Process the termination with an effective date within 3 calendar days of receipt of the request for termination.

(*2*) Provide the individual with a notice of termination after the individual notifies the Part D sponsor

that they intend to opt out under the Part D sponsor's established process.

(*i*) *Timing.* The Part D sponsor must send the notice of termination within 10 calendar days of receipt of the request for termination.

(*ii*) *Contents.* The notice of voluntary termination must include all of the following. The date on which the individual's participation in the program ends. An explanation of why the individual is receiving the notice. A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan. A statement clarifying that the individual will continue to be billed monthly or can choose to pay the amount owed all at once, and that the individual will not pay interest or fees on the amount owed. A statement clarifying that the individual can join the Medicare Prescription Payment Plan again and instructions for how to do so. An overview of other Medicare programs that can help lower costs and how to learn more about these programs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and a manufacturer's Pharmaceutical Assistance Program.

(*3*) Offer the participant the option to repay the full outstanding amount in a lump sum. A Part D sponsor is prohibited from requiring full immediate repayment from a participant who has been terminated from the Medicare Prescription Payment Plan.

(*4*) If the participant opts not to repay the full outstanding amount in a lump sum, continue to bill amounts owed under the program in monthly amounts not to exceed the maximum monthly cap according to the statutory formula for the duration of the plan year after an individual has been terminated.

(*5*) Maintain appropriate records of the termination once the termination is processed.

(B) [Reserved]

(ii) *Involuntary termination.* If a participant fails to pay their monthly billed amount under the program, a Part D sponsor is required to terminate that individual's Medicare Prescription Payment Plan participation.

(A) A participant will be considered to have failed to pay their monthly billed amount only after the conclusion of the required grace period as specified at paragraph (f)(4) of this section.

(B) When a Part D sponsor involuntarily terminates a participant, the sponsor must do all of the following:

(*1*) Provide the individual with a notice of termination consistent with the requirements of paragraphs (f)(2)(ii)(C) and (D) of this section.

(*2*) Offer the participant the option to repay the full outstanding amount in a lump sum. A Part D sponsor is prohibited from requiring full immediate repayment from a participant who has been terminated from the Medicare Prescription Payment Plan.

(*3*) If the participant opts not to repay the full outstanding amount in a lump sum, continue to bill amounts owed under the program in monthly amounts not to exceed the maximum monthly cap according to the statutory formula for the duration of the plan year after an individual has been terminated.

(C) If a Part D sponsor involuntarily terminates a participant under this paragraph (f)(2)(ii), the Part D sponsor must send the individual an initial notice explaining that the individual has failed to pay the billed amount.

(*1*) *Timing.* The notice of failure to pay must be sent within 15 calendar days of the payment due date.

(*2*) *Contents.* The notice of failure to pay must include all of the following:

(*i*) Pertinent dates, including the date the missed monthly payment was due, the amount the individual must pay to remain in the program, and the date by when payment must be received, which is the date of the end of the grace period.

(*ii*) A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan.

(*iii*) Instructions for how to submit payment.

(*iv*) Information about procedures for involuntary termination due to failure to pay, including the date on which the participant would be removed if payment is not received, and how to submit an inquiry or file a grievance.

(*v*) A statement describing how individuals should pay their Part D plan premium first if they cannot afford both their premium and their program balance.

(*vi*) An overview of other Medicare programs that can help lower costs and how to learn more about these programs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and a manufacturer's Pharmaceutical Assistance Program.

(D) If the individual has failed to pay the amount due by the end of the grace period described at paragraph (f)(4) of this section, the Part D sponsor must send the individual a termination notice explaining that the individual has been terminated from the Medicare Prescription Payment Plan.

(*1*) *Timing.* The involuntary termination notice must be sent within 3 calendar days following the last day of the end of the grace period.

(*2*) *Contents.* The involuntary termination notice must include all of the following:

(*i*) Pertinent dates, including the date the individual was originally notified of the missed monthly payment and the due date for that payment, as well as the date on which the individual's participation in the program ends, which should be the same date as the notice.

(*ii*) A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan, and that the individual's Part D drug coverage will not be impacted.

(*iii*) Instructions for how to submit payment and the amount owed.

(*iv*) Instructions for how to submit an inquiry or file a grievance.

(*v*) A statement clarifying that the individual can join the Medicare Prescription Payment Plan again if they pay the amount owed.

(*vi*) An overview of other Medicare programs that can help lower costs and how to learn more about these programs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and a manufacturer's Pharmaceutical Assistance Program.

(E) If either notice is returned to the Part D sponsor as undeliverable, the Part D sponsor must immediately implement its existing procedure for researching a potential change of address.

(3) *Required grace period and reinstatement.* When a program participant fails to pay a program bill, the Part D sponsor must provide individuals with a grace period of at least two months upon notifying the individual of the initial missed payment.

(i) The grace period must begin on the first day of the month following the date on which the initial notice described in this paragraph (f)(3) is sent.

(ii) A participant must be allowed to pay the overdue balance in full during the grace period to remain in the program.

(iii) If a participant fails to pay their monthly billed amount under the program with fewer than two full calendar months remaining in the calendar year, the grace period must carry over into the next calendar year.

(A) If the program participant is within their grace period from the prior year, the Part D sponsor must allow the participant to opt into the program for the next year.

(B) If that participant fails to pay the amount due from the prior year during the required grace period, the Part D

sponsor may terminate the individual's participation in the program in the new year following the procedures outlined in paragraph (f)(2)(ii) of this section.

(iv) If an individual who has been terminated from the Medicare Prescription Payment Plan demonstrates good cause for failure to pay the program billed amount within the grace period and pays all overdue amounts billed, a Part D sponsor must reinstate that individual into the Medicare Prescription Payment Plan.

(A) A Part D sponsor is expected to reinstate an individual into the program within a reasonable timeframe after the individual has repaid their past due Medicare Prescription Payment Plan balance in full.

(B) To demonstrate good cause, the individual must establish by a credible statement that failure to pay the monthly amount billed within the grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(v) If an individual who has been terminated from the Medicare Prescription Payment Plan pays all overdue amounts billed in full, a Part D sponsor may also reinstate that individual, at the sponsor's discretion and within a reasonable timeframe, even if the individual does not demonstrate good cause.

(4) *Preclusion of election in a subsequent plan year.* If an individual fails to pay the amount billed for a month as required under the Medicare Prescription Payment Plan, a Part D sponsor may preclude that individual from opting into the Medicare Prescription Payment Plan in a subsequent year.

(i) A Part D sponsor may only preclude an individual from opting into the Medicare Prescription Payment Plan in a subsequent year if the individual owes an overdue balance to that Part D sponsor.

(ii) If an individual enrolls in a Part D plan offered by a different Part D sponsor than the Part D sponsor to which the individual owes an overdue balance, that individual cannot be precluded from opting into the Medicare Prescription Payment Plan in a subsequent year by that different Part D sponsor.

(iii) If a Part D enrollee remains in a plan offered by the same Part D sponsor and continues to owe an overdue balance, preclusion may extend beyond the immediately subsequent plan year.

(A) If an individual pays off the outstanding balance under the Medicare Prescription Payment Plan during a subsequent year, the Part D sponsor must promptly permit them to opt into the Medicare Prescription Payment Plan after the balance is paid.

(B) [Reserved]

(iv) A Part D sponsor that offers more than one Part D plan may have different preclusion policies for its different plans. However, the Part D sponsor must apply its preclusion policy consistently among all enrollees of the same Part D plan.

(5) *Prohibition on Part D enrollment penalties.* A Part D plan sponsor is prohibited from doing any of the following:

(i) Disenrolling a Part D enrollee from a Part D plan for failure to pay any amount billed under the Medicare Prescription Payment Plan.

(ii) Declining future enrollment into a Part D plan based on an individual's failure to pay a monthly amount billed under the Medicare Prescription Payment Plan.

(6) *Disenrollment.* (i) If a participant in the Medicare Prescription Payment Plan is disenrolled voluntarily or involuntarily from their Part D plan under the provisions in § 423.44(b), the participant is also terminated from the Medicare Prescription Payment Plan in that plan.

(ii) If the participant enrolls in a different plan, they may opt into the Medicare Prescription Payment Plan under their new plan.

(7) *Billing for amounts owed.* Nothing in this section prohibits a Part D sponsor from billing an individual for an outstanding Medicare Prescription Payment Plan amount owed.

(g) *Participant billing rights*—(1) *General rule.* For each billing period after an individual has opted into the program and incurred out-of-pocket costs, a Part D sponsor must calculate a monthly amount that takes into account the out-of-pocket costs in that month that were incurred on or after the date on which the individual opted into the program.

(i) A Part D sponsor must not bill a participant who is in the program but has not yet incurred any out-of-pocket costs during the plan year.

(ii) While past due balances from prior monthly bills may also be included in a billing statement, which could result in the total amount on the billing statement exceeding the maximum monthly cap, the amount billed for the month for which the maximum monthly cap is being calculated cannot be higher than the cap for that month.

(iii) A Part D sponsor must not charge late fees, interest payments, or other fees, such as for different payment mechanisms.

(A) A Part D sponsor must ensure that—

(*1*) Any third party it contracts with complies with such requirements.

(*2*) Participants do not incur any charges or fees as a result of overbilling or overpayment errors made by the Part D sponsor.

(B) [Reserved]

(iv) A Part D sponsor must send a bill for the Medicare Prescription Payment Plan that is separate from the bill for collection of premiums, if applicable.

(2) *Billing period.* Each billing period will be a calendar month.

(i) The billing period begins on either of the following:

(A) The effective date of a Part D enrollee's participation in the Medicare Prescription Payment Plan (for the first month a participant elects into the program during the plan year).

(B) The first day of the month (for each subsequent month or for the first month of a participant who elects into the program prior to the start of the plan year).

(ii) The billing period ends on the last date of that month.

(3) *Billing statement.* Billing statements must include all of the following information:

(i) A statement that the bill is for the Medicare Prescription Payment Plan.

(ii) A brief description of the program.

(iii) A reference to where additional information about the program can be found.

(iv) The effective date of program participation.

(v) The last payment received, showing the date, amount of the last payment, and the means of payment made by the participant.

(vi) Any balance carried over from the prior month, including any missed payments.

(vii) Itemized out-of-pocket costs by prescription for the month being billed.

(viii) The amount due from the participant for the month being billed (that is, the amount based on the application of the monthly cap calculation).

(ix) The remaining total out-of-pocket cost sharing balance.

(x) Information on the next steps if the participant fails to pay by the stated due date.

(xi) Information on how to voluntarily opt out of the program and balances due if participation is terminated.

(xii) Information on the dispute processes available if the individual disputes their bill.

(xiii) LIS program information, including the following:

(A) General information about how to enroll in the LIS program (as an additional or alternative avenue for addressing prescription drug costs).

(B) A statement that LIS enrollment, for those who qualify, is likely to be more advantageous than participation in the Medicare Prescription Payment Plan.

(xiv) Plan contact information for participant questions about the billing statement.

(4) *Treatment of unsettled balances.* Any unsettled balances with respect to amounts owed under the program will be treated as plan losses.

(i) The Secretary is not liable for any such balances outside of those assumed as losses estimated in a Part D sponsor's plan bid.

(ii) If a Part D sponsor is compensated by or on behalf of the participant for an unsettled balance or sells an unsettled balance as a debt, that Part D sponsor cannot treat the amount as a loss and cannot include it in its bid.

(5) *Prioritization of premium payments.* If a Part D enrollee has opted into the program and makes payments directly to the Part D sponsor, and it is unclear whether a payment should go towards the participant's outstanding Part D plan premium or Medicare Prescription Payment Plan balance, then the payment must be applied to the Part D premium.

(6) *Financial reconciliation.* A Part D sponsor must have a financial reconciliation process in place to correct inaccuracies in billing or payments or both.

(i) *Participant payment.* (A) A participant may pay more than the maximum monthly cap, up to the annual out-of-pocket threshold.

(B) The participant cannot pay more than their total OOP costs for the Medicare Prescription Payment Plan.

(C) If a participant does pay more than their total OOP costs for the Medicare Prescription Payment Plan, then the Part D sponsor must reimburse the participant the amount that is paid above the balance owed.

(ii) *Reimbursements for excess participant payments.* A Part D sponsor must develop standardized procedures for determining and processing reimbursements for excess Medicare Prescription Payment Plan payments made by program participants.

(iii) *Claims adjustments resulting in increased amounts owed.* When Part D claims adjustments result in increased amounts owed by the participant, and these amounts have not yet been billed to the participant, they must be included in the revised remaining OOP costs owed by the participant (as defined at paragraph (b)(1) of this section) and, thus, in the subsequent month maximum cap for the next billing period.

(h) *Participant disputes*—(1) *Coverage determination and appeals procedures.* A Part D sponsor must apply the Part D coverage determination and appeals procedures specified at § 423.566(a) to any disputes made by program participants concerning the cost sharing amount of a covered Part D drug.

(2) *Grievance procedures.* A Part D sponsor must apply the Part D grievance procedure specified at § 423.562 to any dispute made by a program participant related to any aspect of the Medicare Prescription Payment Plan.

(i) *Pharmacy point of sale notification process.* (1) When a Part D sponsor is notifying a pharmacy that a Part D enrollee has incurred out-of-pocket costs with respect to covered Part D drugs that make it likely the enrollee may benefit from participating in the program, as required at paragraph (e)(2) of this section, the Part D sponsor must use standard code values for notifying the pharmacy that an enrollee has been identified as likely to benefit, as outlined by the National Council for Prescription Drug Programs.

(2) A Part D sponsor must ensure that the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' is provided to enrollees identified as likely to benefit (or the person acting on their behalf) through the pharmacy point of sale notification process.

(i) In pharmacy settings in which there is direct contact with enrollees (for example, community pharmacies where enrollees present in person to pick up prescriptions), the Part D sponsor must ensure that a hard copy of the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' is provided to enrollees identified as likely to benefit (or the person acting on their behalf) at the time the prescription is picked up.

(ii) For non-retail pharmacy settings without in-person encounters (such as mail order pharmacies), a Part D sponsor must require the pharmacy to notify the Part D enrollee via a telephone call or their preferred contact method.

(iii) For long-term care pharmacy settings, the Part D plan sponsor should not require that the pharmacy notify the Part D enrollee prior to dispensing the medication. Instead, the Part D plan sponsor should require the long-term care pharmacy to provide the notice to the Part D enrollee (or their authorized representative) at the time of its typical enrollee cost-sharing billing process.

(iv) If the pharmacy is in contact with a Part D enrollee identified as likely to benefit and the enrollee declines to complete the prescription filling process, the Part D sponsor must ensure that the pharmacy provides the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' to the Part D enrollee.

(3) A Part D sponsor must ensure that any contract between the Part D sponsor and a pharmacy (or between a first tier, downstream, or related entity and a pharmacy on the Part D sponsor's behalf) for participation in one or more of the Part D sponsor's networks includes a provision requiring pharmacies to provide this notification to Part D enrollees.

(j) *Pharmacy claims processing*—(1) *Electronic claims processing methodology.* Part D sponsors must use, and must ensure pharmacies use, a bank identification number (BIN) or processor control number (PCN) electronic claims processing methodology for applicable Medicare Prescription Payment Plan transactions.

(i) Part D sponsors must utilize, and ensure pharmacies utilize, an additional BIN/PCN that is unique to the Medicare Prescription Payment Plan to facilitate electronic processing of supplemental coordination of benefits (COB) transactions for program participants.

(ii) A Part D sponsor must provide the unique Medicare Prescription Payment Plan BIN/PCN and any other pertinent billing information to the pharmacy on paid claim responses when the enrollee is also a Medicare Prescription Payment Plan participant.

(iii) A Part D sponsor must assign a program-specific PCN that starts with ''MPPP'' and report the new BIN/PCN to CMS.

(iv) The transaction processed through the Medicare Prescription Payment Plan BIN/PCN will be submitted after processing any applicable other payer transactions in order to capture the final patient responsibility amount after all other payers have paid.

(2) *Supplemental coverage that increases final patient pay amount.* When a Part D enrollee has supplemental coverage that modifies their final out-of-pocket responsibility for covered Part D drugs:

(i) When the final patient pay amount returned to the pharmacy by a supplemental payer for a covered Part D drug is higher than the original Part D patient pay amount, the Part D sponsor may only include in the Medicare Prescription Payment Plan the participant's original Part D cost sharing, as determined by their plan-specific benefit structure.

(ii) [Reserved]

(3) *Prescription drug event reporting.* A Part D sponsor must ensure that the claims processing methodology described in paragraph (j)(1) of this section has no impact on prescription drug event (PDE) cost/payment field reporting, meaning PDE records must reflect participant and plan liability amounts as if the Medicare Prescription Payment Plan did not apply.

(4) *Real-time benefit tools.* A Part D sponsor must ensure that participation in the Medicare Prescription Payment Plan or the associated claims processing methodology described in paragraph (j)(1) of this section or both has no impact on the cost-sharing information displayed in real-time benefit tools.

(5) *Inclusion of retroactive claims.* A Part D sponsor is not required to retroactively include under this program claims submitted to the Part D sponsor by a Medicare Prescription Payment Plan participant (whether the request is made via paper form, telephonically, or electronically) except as provided in paragraph (d)(6) of this section.

(6) *Re-adjudication of prescription drug claims for new program participants.* (i) When a Part D enrollee receives the ''Medicare Prescription Payment Plan Likely to Benefit Notice'' from the pharmacy, they may choose to take time to consider opting into the program and leave the pharmacy without the prescription that triggered the notification.

(ii) When the Part D enrollee returns to the pharmacy after their election into the Medicare Prescription Payment Plan has been effectuated, the plan sponsor must require the pharmacy to reverse and reprocess the high-cost claim that triggered the likely to benefit notification.

(A) Should a Part D enrollee have other unpaid claims at the same pharmacy for covered Part D drugs from prior dates of service, in addition to the prescription that may have triggered the likely to benefit notification, they may also request that those claims be readjudicated.

(B) [Reserved]

(iii) When the Part D claim date of service is the same as the date of program effectuation), the Part D sponsor is not required to ensure the pharmacy reverse and resubmit the Part D claim, provided that they otherwise obtain the necessary Medicare Prescription Payment Plan BIN/PCN for the program-specific transaction.

(k) *Pharmacy payment obligations.* A Part D sponsor must ensure that enrollee participation in the Medicare Prescription Payment Plan does not affect the amount paid to pharmacies or the timing of such payments, consistent with § 423.520. A Part D sponsor must not do either of the following:

(1) Impose any fees or costs related to program implementation on pharmacies.

(2) Hold pharmacies responsible for any unsettled balances of a participant or for collecting unpaid balances from the participant on the Part D sponsor's behalf.

(l) [Reserved]

(m) *General Part D sponsor outreach and education requirements.* The requirements described in this paragraph (m) are applicable beginning October 1, 2025, with respect to general outreach for the Medicare Prescription Payment Plan for 2026.

(1) *Mailing.* A Part D sponsor, except a dual eligible special needs plan (D–SNP), must provide a Medicare Prescription Payment Plan election request form, described at paragraph (d)(10)(i) of this section, and additional educational information on the program in a hard copy mailing.

(i) The mailing must be sent by the later of—

(A) Within 10 calendar days from receipt of CMS confirmation of enrollment in the Part D plan; or

(B) The last day of the month prior to the plan effective date.

(ii) The election request form and supplemental information may be sent—

(A) With the membership ID card mailing described at § 423.2267(e)(32); or

(B) In its own envelope.

(iii) The mailing may be sent only to a Part D enrollee who is receiving a new membership ID card or to all Part D enrollees.

(iv) The additional information requirement may be fulfilled by including in the mailing the CMS-developed fact sheet about the program. If the Part D sponsor develops and uses alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this paragraph (m)(1)(iv), they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at subpart V of this part.

(2) *Websites.* In addition to meeting requirements described at §§ 423.128(d)(2) and 423.2265(b), a Part D sponsor is required to include all of the following on its website:

(i) An election request mechanism, as described at paragraph (d)(2) of this section.

(ii) An overview of the Medicare Prescription Payment Plan.

(iii) Examples of the program calculation and explanations.

(iv) A description of Part D enrollees who may be likely to benefit from the program.

(v) The financial implications of participation.

(vi) The implications of not paying monthly bills.

(vii) Instructions for how to opt into and out of the program, including timing requirements around election effectuation.

(viii) A description of the standards for retroactive election in cases where an enrollee believes that a delay in filling a prescription may seriously jeopardize their life, health, or ability to regain maximum function.

(ix) A description of the dispute and grievance procedure, as required under § 423.137(h).

(x) Contact information Part D enrollees can use to obtain further information

(xi) General information about the LIS program, including an overview of how LIS enrollment, for those who qualify, is likely to be more advantageous than program participation.

■ 21. Section 423.325 is added to read as follows:

§ 423.325 PDE submission timeliness requirements.

(a) *General PDE submission timeliness requirements.* Unless paragraph (b) of this section applies, a Part D sponsor must submit PDE records to CMS as follows:

(1) Initial PDE records within 30 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim.

(2) Adjustment or deletion PDE records within 90 calendar days of the Part D sponsor (or its contracted first tier, downstream, or related entity) discovering or receiving notification of an issue that requires a change to the previously submitted PDE record.

(3) Revised PDE records to resolve CMS rejected records within 90 calendar days of the rejection.

(b) *Selected Drugs PDE submission timeliness requirement.* A Part D sponsor must submit initial PDE records for selected drugs (as described at section 1192(c) of the Act) within 7 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim.

■ 22. Section 423.505 is amended by adding paragraph (q) to read as follows.

§ 423.505 Contract provisions.

* * * * *

(q) *Enrollment in the Medicare Transaction Facilitator Data Module for*

the Medicare Drug Price Negotiation Program. For contract year 2026 and all subsequent years, any contract between the sponsor and a pharmacy, or between a first tier, downstream, or related entity and a pharmacy on the sponsor's behalf, for participation in one or more of the Part D sponsor's networks must include a provision requiring the pharmacy to be enrolled in the Medicare Transaction Facilitator Data Module (MTF DM) (or any successor to the MTF DM) in a form and manner determined by CMS. Such provision must also require the pharmacy to maintain and certify up-to-date, complete, and accurate enrollment information with the MTF DM, in accordance with applicable terms and conditions of participation with the MTF DM, including but not limited to contact, third-party support entity or entities, and banking information, in a form and manner determined by CMS.

■ 23. Section 423.2265 is amended by adding paragraph (b)(16) to read as follows:

§ 423.2265 Websites.

* * * * *

(b) * * *

(16) Information about the Medicare Prescription Payment Plan as described in § 423.137(m)(2).

* * * * *

■ 24. Section 423.2267 is amended by—

■ a. Removing the word ''and'' at the end of paragraph (e)(32)(vi);

■ b. Removing the period and adding in its place ''; and'' at the end of paragraph (e)(32)(vii); and

■ c. Adding paragraphs (e)(32)(viii) and (e)(45) through (51).

The additions read as follows:

§ 423.2267 Required materials and content.

* * * * *

(e) * * *

(32) * * *

(viii) For dual eligible special needs plans that are applicable integrated plans, as defined in § 422.561 of this chapter, must be an integrated member ID card that serves as the ID card for both the Medicare and Medicaid plans in which the enrollee is enrolled, beginning no later than contract year 2027.

* * * * *

(45) *Election request form.* This is a model communications material that Part D sponsors must provide to allow enrollees to request to opt into the Medicare Prescription Payment Plan, as required under § 423.137(d)(10)(i).

(46) *Notice of election approval.* This is a model communications material that Part D sponsors must provide upon accepting a Medicare Prescription Payment Plan election request, as required under § 423.137(d)(10)(ii).

(47) *Medicare Prescription Payment Plan Likely to Benefit Notice.* This is a standardized communications material that Part D sponsors must provide to enrollees identified as being likely to benefit from opting into the Medicare Prescription Payment Plan, as required under § 423.137(e)(4).

(48) *Notice of failure to pay.* This is a model communications material that Part D sponsors must provide to Medicare Prescription Payment Plan participants who fail to pay a program bill, as required under § 423.137(f)(2)(ii)(C).

(49) *Involuntary termination notice.* This is a model communications material that Part D sponsors must provide to Medicare Prescription Payment Plan participants who are being involuntarily terminated from the program due to failure to pay, as required under § 423.137(f)(2)(ii)(D).

(50) *Voluntary termination notice.* This is a model communications material that Part D sponsors must provide to Medicare Prescription Payment Plan participants who request to voluntarily leave the program, as required under § 423.137(f)(2)(i)(A)(*2*).

(51) *Renewal notice.* This is a model communications material that Part D sponsors must send to Medicare Prescription Payment Plan participants alerting them that their participation in the program will automatically renew for the subsequent plan year, as required under § 423.137(d)(10)(iv).

■ 25. Section 423.2420 is amended by adding paragraph (b)(4)(i)(D) to read as follows:

§ 423.2420 Calculation of medical loss ratio.

* * * * *

(b) * * *

(4) * * *

(i) * * *

(D) Unsettled balances from the Medicare Prescription Payment Plan.

* * * * *

■ 25. Section 423.2536 is amended by—

■ a. Redesignating paragraphs (c) through (k) as paragraphs (d) through (l);

■ b. Adding a new paragraph (c); and

■ c. Revising newly redesignated paragraphs (i)(1) and (4).

The addition and revisions to read as follows:

§ 423.2536 Waiver of Part D program requirements.

* * * * *

(c) *Medicare Prescription Payment Plan.* Section 423.137.

* * * * *

(i) * * *

(1) Section 423.2265(b)(4), (5), (11), (13), and (16);

* * * * *

(4) Section 423.2267(e)(3) through (5), (9) through (12), (14) through (17), (25), (29), (33), and (45) through (51); and

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 26. The authority for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

§ 460.70 [Amended]

■ 27. Section 460.70 is amended in paragraph (e)(2) by removing the reference ''§ 460.98(c)'' and adding in its place the reference ''§ 460.98(d)''.

■ 28. Section 460.112 is amended by—

■ a. Revising paragraphs (a)(1) and (2);

■ b. Adding paragraphs (a)(3) through (8); and

■ c. Revising paragraph (b).

The revisions and additions read as follows:

§ 460.112 Specific rights to which a participant is entitled.

(a) * * *

(1) To receive comprehensive health care in a safe and clean environment and in an accessible manner.

(2) To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care and be provided humane care.

(3) Not to be required to perform services for the PACE organization.

(4) To have reasonable access to a telephone.

(5) To be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraint imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms.

(6) To be encouraged and assisted to exercise rights as a participant, including the Medicare and Medicaid appeals processes as well as civil and other legal rights.

(7) To be encouraged and assisted to recommend changes in policies and services to PACE staff.

(8) To have all information regarding PACE services and treatment options explained in a culturally competent manner.

(b) *Right to treatment.* Each participant has the right to appropriate and timely treatment for their health conditions, including the right to both of the following:

(1) Receive all care and services needed to improve or maintain the participant's health condition and attain the highest practicable physical, emotional, and social well-being.

(2) Access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team.

* * * * *

■ 29. Section 460.180 is amended by revising paragraph (b)(3) to read as follows:

§ 460.180 Medicare payment to PACE organizations.

* * * * *

(b) * * *

(3) CMS adjusts the monthly capitation payment amount derived under paragraph (b)(2) of this section based on a risk adjustment that reflects the individual's health status. The provisions of § 422.310 of this chapter apply to PACE organizations and risk adjustment data submitted by PACE organizations to CMS. In applying § 422.310 to PACE organizations and risk adjustment of payments to PACE organizations, references to MA organizations are read as references to PACE organizations. CMS ensures that payments take into account the comparative frailty of PACE enrollees relative to the general Medicare population.

* * * * *

Robert F. Kennedy Jr.,

Secretary, Department of Health and Human Services.

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