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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422, 423, 460, and 516

[CMS-4214-P2]

RIN 0938-AV88

Medicare Program; Contract Year 2028 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Programs of All-Inclusive Care for the Elderly

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), and Programs of All-Inclusive Care for the Elderly regulations to implement changes related to marketing and communications, drug coverage, enrollment processes, special needs plans, and other programmatic areas. Additionally, it would establish and implement a mandatory Medicare Advantage (MA) CMS Innovation Center model.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Time on **[**Insert date 60 days after date of filing for public inspection in the **Federal Register]**.

ADDRESSES: In commenting, please refer to file code CMS-4214-P2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically*. You may submit electronic comments on this regulation to **https://www.regulations.gov/docket/CMS-2026-3533**. Follow the "Submit a comment"

instructions.

2. *By regular mail*. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-4214-P2,

P.O. Box 8013,

Baltimore, MD 21244-8013.

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

3. *By express or overnight mail*. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-4214-P2,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

FOR FURTHER INFORMATION CONTACT:

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

James Clark, (410) 786-3875 – Part C and Cost Plan Issues.

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Alissa Gross, (410) 786-1120 – Parts C and D Payment Issues.

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

Elisabeth Daniel, (667) 290-8793 – Medicare Drug Price Negotiation Program Issues

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

ADVaNCEMA@cms.hhs.gov – ADVaNCE MA Model

SUPPLEMENTARY INFORMATION:

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

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

I. Executive Summary

A. Purpose

The primary purpose of this proposed rule is to amend the regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, and Programs of All-Inclusive Care for the Elderly. This proposed rule includes a number of changes that would improve these programs for contract year 2028 as well as codify existing subregulatory guidance.

We note that, as with previous rules, the new marketing and communications policies in this rule are proposed to be applicable for all contract year 2028 marketing and communications, beginning October 1, 2027.

B. Summary of the Key Provisions

1. Establishing a "Healthy Food" Standard for MA Supplemental Benefits

CMS proposes to establish a "healthy food" standard applicable to all MA supplemental benefits that include food items. Specifically, the proposal would apply a CMS-defined healthy food standard, aligned with the HHS and USDA's 2025–2030 Dietary Guidelines for Americans, across both primarily health-related supplemental benefits and Special Supplemental Benefits for the Chronically Ill (SSBCI). Under this proposal, food items offered as supplemental benefits would be required to either meet the CMS-defined healthy food standard or be specifically recommended by a healthcare provider to meet an enrollee's medical needs.

2. Using a CMS Approval Mechanism for Use of the Disaster/Emergency Special Enrollment Period (SEP) and Other Technical Changes

We propose that use of the Disaster/Emergency SEP (42 CFR 422.62(b)(18) and 423.38(c)(23)) requires prior CMS approval through the use of a CMS-operated mechanism. Initially, this SEP will be restricted to use through 1-800-MEDICARE only, similar to other SEPs, though CMS may consider expanding this to other mechanisms, including the Online Enrollment Center, in the future. This requirement would allow for CMS oversight of the SEP and the election mechanism to ensure appropriate use.

3. Seamless Continuation of Coverage for Newly Medicare-Eligible Individuals

CMS is considering creating an optional process for transitioning enrollees of commercial and Marketplace health plans into an MA plan under the same MA organization during an enrollee's initial coverage election period if they fail to elect other coverage. Congress established seamless conversion in section 1851(c)(3) of the Social Security Act (the Act) in 1997. CMS addressed seamless conversion in rulemaking (Medicare Program; Establishment of the Medicare Advantage Program, 70 FR 4588) in 2005, and guidance was established that same year. CMS granted its first approval for an MA organization to implement seamless enrollment for June 2005. The second approval was granted for March 2010 and the third for January 2012.

As of August 2016, CMS had approved 24 MA organizations to use the seamless enrollment mechanism, although not all approved organizations had begun to enroll individuals using this mechanism. We are considering to model a process and the participation requirements on the existing default enrollment mechanism for Medicaid beneficiaries. We are soliciting comments on a potential return to an opt-out process for seamless enrollment and the expected administrative and implementation issues and opportunities for plans intending to utilize seamless enrollment.

4. Cost Sharing Standards for Ground Ambulance and Emergency Services

CMS proposes changes to the MA cost sharing standards for ground ambulance and emergency services to better align beneficiary cost sharing across these services. Specifically, CMS proposes to apply a range of cost sharing limits for ground ambulance services based on maximum out-of-pocket (MOOP) type and to establish emergency services cost sharing limits that are actuarially equivalent to 15 to 20 percent of Original Medicare costs using the most recent Medicare fee-for-service projections.

CMS also proposes to update the applicable cost sharing limits for ground ambulance and emergency services annually through the sub-regulatory guidance process outlined in § 422.100(f)(7)(iii).

5. Enrollee Notification Requirements for Provider Terminations, Continuity of Care, and SEP Notice Consolidation

CMS proposes requirements for MA organizations to notify affected enrollees of provider terminations upon the effective date of the termination, revise the criteria for identifying affected enrollees using a 12-month lookback period, and establish a continuity of care requirement under which affected enrollees would continue to receive coverage at in-network cost sharing following a provider termination. The proposal would also define what qualifies as a "significant" change in an MA plan provider network and codify the notification requirements, evaluation criteria, and applicable timeframes used to determine when a provider termination

triggers a SEP. The proposal would also align provider termination and SEP notification requirements so that affected enrollees receive a single notification regarding provider terminations and SEP eligibility, as applicable.

6. Enrollment Capacity Limits

CMS proposes to codify the process for MA organizations to request enrollment capacity limits during the annual bid submission process, and to rescind § 422.60(b)(3), which permits MA organizations to request enrollment capacity limits outside of the bid submission process, given concerns about the potential for contract gaming and alternative tools available to address any relevant risks to health and safety. CMS also proposes to establish a SEP for individuals who enroll in an MA plan that has reached its approved enrollment capacity limit, allowing those individuals to elect a different MA plan.

7. Use of Existing Interoperability API for Prior Authorization Transactions

CMS proposes to require MA organizations to include a provision in their contracts with in-network providers requiring providers to use the MA organization's HL7® Fast Healthcare Interoperability Resources (FHIR®)-based Prior Authorization Application Programming Interface (API) to transmit information and documentation pertaining to prior authorization requests, and to require MA organizations to annually test and confirm the ability of their in-network providers to send and receive information through the FHIR-based Prior Authorization API.

8. Strengthening Maximum Fair Price Effectuation Policies for Medicare Advantage

a. Medicare Transaction Facilitator Requirements for Network Providers

CMS proposes to amend § 422.504 by adding paragraph (p) to require that any contract between the MA organization and a provider, or between a first tier, downstream, or related entity and a provider on the MA organization’s behalf, for participation in one or more of the MA organizations’ networks must include a provision requiring that if the provider furnishes or administers selected drugs payable under Part B during the period when such drugs are subject to

a maximum fair price (MFP) (as defined in proposed § 422.2), the provider must be enrolled in the Medicare Drug Price Negotiation Program's (Negotiation Program) Medicare Transaction Facilitator (MTF) Data Module (DM) (or any successor to the MTF DM). Such provider must also 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, in a form and manner determined by CMS. The MTF DM helps support Primary Manufacturers of selected drugs effectuate the MFP by assisting necessary operations related to administration of the Negotiation Program and the Part C program, including creating and making available remittances or electronic remittance advices (ERAs), maintaining provider access to the complaints and disputes submission portal, and facilitating continued access to selected drugs payable under Part B. We believe this requirement, if finalized, would facilitate continued access to selected drugs that are payable under Part B for MA enrollees and providers by facilitating manufacturer effectuation of negotiated MFPs under the Negotiation Program.

b. Encounter Data Collection Requirements for Selected Drugs Payable Under Part B

To facilitate MFP effectuation by Primary Manufacturers and to help ensure prompt MFP refund payments by Primary Manufacturers to providers with respect to selected drugs payable under Part B administered or furnished to individuals enrolled in MA plans, encounter records for selected drugs payable under Part B and subject to an MFP warrant a submission deadline that is different from the risk adjustment encounter data submission deadline requirements of § 422.310(g). For the purposes of risk adjustment, MA organizations typically have 13 months following the service year of which payment is based (i.e., the year before the payment year) to submit encounters to CMS for inclusion in final reconciliation. Therefore, if the final risk adjustment data submission deadline were used, providers could wait up to approximately 14 to 26 months to receive MFP refund payments, potentially causing financial hardship. To mitigate potential financial hardship on providers, which could impact Part C enrollee access to selected drugs payable under Part B and subject to an MFP, CMS proposes to amend § 422.504 by adding

paragraph (q)(1)(i) to require encounter data submission for selected drugs payable under Part B and for which an MFP (as defined in proposed § 422.2) is in effect, within 30 days of the claim-from date to reduce the maximum amount of time a provider could wait to receive access to the MFP with respect to the administration or furnishment of selected drugs payable under Part B to MA enrollees. Additionally, to facilitate Primary Manufacturer effectuation of the MFP, with respect to the administration or furnishment of selected drugs payable under Part B to MA enrollees, CMS proposes to amend § 422.504 by adding paragraph (q)(1)(ii) to require MA organizations to collect and submit the 11-digit National Drug Codes (NDC-11 codes) on each MA encounter data record for a selected drug payable under Part B for which an MFP is in effect on the claim-from date. Finally, CMS proposes to amend § 422.504 by adding paragraph (q)(2) to require the Chief Executive Officer (CEO), Chief Financial Officer (CFO), or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, to certify (based on best knowledge, information, and belief) that the data the MA organization submits under § 422.504(q)(1) are accurate, complete, and truthful.

c. Medicare Advantage Out-of-Network Cost Sharing for Selected Drugs Payable Under Part B

CMS proposes to amend § 422.100(f)(6)(i) to require that any out-of-network cost sharing for selected drugs payable under Part B and subject to an MFP (as defined in proposed § 422.2) is calculated based on a price that does not exceed the MFP. CMS believes that this requirement is necessary to ensure that MA enrollees are not subject to benefit design that discriminates on the basis of health status-related factors or is likely to substantially discourage enrollment by certain MA-eligible individuals, as prohibited by section 1852(b)(1) of the Act.

9. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System

We have continued to identify enhancements to the Star Ratings program over time to increase the health and well-being of enrollees. In this proposed rule, we are proposing changes to simplify and refocus the areas included in the Star Ratings, including changes to the measure set, building on the changes finalized in the “Medicare Program; Contract Year 2027 and Certain

Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program" final rule, which appeared in the **Federal Register** on April 6, 2026 (91 FR 17384) ("Contract Year 2027 final rule"). The proposed measure set of 15 measures reflects our ongoing effort to sharpen the Star Ratings program's focus on clinical outcomes while continuing to encourage high performance on patient experience and would also include a small number of process measures in areas of high clinical importance where contracts' current performance is low. The measure removals would apply (that is, data will be collected and performance measured) for the 2028 measurement period and the 2030 Star Ratings.

In the Contract Year 2027 final rule, we also solicited comments on ways to simplify and modify the Star Ratings methodology to further improve quality of care. Consistent with that intent, we propose removing the reward factor and modifying the improvement measure hold harmless to apply only to contracts receiving 4.5 or higher stars for their highest rating. These changes to the measure set and methodology would streamline and simplify the Star Ratings while also raising the bar to achieve high Star Ratings and associated Quality Bonus Payments (QBPs) by incentivizing plans to improve performance and ensure the highest quality of care for their enrollees.

We are also proposing a change to the methodologies for setting cut points to account for the potential impact of the ADVaNCE MA model proposed in section VIII of this proposed rule, a substantive update to the Controlling Blood Pressure measure, a clarification related to displaying Star Ratings domains on the Medicare Plan Finder (MPF) website, language related to disclosing preliminary data shared with plans during the plan preview periods, and a clarification related to the extreme and uncontrollable circumstances policy.

10. Burden Reduction in the MA Application Process and MA Network Adequacy

CMS proposes changes to the MA application requirements for new MA contracts and service area expansions. Specifically, CMS proposes to revise the timing of network adequacy

reviews by shifting those reviews from the MA application process to the first year of operation for newly approved contracts and service areas.

In addition, CMS proposes modifications to network adequacy requirements that are intended to promote competition, provide operational flexibility for MA organizations, and support beneficiary access to behavioral health services and telehealth.

Finally, CMS requests comment on potential changes to policies that can improve access to healthcare via adjustments to provider network adequacy standards, as well as other policy approaches to lower costs and improve competition in the MA program.

11. Updating Agent and Broker Compensation and Oversight

CMS is proposing to revise the MA and Part D agent and broker compensation framework to better align with statutory requirements, reflect current market practices, and respond to a recent court decision vacating portions of the April 2024 compensation regulations. The proposal would provide a new market-based approach definition for compensation, including distinctions between base compensation and supplemental compensation. The proposal would expand the safeguards designed to ensure that the use of compensation creates incentives for agents and brokers to enroll beneficiaries in the MA plan that is intended to best meet their health care needs. CMS proposes a methodology for identifying compensation outliers, which would enable CMS to disapprove outliers and require MA organizations and Part D sponsors to resubmit compensation amounts. The proposal would also require MA organizations and Part D sponsors to report actual base compensation amounts and details regarding supplemental compensation. CMS proposes to require MA organizations and Part D sponsors provide supporting documentation upon request and comply with new oversight and reporting requirements intended to strengthen transparency and program integrity.

CMS is also proposing to reorganize and streamline agent, broker, and third-party marketing organization (TPMO) regulations by consolidating requirements, eliminating duplicative provisions, and reducing administrative burden. Proposed changes include

modifications to training and testing requirements, allowing greater flexibility for acceptance of third-party training programs, enhancing reporting of agent and broker terminations, prohibiting contracts with agents or brokers terminated from participation in the Federally Facilitated Exchange, and clarifying oversight responsibilities for MA organizations and Part D sponsors. In addition, CMS proposes to remove certain requirements that it believes are redundant or no longer necessary, while retaining key beneficiary protections through existing enrollment, marketing, and compliance safeguards. Collectively, these changes are intended to modernize compensation oversight, improve transparency, and ensure that compensation arrangements support beneficiary enrollment in plans that best meet their health care needs.

12. Improvements for Special Needs Plans

In the CY 2027 MA and Part D proposed rule, CMS included a request for information (RFI) that described substantial growth in chronic condition special needs plan (C-SNP) enrollment among dually eligible individuals and more stable growth in dually eligible enrollment in institutional special needs plans (I-SNPs). Informed by the RFI, this rule proposes to require C-SNPs, institutional equivalent special needs plans (IE-SNPs), and hybrid institutional special needs plans (HI-SNPs) with 60 percent or more dually eligible individuals to coordinate with Medicaid for full-benefit dually eligible individuals. This proposal builds on existing SNP requirements and would allow C-SNPs, IE-SNPs, and HI-SNPs to determine for which full-benefit dually eligible individuals they would coordinate with Medicaid, the types of Medicaid services the plans would coordinate with, and the methods for coordination, allowing plans to implement this requirement in a way that best meets their enrollees' needs, including by leveraging data and technology.

13. Aligning Data and Value to Nurture Competition and Efficiency in Medicare Advantage (ADVaNCE MA) Model

This proposal would establish and implement the Aligning Data and Value to Nurture Competition and Efficiency in Medicare Advantage model ("ADVaNCE MA model"), the first

MA mandatory model under section 1115A of the Act. The ADVaNCE MA model would test whether a change to payment and care delivery in MA that uses an alternative quality program, allows targeting of certain supplemental benefits, and shadow tests an alternative risk adjustment methodology (that is, a methodology that is used for informational purposes only) can improve care quality for MA enrollees while reducing costs to the Medicare program.

C. Summary of Costs and Benefits

TABLE I.C-1: SUMMARY OF PROVISIONS AND FINANCIAL IMPACTS

Provision	Description	Financial Impact
Establishing a "Healthy Food" Standard for MA Supplemental Benefits	Establishes a "healthy food" standard applicable to MA supplemental benefits that include food items.	The proposal is not expected to significantly increase overall MA program costs but may result in modest administrative costs associated with updating benefit designs and vendor arrangements.
Using a CMS Approval Mechanism for Use of the Disaster/Emergency Special Enrollment Period (SEP)	This proposal would require prior CMS approval of the Disaster/Emergency SEP through the use of a CMS-operated mechanism.	We do not expect that these proposed regulatory changes will have an impact on the Medicare Trust Fund.
Seamless Continuation of Coverage for Newly Medicare-Eligible Individuals	CMS is considering creating a process for transitioning enrollees of health plans into an MA plan under the same MA organization during an enrollee's initial election period if they fail to elect other coverage.	N/A
Cost Sharing Standards for Ground Ambulance and Emergency Services	Revises MA cost sharing standards for ground ambulance and emergency services, including updated cost sharing limits and annual updates based on Medicare fee-for-service projections.	While MA organizations may adjust cost sharing across affected services, overall beneficiary financial impact is expected to be limited because MA plans must ensure total cost sharing for basic benefits does not exceed Original Medicare cost sharing.
Enrollee Notification Requirements for Provider Terminations, Continuity of Care, and SEP Notice Consolidation	Revises MA requirements related to provider terminations by establishing updated notification requirements, continuity of care protections, codified SEP criteria for significant provider network changes, and consolidated enrollee notices.	The proposal may increase costs for MA organizations associated with continuity of care requirements and implementation of revised notification processes, although some administrative efficiencies may result from consolidating enrollee notices.
Enrollment Capacity Limits	Codify MA enrollment capacity limit requirements for capacity limit requests submitted through the bid process, removing the ability to request limits outside the bid process, and creating a special election period (SEP) for affected enrollees.	The proposal is expected to have minimal financial impact, with only negligible administrative costs for CMS and MA organizations associated with enrollment capacity limit requests and oversight.
Use of Existing Interoperability API for Prior Authorization Transactions	Requires MA organizations to contractually require in-network providers to use the FHIR-based Prior Authorization API for prior authorization transactions and to annually test provider connectivity and functionality.	The proposal is not expected to significantly increase costs because MA organizations are already required to implement a Prior Authorization API, and broader use of the technology is expected to reduce administrative burden over time.
Medicare Transaction Facilitator Requirements for Network Providers	We propose at § 422.504(p) to require that any contract between the MA organization and a provider (as defined in § 422.2), or between a first tier, downstream, or related entity and a provider on the MA organization's behalf, for participation in one or more of the MA organization's networks, require that if the provider furnishes or administers selected drugs payable under Part B during the period when such drugs	We do not expect that these proposed regulatory changes will have an impact on the Medicare Trust Fund.

Provision	Description	Financial Impact
	are subject to a maximum fair price (MFP) (as defined in § 422.2), the provider must be enrolled in the Negotiation Program's Medicare Transaction Facilitator Data Module (MTF DM) (or any successor to the MTF DM).	
Requirement to Collect and Submit Data for Encounters Involving Selected Drugs Payable Under Part B	We propose at § 422.504(q)(1) to require MA organizations to submit to CMS MA encounter data (as described at § 422.310(d)(5)) records involving the furnishing or administration of a selected drug payable under Part B for which an MFP is in effect on the claim-from date and to collect and submit NDC-11 codes on each MA encounter data record for a selected drug payable under Part B for which an MFP is in effect, within 30 days of the claim-from date. We also propose at § 422.504(q)(2) to require the CEO, CFO, or individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, to certify that the data the MA organization submits under § 422.504(q)(1) are accurate, complete, and truthful.	We do not expect that these proposed regulatory changes will have an impact on the Medicare Trust Fund. The requirement to submit encounter data records involving the furnishing or administration of a selected drug payable under Part B and subject to an MFP by an earlier deadline and to collect and submit NDC-11 codes on each MA encounter data record for selected drugs payable under Part B and subject to an MFP may cause MA organizations to incur some upfront costs to make administrative updates, but these should be a one-time cost.
Medicare Advantage Out-of-Network Cost Sharing for Selected Drugs Payable Under Part B	We propose to amend § 422.100(f)(6)(i) to require that any out-of-network cost sharing for selected drugs payable under Part B and subject to an MFP is calculated based on a price that does not exceed the MFP.	We do not expect that these proposed regulatory changes will have an impact on the Medicare Trust Fund.
Burden Reduction in the MA Application Process and MA Network Adequacy	Revises MA application requirements by shifting network adequacy reviews from the application process to the first year of operation for newly approved contracts and service area expansions and proposes other network adequacy policy changes related to behavioral health and telehealth.	The proposal is not expected to have a significant financial impact and would reduce administrative burden associated with the MA application process and formal network adequacy reviews.
Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System	This proposal would sharpen Star Ratings' focus on clinical outcomes. It would streamline and simplify the measure set and methodology by removing the reward factor and modifying the improvement measure hold harmless. These proposed changes raise the bar for high Star Ratings and Quality Bonus Payments to incentivize plans to improve performance and ensure the highest quality of care for their enrollees.	The net impact of the Star Ratings updates to the Medicare Trust fund is estimated to be $106.96 billion savings from 2028 through 2037 or 1.17% percent of Medicare payments to private health plans during this 10-year period.
Updating Agent and Broker Compensation and Oversight	Establishes a revised framework for agent and broker compensation and oversight by replacing CMS-set compensation limits with transparency requirements, compensation guardrails, enhanced reporting, and streamlined administrative requirements.	The proposal may increase reporting and oversight costs for MA organizations, Part D sponsors, and CMS while reducing administrative burden associated with certain training and testing requirements.
Improvements for Special Needs Plans	This proposal would require C-SNPs and IE-SNPs with 60 percent or more dually eligible individuals to coordinate with Medicaid for full-benefit dually eligible individuals.	We do not expect that this proposed regulatory change will have an impact on the Medicare Trust Fund.
ADVaNCE MA model	This proposal would implement the ADVaNCE MA model, a mandatory, 10-year model within limited, state-based geographies that tests reforms to risk adjustment, quality, and supplemental benefits to produce meaningful improvements in quality, competition, enrollee value, and reducing program expenditures.	This proposal includes multiple tests of the MA program. The payment and incentive structures are designed to reduce program expenditures. Some potential savings are anticipated (for example, through the removal of "double bonus counties" and

Provision	Description	Financial Impact
		through supplemental benefit offerings, for which some evidence in the literature supports medical savings).

D. Conclusion

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

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

A. Establishing a "Healthy Food" Standard for MA Supplemental Benefits

1. Background

MA plans have the ability to offer items and services beyond what Original Medicare covers, known as supplemental benefits. Section 50322 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123) expanded the scope of what MA plans may offer as supplemental benefits by amending section 1852(a)(3) of the Act to create Special Supplemental Benefits for the Chronically Ill (SSBCI).[1] SSBCI are supplemental benefits that MA plans may offer to qualifying eligible chronically ill enrollees and, unlike other supplemental benefits, are not required to be primarily health related. Rather, SSBCI may include items and services that have a reasonable expectation of improving or maintaining an enrollee's health or overall function, including food-related SSBCI.

MA plans may offer food-related supplemental benefits in different ways. For example, MA plans may offer meals on a limited basis following an acute health event as a primarily health-related supplemental benefit available to all their enrollees. MA plans may also cover protein bars and nutritional drinks or shakes as primarily health-related over-the-counter (OTC) items available to all their enrollees. Additionally, plans may offer a Food and Produce benefit or meals provided on an unlimited or ongoing basis as SSBCI to their chronically ill enrollees.[2]

MA plans have increasingly incorporated food-related benefits into their supplemental benefit design. For example, the percentage of MA plans offering Food and Produce as an SSBCI has grown from about 16 percent in 2024, to roughly a third (35 percent) in 2026.

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[1] CMS implemented these provisions in the Contract Year 2021 Medicare Advantage and Part D Final Rule (85 FR 33800 through 33805).

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

Moreover, around 60 percent of MA plans now offer a primarily health related meal benefit.[3] Additionally, based on 2025 CMS internal data received as part of Part C Reporting Requirements, beneficiaries utilized a Food and Produce SSBCI about 40 million times. These utilizations were recorded for 45 percent of eligible enrollees, making it one of the most popular benefits among eligible enrollees. Given that so many MA enrollees are using these benefits, they have real potential to meaningfully address nutrition-related chronic conditions, reduce avoidable hospitalizations, and support the overall well-being of Medicare beneficiaries.

As the availability and utilization of these benefits has expanded, CMS has also received recurring questions seeking examples of foods that qualify as healthy under these regulations versus those that do not—an issue that became especially prominent after CMS codified at § 422.102(f)(1)(iii)(I) in the Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, hereafter referred to as the April 2025 final rule (90 FR 15868), that non-healthy food items are not permissible as SSBCI. Currently, there is no affirmative definition or standard in regulation for what constitutes healthy or non-healthy foods for purposes of SSBCI, although CMS specified in the April 2025 final rule that non-healthy foods are those that do "not assist in meeting the nutritional needs of a chronically ill enrollee" (90 FR 15867). As a result, MA plans currently exercise broad discretion in determining what foods qualify as healthy or non-healthy under the current regulations, which could result in inconsistent application of the prohibition on offering non-healthy food items as SSBCI. Additionally, a clear affirmative standard for what constitutes healthy food would promote CMS' ability to conduct meaningful compliance and enforcement work. For CMS to determine whether MA plans offer food benefits that are primarily health related or are appropriate as SSBCI, CMS is proposing to specifically require

[3] CMS internal analysis based on bid data.

food-related supplemental benefits to be limited to "healthy food," and to define what it means by "healthy food" for this purpose.

As food-related supplemental benefit spending continues to grow, so does the importance of ensuring that such spending is directed toward foods that genuinely support improved health outcomes. This aligns with the Make America Healthy Again (MAHA) initiative,[4] which emphasizes improving population health by addressing upstream drivers of chronic disease—particularly diet and nutrition, alongside broader efforts across HHS to translate the new 2025-2030 Dietary Guidelines for Americans (DGA)[5] into more practical standards for program design and administration. MAHA reflects a broader shift in federal health policy toward ensuring that public programs not only provide access to services, but also promote healthier choices, particularly in areas like food where poor nutrition can contribute to worsening health outcomes.[6] This edition of the DGA is organized around a simple principle: minimally processed, naturally nutrient-dense foods are the reference point for dietary guidance, and strong causal evidence is needed before recommending foods or ingredients that are highly processed. In practical terms, this means that minimally processed vegetables, fruits, meats, eggs, nuts, seeds, dairy, whole grains, beans, and seafood are the foundation for healthful diets. Clearly defining "healthy food" for purposes of MA supplemental benefit offerings supports MAHA's core objective of aligning federal health spending with interventions that improve long-term health and reduce diet-related disease.

Establishing a clear definition of "healthy food" to be required for supplemental benefit offerings directly supports these objectives by creating a consistent baseline for nutrition quality across the MA program—ensuring that all food-related supplemental benefits are contributing to better health outcomes rather than simply expanding access to food.

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[4] https://www.hhs.gov/maha/index.html
[5] https://cdn.realfood.gov/DGA.pdf
[6] https://www.whitehouse.gov/wp-content/uploads/2025/05/MAHA-Report-The-White-House.pdf

Based on a review of annual bid packages, CMS has noted that plan-issued debit cards are frequently used to administer a wide range of supplemental benefits, most notably Food and Produce offered as SSBCI. In the Contract Year 2027 final rule (91 FR 17384), CMS codified several safeguards for MA plans using debit cards to administer covered benefits. The purpose of that rule was, in part, to ensure enrollees were receiving the covered benefits to which they are entitled — as CMS had received numerous reports that MA plan debit card administration varied widely and that MA plans had varying success in ensuring enrollees received their approved, covered benefits through these cards. Adding a "healthy food" definition for purposes of MA supplemental benefits would build on these safeguards to help ensure enrollees receive only covered benefits.

2. HHS and USDA's 2025-2030 Dietary Guidelines for Americans

The new 2025–2030 DGA were released in January 2026. The 2025–2030 DGA rests on a documented evidence-review process: subject-matter experts were selected through a federal contracting process; standardized protocols — covering inclusion criteria, risk of bias, synthesis, and evidence grading—was set in advance by a methodology expert; the review relied on rapid systematic reviews, umbrella reviews, and literature syntheses; and the review was subject to external peer review coordinated by the NIH Office of Nutrition Research, with two independent reviewers assigned to each topic. Reviewer financial interests were disclosed as part of this process.

CMS recognizes that the information and guidelines contained in the DGA are based on the preponderance of the scientific and medical knowledge which is current at the time the DGA are prepared and is subject to ongoing refinement as new research emerges.[7] CMS believes this makes the DGA the most appropriate and reliable scientific anchor currently available for this definition, notwithstanding the inherent limitations of any evolving scientific field. Because the "healthy food" standard is anchored to the DGA rather than to a fixed guideline or definition, the

[7] https://cdn.realfood.gov/Scientific%20Report_1.8.26.pdf

standard can evolve as the science changes and future DGA cycles are completed, rather than being bound to a static standard that cannot adapt over time. CMS seeks public comment on any additional evidence, data, or research that should be considered in finalizing this proposal.

The DGA emphasizes dietary patterns centered on whole, nutrient-dense foods, including proteins, fruits and vegetables, healthy fats, dairy, and whole grains. The DGA also encourages foods that are minimally processed and recommends limiting highly processed foods, refined carbohydrates, added sugars, excess sodium, sugar sweetened beverages, and other ingredients associated with poorer health outcomes such as artificial flavors, petroleum-based dyes, artificial preservatives, and low-calorie non-nutritive sweeteners. The DGA further emphasizes variety across both animal- and plant-based food sources and the importance of dietary patterns that support overall health, healthy aging, and chronic disease prevention. The DGA also includes recommendations specific to older adults, recognizing that while some older adults require fewer calories, they generally require equal or greater amounts of protein, vitamin B12, vitamin D, and calcium. Consistent with this recognition, the DGA recommends nutrient-dense foods and, where dietary intake or absorption is inadequate, medically supervised fortified foods or supplements under medical supervision. The DGA further addresses cardiovascular disease, obesity, and type 2 diabetes — conditions highly relevant to the Medicare population. For example, the DGA recommends for individuals at risk of calcium oxalate kidney stones, dietary oxalate should be monitored by avoiding foods such as spinach, chard, and rhubarb; limiting intake of potatoes, chocolate, nuts, beets, and bran; and ensuring adequate calcium consumption with meals.

Additionally, the DGA recommends vegetables, fruits, fiber-rich whole grains, and a variety of protein foods, while limiting saturated fat, added sugars, and sodium. The DGA states that adherence to the guidelines can help prevent or slow the progression of chronic disease, including cardiovascular disease, obesity, and type 2 diabetes, but advise individuals with chronic conditions to discuss their dietary needs with a health care professional. CMS seeks comment on whether other sources of information should be considered in addressing chronic

conditions relevant to the Medicare population, such as the American Heart Association's recommendations. CMS notes that other federal programs also refer to the DGA. For instance, Section 339(2)(A)(i) of the Older Americans Act, codified at 42 U.S.C. § 3030g–21(2)(A)(i), requires that meals funded under its nutrition programs "comply with the most recent Dietary Guidelines for Americans." Individualized needs arising from conditions such as kidney disease, dysphagia, or diabetes are addressed separately under proposed § 422.102(h)(2) discussed later in this proposed rule. These recommendations are consistent with the goals of many food-related supplemental benefits offered by MA plans, including SSBCI which are intended to maintain or improve chronically ill enrollees' health and overall functioning through improved nutrition.

Consistent with these efforts, and based on our authority under section 1856(b)(1) of the Act to establish standards for MA plans consistent with, and to carry out, Part C, along with our authority in section 1857(e)(1) of the Act to adopt additional terms and conditions for MA contracts that are not inconsistent with the Part C statute and that are necessary and appropriate for the MA program, CMS proposes to establish a definition for what it considers "healthy foods" for purposes of MA supplemental benefits that aligns with the DGA and require that any food- or beverage-related supplemental benefit meet that definition. This standard is intended to ensure that such benefits are appropriately offered as supplemental benefits under Part C and are consistent with applicable statutory requirements.

3. "Healthy Food" Definition for MA Supplemental Benefits

The 2025–2030 DGA provide the nutritional foundation for this proposal. In developing this proposed definition, CMS worked closely with experts throughout HHS involved in the development of the DGA. The goal was to develop an MA-specific definition that is both consistent with the DGA nutritional principles and practical to administer within the MA supplemental benefit structure. CMS recognizes that the DGA provides broad nutrition guidance for the general population and is not written as regulatory standards for MA supplemental benefits. CMS therefore developed this proposed definition to translate the core nutritional

principles reflected in the DGA into a clear, administrable standard for MA plans offering food-related supplemental benefits to Medicare beneficiaries.

In developing a "healthy food" standard for MA supplemental benefits, CMS considered adopting the U.S. Food and Drug Administration (FDA) criteria for use of the term "healthy" as a nutrient content claim. CMS determined that approach is not well suited to the MA program because it was developed as a voluntary labeling definition for a claim that appears primarily on packaged foods and relies on product-specific nutrient analyses, standardized serving sizes, and other requirements that do not readily apply to many foods provided through MA supplemental benefits, including prepared meals, medically tailored meals, and groceries or other items that may be administered through plan debit cards. Adopting the FDA criteria would also create additional operational and administrative burdens for plans and vendors and would tie MA policy to a set of criteria developed for a different statutory purpose. CMS believes that a DGA-based definition tailored to the MA program provides a more practical, administrable, and enforceable standard for food-related supplemental benefits while remaining aligned with current Federal nutrition policy.

CMS proposes to remove the existing provision at § 422.102(f)(1)(iii)(I) specifically prohibiting non-healthy food items as SSBCI and instead add a broad affirmative, standardized definition of "healthy food" applicable to all supplemental benefits that include food or beverage items. We propose to amend § 422.102 by adding paragraph (h) to provide that food and beverage items offered as supplemental benefits must meet the definition of "healthy food" in paragraph (h)(1). Under this proposal and consistent with the DGA, CMS would define "healthy food" at § 422.102(h)(1) as whole, nutrient-dense foods. For purposes of this definition, CMS intends the phrase "whole, nutrient-dense foods" to refer to minimally processed foods that are naturally rich sources of protein, fiber, essential fatty acids, vitamins, and minerals, and that contain no added sugars, refined starches, or chemical additives, and that provide meaningful nutritional value and support overall health, healthy aging, and physical functioning.

Additionally, CMS seeks comment on this understanding of whole, nutrient-dense foods, and on whether CMS should establish a formal, codified definition of this term in future rulemaking.

To support clarity and consistent application by MA plans, CMS proposes to codify at § 422.102(h)(1)(i) through (viii) non-exhaustive examples of foods that align with this definition, including proteins from a variety of animal and plant-based sources, such as eggs, poultry, seafood, red meat, and soy; fresh fruits and vegetables, as well as frozen, dried, or canned fruits and vegetables with no or limited added sugars; legumes including beans, lentils, chickpeas; nuts, seeds, and natural nut butters with limited added sugars; fats and oils such as olive oil, avocado oil, butter, and beef tallow; dairy products with limited added sugars; and fiber-rich whole grains such as sprouted bread, whole grain rye or pumpernickel bread, whole wheat pasta, buckwheat flour, and wheat or oat bran with limited added sugars. CMS selected these categories because they reflect a variety of foods commonly associated with healthy dietary patterns and align with nutritional principles emphasized throughout the DGA. CMS also seeks comment on whether the food-based examples at proposed § 422.102(h)(1)(i)–(viii) provide sufficient clarity and welcomes any suggestions for additional or alternative examples.

CMS notes that the proposed definition and examples at § 422.102(h)(1)(ii), (iv), (vi), and (vii) reference foods with “limited added sugars.” Consistent with the DGA, CMS intends these references to reflect the general principle that foods with lower amounts of added sugars more closely align with healthy dietary patterns and chronic disease mitigation. The DGA treats saturated fat and sodium as daily, whole-of-diet limits rather than item-level bans—specifically, saturated fat should not exceed 10 percent of total daily calories, and sodium should be less than 2,300 mg per day for individuals ages 14 and older. An item-level saturated fat ban would exclude whole foods the DGA otherwise promotes, such as full-fat dairy, eggs, and red meat; the DGA's Scientific Foundation (SF) finds that current evidence "does not provide causal support for reducing saturated fat below 10 percent of energy". On the other hand, CMS’s proposed definition already addresses sodium through food-based exclusions, consistent with the DGA's

instruction that "highly processed foods that are high in sodium should be avoided". As an alternative to this food-based approach, CMS is considering per-meal nutrient targets for food-related supplemental benefits — for example, sodium ≤600 mg and saturated fat ≤7 g per meal, consistent with the DGA's daily limits. CMS seeks comment on whether item-level numeric limits on sodium or saturated fat, as well as other nutrients, are warranted and, if so, what thresholds would be most appropriate given that food related supplemental benefits may include meals provided by a vendor or individual food items which may be purchased at a grocery store. CMS additionally seeks comment on the inclusion of examples of specific fats (such as butter and beef tallow) in its healthy food standard.

While this definition focuses on specific food items and not necessarily how those food items are prepared, CMS notes that foods which are baked, broiled, roasted, stir-fried, or grilled are preferable to those deep-fried, for example. CMS acknowledges that food preparation contributes to the overall healthfulness of a particular food item or meal. Since food related supplemental benefits may include either individual food items or full meals, CMS solicits comment on whether food preparation, and specific food additives, should be addressed in CMS' healthy food standard and what sources of information CMS should consider in adding such specifications.

In grounding this proposed standard in the DGA, CMS recognizes that nutrition science continues to evolve — which is why CMS has generally avoided highly prescriptive, item-level criteria in favor of the approach described above. If finalized as proposed, CMS intends to evaluate this definition on a regular basis consistent with the DGA's 5-year review cycle (7 U.S.C. 5341(a)) as well as monitor subsequent DGA revisions. Another reason CMS believes it is important to maintain flexibility in the healthy food standard rather than imposing fixed, item-level thresholds is to account for differences in enrollee populations and local market conditions. For example, rural enrollees may face unique challenges accessing foods meeting specific thresholds due to limited availability of grocery stores offering fresh fruits and vegetables.

Maintaining flexibility in the standard allows plans to tailor their food related benefits better to suit their enrollee population, vendor arrangements and local markets.

CMS seeks comment on this approach, including whether establishing a quantitative threshold for added sugar, sodium, saturated fats or other nutrients would provide greater clarity and consistency for MA plans and, if so, what thresholds would be most appropriate.

4. Foods and Beverages That Generally Would Not Meet the Proposed Definition of Healthy Food for MA Supplemental Benefits

The 2025–2030 DGA generally emphasize dietary patterns centered on whole, nutrient-dense foods and recommend limiting foods that may be associated with negative health outcomes. Consistent with the principles reflected in the DGA and informed by input from subject matter experts involved in development of the DGA, CMS has created a list of certain categories of foods and beverages that generally would not align with the proposed definition of "healthy food" for purposes of MA supplemental benefits due to their nutritional composition and association with dietary patterns linked to poorer health outcomes.[8] This approach is also consistent with the standards governing MA supplemental benefits. Food-related supplemental benefits must either be primarily health related or, in the case of SSBCI, have a reasonable expectation of improving or maintaining the health or overall function of an eligible chronically ill enrollee. As such, CMS believes foods and beverages furnished through these benefits generally should align with dietary patterns that support those objectives.

CMS recognizes that stakeholders may have questions regarding how the proposed definition applies to processed foods and foods containing significant amounts of added sugars, refined carbohydrates, excess sodium, hydrogenated oils, and artificial additives. To help alleviate confusion, CMS generally would not consider the following categories of foods or beverages to meet the proposed definition of "healthy food" for MA supplemental benefits:

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[8] Micha, R., Peñalvo, J.L., Cudhea, F., Imamura, F., Rehm, C.D., & Mozaffarian, D., Association Between Dietary Factors and Mortality From Heart Disease, Stroke, and Type 2 Diabetes in the United States, 317(9) JAMA 912–924 (2017), available at: https://pubmed.ncbi.nlm.nih.gov/28267855/.

● Fruit and vegetable juices that are not 100 percent fruit or vegetable juice.

● Sugar-sweetened beverages, including sodas, energy drinks, sports drinks, flavored milks, sweetened iced teas, and other beverages with significant added sugars.

● Refined grain products made primarily with refined white flour, including white bread, white pasta, pastries, muffins, cakes, cookies, crackers, tortillas, and similar products.

● Processed meats containing added sugars, nitrates, nitrites, excess sodium, or chemical additives, including certain hot dogs, deli meats, sausages, bacon, and jerky products.

● Frozen or ready-to-eat meals containing significant amounts of added sugars, excess sodium, or artificial preservatives.

● Snack foods high in sodium, added sugars, refined white flour, refined oils, or artificial additives, including chips, crackers, cookies, and similar snack products.

● Foods where refined sugars are a primary ingredient, including candy, chocolate, syrups, jams, jellies, sweetened spreads, and similar confectionary products.

● Margarine, shortening, and foods containing partially hydrogenated or hydrogenated oils.

CMS seeks comment on whether these categories provide sufficient clarity regarding foods that generally would not meet the proposed definition of "healthy food" for MA supplemental benefits.

5. Provider-Recommended Foods and Individualized Nutritional Needs

While this definition represents an important step in identifying what constitutes "healthy food" for MA plans, CMS recognizes that there are certain situations in which foods that meet this definition may not always be appropriate for a particular enrollee. For example, some elderly patients experience poor appetite, weight loss, and functional decline. In these situations, a physician may recommend an oral nutrient supplement that emphasizes caloric density and ease of intake over nutrient density. An example may include a patient who has difficulty swallowing solid foods, making certain whole food items inappropriate. Similarly, a lactose-intolerant

enrollee whose provider recommends a nutritionally equivalent non-dairy milk alternative in place of dairy would qualify under this provision, even if the specific product may not otherwise meet the definition at § 422.102(h)(1). For example, a non-dairy milk alternative may contain significant amounts of added sugar or other additives, which as outlined in section II.A.4 of this proposed rule, would generally not meet the proposed standard. To preserve the treating provider's ability to make individualized recommendations for their patients, CMS proposes to add paragraph (h)(2) to § 422.102 to provide that any food or beverage recommended by an enrollee's health care provider to address the enrollee's medical condition or nutritional needs qualifies as "healthy food" for purposes of MA supplemental benefits provided that the item is not otherwise prohibited under § 422.102(f)(1)(iii) or other applicable law. CMS emphasizes that the definition of "healthy food" in proposed § 422.102(h)(1) establishes a general standard for MA supplemental benefit design and is not intended to supersede the individualized clinical judgment of a treating health care provider. CMS recognizes that nutritional needs may vary significantly based on an enrollee's medical condition, functional status, and overall clinical circumstances. Thus, proposed § 422.102(h)(2) is intended to preserve provider discretion by ensuring that foods or beverages recommended by a treating health care provider to address an enrollee's specific medical condition or nutritional needs remain permissible under § 422.102(h)(2). Under this proposal, any food or beverage item recommended by a provider for a specific enrollee's medical condition or nutritional needs would qualify as "healthy food" that may be offered as a supplemental benefit, even if it would not otherwise meet the proposed definition at § 422.102(h)(1). CMS notes that providers may incorporate individual care needs as well as other factors such as clinical standards of care for chronic health conditions. CMS is not proposing to require a prescription or other specific form of provider order for purposes of this provision. CMS emphasizes that this provision would not require MA plans to cover any particular food or beverage item solely because it is recommended by a provider, nor would it require MA plans to offer food-related supplemental benefits where they do not otherwise do so.

Rather, this provision would apply only in circumstances where an MA plan already offers a food-related supplemental benefit and must determine whether a particular item is permissible under that benefit. In such cases, CMS would consider foods or beverages recommended by a provider to address an enrollee's medical condition to satisfy the proposed definition of "healthy food" for MA supplemental benefits and therefore be eligible for coverage under the terms of the applicable benefit.

CMS notes that while the DGA addresses specific chronic conditions such as cardiovascular disease, obesity, and type 2 diabetes—conditions highly relevant to the Medicare population—and provides general dietary guidelines, the DGA also states specifically that individuals with chronic conditions should consult their providers to establish individualized diets that are appropriate. This is consistent with CMS' proposal at 422.102(h)(2). CMS' proposal is not meant to guide individual enrollee dietary choices, but rather to establish a standard for what MA plans may cover as food related supplemental benefits. CMS seeks public comment on whether the provider-recommendation pathway adequately addresses situations where a nutrient-dense standard may conflict with an enrollee's individual clinical needs, including cases involving multiple chronic conditions with competing dietary requirements. CMS also seeks public comment on whether additional examples or clarifying language are needed to illustrate how this provision would apply across varying clinical circumstances and welcomes suggestions on how CMS can further balance a consistent nutrition standard with the clinical flexibility needed for a diverse, multimorbid population.

CMS notes that coordinated care plans are already required under existing MA regulations to maintain procedures that support effective and continuous patient care, including ensuring appropriate exchange of information among providers, ensuring that providers maintain enrollee health records consistent with MA plan standards, and informing enrollees of health care needs requiring follow-up and self-care measures (see § 422.112(b)(4) and (5)). CMS expects that where a provider recommends a specific food or beverage item to address an enrollee's

medical condition or nutritional needs, this recommendation would be incorporated into the MA plan's existing care coordination and continuity of care functions under § 422.112. Consistent with § 422.112(b)(4)(ii) and (iii), MA plans would be expected to ensure providers maintain appropriate documentation within the enrollee record and that relevant information is appropriately shared among providers and care management personnel, as applicable. CMS also routinely conducts program audits and oversight activities of MA plans, and compliance with coordinated care requirements under § 422.112 may be reviewed as part of those activities. CMS may incorporate review of these activities, as appropriate, into existing oversight and auditing processes and may proceed with compliance actions should CMS discover plans are allowing foods inconsistent with the standard in proposed § 422.102(h)(1) and not recommended by their health care provider as proposed in § 422.102(h)(2).

CMS seeks comment on whether the proposed definition adequately accounts for individualized provider recommendations and the operational realities of MA plan administration, including whether existing MA care coordination and continuity of care processes under § 422.112 are sufficient to support and document provider-recommended food and beverage items.

While there may be some administrative burden on plans should CMS finalize this proposal, this administrative burden should not exceed the normal business operations that plans undertake to ensure their benefits adhere to CMS requirements. CMS notes that the proposed definition of "healthy food" for MA supplemental benefits at § 422.102(h) incorporates a non-exhaustive list of qualifying foods while preserving flexibility for MA plans to tailor food-related supplemental benefits to enrollee needs, local markets, and existing vendor arrangements. Any internal review or adjustment of food-related supplemental benefits that MA plans undertake to align with this definition would occur as part of the ordinary annual benefit design and bid preparation process. While CMS is not privy to specific contractual arrangements between MA plans and their vendors, CMS notes that a vast majority of Food and Produce SSBCI and other

food-related OTC items are currently administered through plan-issued debit cards[9] and MA plans must already have a system established with their vendors to limit card purchases to permissible items at the point-of-sale (91 FR 17384). Therefore, CMS does not anticipate that this provision would impose new administrative costs beyond customary business operations associated with annual supplemental benefit development nor would it impose any new information collection requirements on MA plans.

Finally, CMS is requesting stakeholder comments on the following issues in refining and ultimately implementing a standard for healthy food for MA supplemental benefits:

- CMS defines 'healthy food' as food that is whole and nutrient-dense. How should CMS apply the healthy food standard to prepared meals given that some individual meal components may not meet the standard even though the meal as a whole may meet the standard? Should preparation methods and food additives contribute to a determination of whether prepared foods or meals qualify as “healthy”?
- Should CMS consider additional guidelines and evidence, in addition to the DGA, when creating a healthy food standard for MA supplemental benefits?
- How can CMS better integrate healthy food policies that address common health conditions relevant to the Medicare population? For example, the majority of Medicare beneficiaries have health conditions with recommended dietary interventions of low levels of saturated fat and/or sodium, such as heart disease (31%), hypertension (62%), diabetes (32%), stroke (9%), and high cholesterol (62%).[10]
- Should CMS consider maintaining the prohibition of “unhealthy” foods (as currently specified at 42 CFR § 422.102(f)(1)(iii)(I)). If yes, how should CMS define “unhealthy food” in regulation and what should be the basis of CMS’ regulatory definition of “unhealthy” in contrast to the proposed healthy food standard?

[9] CMS internal data received as part of Part C Reporting Requirements.
[10] Medicare Current Beneficiary Survey, 2023.

- Should CMS consider mechanisms, in addition to any future DGA editions, to ensure this standard reflects the DGA Advisory Committee's vision for more flexible dietary guidance?
- Should the definition of healthy foods account for staple foods (e.g., different types of rice that might otherwise not meet the definition of “nutrient-dense” under the DGA)?
- Should CMS pursue additional oversight and enforcement mechanisms related to the healthy food standard, and if so, what should they look like?

B. Single-Tier Benefit Requirement for Defined Standard Coverage (§§ 423.100, 423.120, 423.2267)

In the proposed rule titled "Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly Proposed Rule" (87 FR 79452, hereinafter referred to as the "CY 2024 Proposed Rule") which appeared in the **Federal Register** on December 27, 2022,[11] CMS proposed to codify its longstanding subregulatory policy that Part D plans offering Defined Standard coverage must apply a single-tier benefit structure and reflect that structure in relevant communications and marketing materials. We received one comment on this proposal in the CY 2024 Proposed Rule. The commenter opposed our proposal and stated that the single-tier requirement makes it impractical for prescribers and beneficiaries to know which drugs are considered by a Part D plan to be more cost-effective and that greater transparency about drug costs at the point of prescribing is needed to improve the functioning of the program. The commenter recommended that Defined Standard plans be allowed to display their formularies as multi-tier. We considered the comment, but we did not finalize the proposal in a subsequent final rule.

We continue to receive questions from Part D sponsors about this policy, and therefore are again proposing to codify our current policy to provide clarification and address any remaining ambiguity. We are not proposing any substantive changes to the policy as originally proposed in the CY 2024 Proposed Rule because, as discussed further in this proposed rule, since the beginning of the Part D program, we have interpreted section 1860D-2(b)(2)(A)(ii) of the Act to permit multi-tier benefit structures for plans offering actuarially equivalent standard coverage

[11] https://www.federalregister.gov/documents/2022/12/27/2022-26956/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program.

but not for plans offering Defined Standard coverage. We are proposing minor changes to the proposed regulatory text to improve clarity.

In the Final Calendar Year 2015 Part D Call Letter[12] we established our policy that a plan offering Defined Standard coverage apply a single-tier benefit structure to drugs on its formulary (if it uses a formulary, as defined at § 423.4). We are now proposing to codify this longstanding subregulatory policy in regulation. In addition, we are proposing to codify our longstanding subregulatory policy that all communications, including marketing (as these terms are defined at § 423.2260), for a plan offering Defined Standard coverage must reflect a single-tier benefit structure.

Under sections 1854(a)(1)(A) and 1860D-11(b) of the Act, initial bid submissions for all MA plans, MA-PD plans, and PDPs must be in a form and manner specified by the Secretary. To facilitate Part D sponsors' submission of their bids, we provided guidance regarding Incomplete and Inaccurate Bid Submissions on page 163 of the Final Calendar Year 2020 Part D Call Letter[13] that a formulary crosswalk is one of the constituent components of a complete bid submission for a Part D sponsor that is offering a Part D plan with a formulary. Additionally, in the February 6, 2026 HPMS memo titled, "Contract Year (CY) 2027 Final Part D Bidding Instructions,"[14] we referenced the Final Calendar Year 2020 Part D Call Letter policy on Incomplete and Inaccurate Bid Submissions as applicable for CY 2027. Further, the Bid Submission User Manual for Contract Year 2027, Chapter 4, Bid Submission Pre-Submission Requirements and Uploads (hereinafter referred to as "Chapter 4" and available to appropriate reviewers in the HPMS via the following path: Plan Bids/Bid Submission/CY 2027/Documentation/View Documentation/Chapter 4: Bid Submission Pre-Submission Requirements and Uploads), provides detailed information about the formulary crosswalk.

[12] https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2015.pdf
[13] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf
[14] https://www.cms.gov/files/document/cy-2027-part-d-bidding-instructions-final-g.pdf.

Chapter 4 instructs all contracts that submitted a formulary through HPMS to submit a formulary crosswalk. Additionally, in order for the formulary crosswalk to be considered complete, Part D sponsors are also instructed to: (1) assign a formulary to all plans that offer Part D and are a part of the contract that submitted the formulary; and (2) assign all formularies submitted for an organization to at least one plan. Further, Chapter 4 provides that one formulary may be mapped to one or more plans. The ability for plans to assign a given formulary to multiple plans reduces Part D sponsor and CMS administrative burden by reducing the number of formularies that CMS must review and Part D sponsors must maintain.

Since the beginning of the Part D program, we have interpreted section 1860D-2(b) of the Act to provide for two distinct types of standard prescription drug coverage—"Defined Standard coverage" and "actuarially equivalent standard coverage." Section 1860D-2(b)(2)(A)(ii) of the Act provides that Part D sponsors offering actuarially equivalent standard coverage will be permitted to substitute cost-sharing requirements (including multi-tier benefit structures tied to Part D plan formularies and particular pharmacies in a Part D plan's network) for costs above the annual deductible and up to the catastrophic coverage limit, provided that those alternative cost-sharing requirements are actuarially equivalent to an average expected coinsurance of 25 percent for costs above the annual deductible and up to catastrophic coverage. Also, since the beginning of the Part D program, we have interpreted this provision to permit multi-tier benefit structures for actuarially equivalent standard coverage but not for Defined Standard coverage (70 FR 4237).

As is noted on page 55 of the Final Calendar Year 2015 Part D Call Letter, for a plan using a formulary (as defined at § 423.4), we expect that the formulary structure for Defined Standard coverage will be consistent with a plan benefit package (PBP) that does not include a multi-tier benefit structure. Similarly, we have stated in our Formulary Submission Module and Reports Technical Manual (available to appropriate reviewers in the HPMS via the following path: Plan Formularies/Formulary Review/CY 2027/Documentation/View Documentation/User

Manual under FDR Documentation) that formularies that will only be associated with plans offering Defined Standard coverage must be submitted as having a single-tier benefit structure. We made an exception to this policy for a plan(s) offering Defined Standard coverage to use a formulary that is linked (via the formulary crosswalk) to at least one other plan with a multi-tier benefit structure (that is, a plan offering Actuarial Equivalent Standard, Basic Alternative, or Enhanced Alternative coverage). We made this exception because a given formulary (as defined in § 423.4) applies to all plans to which such formulary has been assigned, whereas any submitted multi-tier benefit structures are plan-specific and only apply to the individual plans that offer coverage other than Defined Standard. In other words, when a Part D sponsor assigns a formulary to both a plan offering Defined Standard coverage and one or more plans offering Actuarially Equivalent Standard, Basic Alternative, or Enhanced Alternative coverage, the plan offering Defined Standard coverage will cover the same list of drugs associated with that formulary. However, with respect to the plan offering Defined Standard coverage, the cost-sharing for all drugs on the formulary must be a single-tier benefit structure regardless of the tier structure that applies to the other plans assigned the same formulary.

The Final Calendar Year 2015 Part D Call Letter also instructed that all marketing materials for plans offering Defined Standard coverage reflect a single-tier benefit structure regardless of whether such plan offering Defined Standard coverage uses a formulary that is associated with other plans that offer multi-tier benefit structures.

Because we continue to receive questions from Part D sponsors about our policy that a plan offering Defined Standard coverage have a single-tier benefit structure, we are re-proposing our prior proposal from the CY 2024 Proposed Rule to codify this longstanding subregulatory policy. While we have made minor revisions to the proposed regulatory text to improve clarity, the underlying policy is unchanged from both our prior proposal and our longstanding subregulatory policy as established in the Final Calendar Year 2015 Part D Call Letter. Additionally, with regard to the formulary crosswalk policy, we have previously used the terms

"associated," "mapped," "linked," and "assigned" synonymously, but in order to minimize confusion, we have chosen to use the term "assign" in our proposed regulatory requirements.

First, we propose to define the term "formulary crosswalk" at § 423.100 as the process during bid submission through which a Part D sponsor assigns a formulary (as defined at § 423.4) to one or more Part D plans with single- or multi-tier benefit structures.

Second, we propose to add new paragraph (8) to § 423.120(b) to codify the single-tier benefit requirement for plans offering Defined Standard coverage. At new § 423.120(b)(8)(i), we propose to codify that a Part D sponsor must apply a single-tier benefit structure to a Part D plan offering Defined Standard coverage and such benefit must be administered consistent with Defined Standard coverage as defined at § 423.100. At new § 423.120(b)(8)(ii), we propose to codify that, except as provided in paragraph (iii), a Part D sponsor may not assign a formulary (as defined at § 423.4) with a multi-tier benefit structure to a plan offering Defined Standard coverage via the formulary crosswalk (as defined at § 423.100). Additionally, at new § 423.120(b)(8)(iii), we propose to codify an exception providing that when a Part D sponsor offers both Defined Standard coverage plan(s) and one or more other Part D plans with multi-tier benefit structures, the Part D sponsor may assign a formulary with a multi-tiered benefit structure to a plan offering Defined Standard coverage, provided that the benefit administered with respect to the Defined Standard plan is consistent with paragraph (i) of this section, and the formulary is marketed as a single-tier benefit structure (consistent with § 423.2267(e)(52)).

Finally, we propose to codify our subregulatory policy that a plan offering Defined Standard coverage reflect a single-tier benefit structure in all relevant communications, as defined at § 423.2260. Specifically, at new § 423.2267(e)(52), we propose to require that, when addressing the Part D plan's formulary, a plan offering Defined Standard coverage convey that all covered Part D drugs have a single-tier benefit structure. This model content would be included in all relevant communications (as defined at § 423.2260) that pertain to the

formulary—including the complete and abridged formulary, Summary of Benefits, Evidence of Coverage, and other materials, as applicable.

We have been monitoring compliance with this policy via our annual formulary review and approval process, consistent with the requirements at § 423.120(b). Because this proposal codifies longstanding subregulatory policy without substantive changes and plans are already in compliance, we do not anticipate any additional costs or impacts associated with this proposal.

C. Ensuring Value for Enhanced Alternative Part D Plans (§ 423.104)

In this section, CMS proposes to clarify the specific changes that a Part D plan sponsor can make to increase the actuarial value of an Enhanced Alternative (EA) plan as compared to standard prescription drug coverage and to codify a requirement that Part D sponsors offering supplemental benefits under certain EA plans must demonstrate the added value by meeting a minimum 15 percent threshold differential, using the out-of-pocket costs (OOPC) model, when compared to Defined Standard (DS) coverage.

1. Background

CMS has the authority under section 1857(e)(1) of the Act, incorporated into Part D by section 1860D-12(b)(3)(D) of the Act, to establish additional contract terms that CMS finds "necessary and appropriate." In addition, section 1860D-11(d)(2)(B) of the Act provides CMS with the authority to impose "reasonable minimum standards" for Part D plan sponsors.

Part D plan sponsors have the flexibility to offer non- DS plans, under which they can modify certain benefit parameters. This includes two types of basic plans—Actuarially Equivalent standard coverage and Basic Alternative coverage— in addition to EA coverage. EA coverage must meet the requirements of alternative prescription drug coverage and, in accordance with § 423.104(f), includes both required basic prescription drug coverage and supplemental benefits.

Section 11201 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169) made significant changes to the Part D benefit design that affect the structure of the Part D benefit. Because the IRA did not modify the list of permissible supplemental benefits in section 1860D-2(a)(2)(A)(i) of the Act to include a reduction in the annual out-of-pocket (OOP) threshold, Part D plan sponsors may not lower the annual OOP threshold. Thus, under § 423.104(f)(1)(ii), the following supplemental benefits remain as possible enhancement features: coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100 and/or any of the following changes or combination of changes that increase the

actuarial value of benefits under the Part D plan above the actuarial value of defined standard prescription drug coverage:

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

2. Increase of Actuarial Value of Standard Prescription Drug Coverage (§ 423.104(f)(1)(ii)(B)(*1*))

We note that, historically, we have not specified that the waiving of a plan's deductible for a subset of its formulary tiers is an enhancement; however, as described in the Final CY 2026 Part D Redesign Program Instructions,[15] we stated that we believe this does represent increased value for enrollees. We continue to believe that waiving a plan's deductible for a subset of its formulary tiers is an enhancement that can increase the actuarial value of standard prescription drug coverage, and as such, we propose to codify this policy at § 423.104(f)(1)(ii)(B)*(1)*.

3. Evaluating EA Plan Value (§ 423.104(f)(1)(ii)(D))

We recognize that the options available to EA plans to increase the value of the benefit above that of DS coverage are now limited as a result of Part D redesign. CMS therefore believes it is critical to continue using a process for ensuring that beneficiaries receive value relative to the standard prescription drug benefit when they enroll in an enhanced plan in light of the supplemental premiums they may pay for these enhanced plans. This approach is consistent with CMS's broader efforts to promote healthy competition in the Part D marketplace and to advance transparency so that beneficiaries can identify the plan that best meets their individual needs. CMS began to use the Part D OOPC model as the primary mechanism for estimating the value of EA plans relative to the standard prescription drug benefit (specifically comparing EA plans to the DS benefit parameters) in contract year 2025 and again in contract year 2026, as described in the Final CY 2025 and Final CY 2026 Part D Redesign Program Instructions.[16, 17] The Part D

[15] Refer to the Final CY 2026 Part D Redesign Program Instructions.
[16] Refer to the Final CY 2025 Part D Redesign Program Instructions.
[17] Refer to the Final CY 2026 Part D Redesign Program Instructions.

OOPC model, as defined at proposed § 423.104(f)(1)(ii)(D)(*2*), estimates the relative OOPC value—expressed as the estimated beneficiary cost per month—for beneficiaries enrolled in Part D plans. The model takes the drug utilization of a sample cohort of Part D beneficiaries and conducts a simulated processing of claims using each plan's bid submission, including formulary data, to estimate a monthly value. CMS releases the Part D OOPC model in advance of each contract year.

As specified in § 423.104(f)(1)(ii)(A), EA plans may offer excluded drug coverage as an enhancement. CMS is not proposing a new requirement for the value of such coverage and is not seeking comment on this topic. We note that CMS's Part D OOPC model does not include the excluded drug benefit in the estimated OOPC values. Instead of establishing a requirement for an excluded drug value, CMS will continue to perform separate reviews of individual drugs offered under excluded drug coverage. This could include a comparison of drug prices to the cost sharing submitted, and working with Part D plan sponsors to make changes to benefits under our negotiation authority under § 423.272(a) if a plan's proposed benefit does not appear to offer enhanced value. Our reviews in recent years suggest that excluded drug offerings have not demonstrated a significant benefit, and we considered prohibiting the option of *only* offering excluded drugs as a means to meet EA benefit design requirements. In the Draft CY 2026 Part D Redesign Program Instructions we sought comment on eliminating this option for meeting EA design requirements beginning with CY 2026.[18] Based on feedback received, we continued to allow EA plans to offer excluded drugs as their only Part D benefit enhancement for CY 2026. While we are not proposing changes to this policy at this time, we will continue to monitor the value offered by this benefit design and possibly reassess this policy for future years.

In the Final CY 2025 Part D Redesign Program Instructions,[19] CMS did not establish a specific threshold to evaluate the added value of EA plans relative to the standard prescription

[18] See https://www.cms.gov/files/document/final-cy-2026-part-d-redesign-program-instruction.pdf
[19] Refer to the Final CY 2025 Part D Redesign Program Instructions.

drug benefit for CY 2025. We analyzed the submitted CY 2025 bids to calculate the percent difference for all plans, except for those plan types noted previously, and then prepared distributions. In the Final CY 2026 Part D Redesign Program Instructions,[20] CMS established a threshold of 15 percent, which represented the fifth percentile of the percent difference calculation, based on analysis of CY 2025 bids. We believe this threshold strikes a balance between ensuring value for beneficiaries while maintaining a feasible approach for Part D plan sponsors.

Given our experience with using the OOPC model to evaluate value for EA plans as we implemented Part D redesign, in this rule, we propose to codify a minimum 15 percent difference threshold to establish that an EA plan is offering sufficient value beyond the standard prescription drug benefit by revising § 423.104(f)(1)(ii) to add a new paragraph (D)(*1*). CMS also proposes to use the Part D OOPC model, added as § 423.104(f)(1)(ii)(D)(*2*), as the primary mechanism for estimating the value of EA plans relative to the DS benefit. For the purpose of evaluating the proposed 15 percent EA plan value threshold, CMS proposes several calculation steps in new § 423.104(f)(1)(ii)(D)(*3*)(*i*) through (*iii*). First, CMS would calculate an estimated OOPC value for each submitted EA plan (referred to as EA OOPC) that has indicated one or more of the following enhancement features: a reduction (or elimination) of the deductible; a waiver of the plan deductible for a subset of at least one formulary tier; and/or a reduction in cost sharing in the initial coverage phase. Using the same formulary submitted for the EA plan, CMS proposes to also calculate an estimated OOPC value for that plan's formulary applied under the DS benefit design (referred to as DS EA OOPC). To determine the absolute OOPC difference, we would subtract the estimated EA OOPC value from the estimated DS EA OOPC value calculated using the EA plan's formulary simulated through the DS benefit scenario. We then would calculate the percent difference by dividing the absolute difference by the estimated DS EA OOPC value and multiplying by 100, as illustrated in Table II.C-1.

[20] Refer to the Final CY 2026 Part D Redesign Program Instructions.

TABLE II.C-1: CALCULATION TO EVALUATE EA PLAN OFFERINGS

Value	Source	Description	Calculation	Requirement
[A] EA OOPC	Output from the Part D OOPC model	Estimated OOPC value of EA plan (formulary and intended plan design)	Not applicable	Not applicable
[B] DS EA OOPC	Output from the Part D OOPC model	Estimated OOPC value of EA plan's formulary using the simulated DS benefit scenario	Not applicable	Not applicable
[C] Difference	Calculation	Represents the absolute OOPC difference between the EA plan as compared to the EA formulary applying the DS benefit	[B]−[A]	Not applicable
[D] Percent Difference	Calculation	Represents the proportion of additional value attributed to the EA plan as compared to the EA formulary applying the DS benefit	([C] / [B]) x 100	Greater than or equal to 15 percent

Consistent with the policies established in the Final CY 2025 Part D Redesign Program Instructions[21] and continued through CY 2027, CMS proposes at § 423.104(f)(1)(ii)(D)*(1)(ii)* to exclude PACE organizations and Employer Group Waiver Plans (EGWPs) from the EA plan value review, as these plan types do not submit the necessary portions of the plan benefit packages (PBPs) CMS needs to conduct the review. We also propose to exclude Dual Eligible Special Needs Plans (D-SNPs) because the OOPC model does not account for the low-income subsidy (LIS) cost-sharing protections that would be available to the majority—if not all—of the beneficiaries enrolled in these plan types, and inclusion of such plans would therefore produce estimated OOPC values that do not accurately reflect the value experienced by their enrollees. In the Draft CY 2026 Part D Redesign Program Instructions, we sought comment on additional plan types that we should exclude from this analysis. Based on recommendations we received, we are proposing to maintain the plan exclusions as noted above with one addition at proposed

[21] Refer to the Final CY 2025 Part D Redesign Program Instructions.

§ 423.104(f)(1)(ii)(D)(*1)(iii).* During the rebate reallocation period, we have also excluded all Special Needs Plan types if CMS requires them to change from a DS plan to an EA plan to add Part D supplemental benefits to address a negative Part D basic premium, as described in § 423.272(e). Under these circumstances, the estimated EA OOPC value must be no worse than that compared to the estimated DS EA OOPC value.

Section 423.104 codifies requirements related to qualified prescription drug coverage, and the burden requirements of disclosing data to CMS to demonstrate compliance with this regulatory provision are already captured in CMS-10141, OMB 0938-0964. CMS would use data that Part D sponsors already submit to CMS under this provision to evaluate compliance with revised § 423.104, as described in the proposal. Therefore, this provision would not impose new burden requirements on Part D plan sponsors or change existing operational processes. We also do not anticipate that this provision would have additional measurable economic impact on Part D sponsors, beneficiaries, or the Medicare program, as it would only provide specificity to an existing requirement.

D. Ensuring Meaningful Differences Between Standalone PDPs (§ 423.265)

In this section, CMS proposes to codify a 15 percent value threshold to establish that an enhanced alternative (EA) PDP plan is meaningfully different from the basic plan offered by the same PDP sponsor within the same region. CMS also proposes a threshold such that the share of meaningful difference attributed to formulary robustness be greater than or equal to zero percent and that the share of meaningful difference attributed to benefit design be greater than 50 percent. CMS would use an out-of-pocket (OOPC) model to determine compliance with these thresholds, if codified.

1. Background

a. Legal Authority

CMS has the authority under section 1857(e)(1) of the Act, incorporated into Part D by section 1860D-12(b)(3)(D) of the Act, to establish additional contract terms that CMS finds "necessary and appropriate." In addition, section 1860D-11(d)(2)(B) of the Act provides CMS with the authority to impose "reasonable minimum standards" for PDP sponsors. Under this authority, we can deny bids that are not substantially different from other bids submitted by the same PDP sponsor in the same service area with respect to the benefit package or plan costs (§ 423.272(b)(3)(i)). This is an important protection, as it helps to ensure beneficiaries can distinguish between the plans available to them and make the best choice for their needs. While the regulation uses the terms "substantial difference" and "substantially different," we refer to this as our "meaningful difference" requirement to emphasize the importance of ensuring beneficiaries have meaningful plan choice.

b. History of the Part D OOPC Model

As discussed in the Final CY 2025 Part D Redesign Program Instructions,[22] CMS has used a Part D OOPC model since CY 2012 to conduct the annual standalone PDP meaningful difference evaluation and has refined it over the years based on experience and stakeholder

[22] Refer to the Final CY 2025 Part D Redesign Program Instructions.

feedback. The Part D OOPC model estimates the relative OOPC value (that is, the estimated beneficiary cost per month) for beneficiaries in PDPs. Annually, CMS has established meaningful difference value thresholds for the upcoming contract year by evaluating the estimated Part D OOPC values using the prior year's approved bid and formulary data. Between CY 2012 and CY 2022, CMS used an absolute dollar threshold to assess whether the estimated Part D OOPC value for the EA plan(s) is equal to or lower than the established dollar threshold compared to the estimated Part D OOPC value for the basic plan offered in the same region.

Beginning in CY 2023, CMS moved to an outlier approach to ensure that PDP offerings met the requirements under § 423.272(b)(3)(i) due to significant updates CMS made to the Part D OOPC model. To improve upon the accuracy and timeliness of estimated Part D OOPC values, CMS enhanced the model to estimate Part D OOPC values based on a cohort of a 0.1 percent sample of all Part D enrollees and their associated PDEs, as opposed to the previous approach of using the Medicare Current Beneficiary Survey (MCBS) data, which lagged in some cases by many years and required complex mapping of survey data.

Stakeholders supported these enhancements and agreed the change provided for a larger, more representative cohort, more timely data, and up-to-date drug estimates, compared to the fee-for-service cohort from the MCBS data. Based on commenters' additional feedback, CMS further enhanced estimated Part D OOPC values by accounting for therapeutic alternatives and formulary exception cost-sharing when a model drug is not on a PDP sponsor's formulary.[23] Since 2023, the current model simulates real-world beneficiary behavior and takes into account therapeutic alternative and exception tier cost sharing, whereas the model had historically estimated OOPC value for non-formulary drugs at their full cash price. The Medicare Payment Advisory Commission (MedPAC) stated that the actuaries MedPAC interviewed believe these

[23] See memorandum "Enhanced Out-of-Pocket Cost Model Update," November 19, 2021, released by CMS through HPMS.

combined enhancements were an improvement to the model and would make the meaningful difference requirement more rigorous.[24]

Given the impact of these various model changes on Part D estimated OOPC values, CMS chose to temporarily evaluate bid submissions using a distribution analysis approach. We thus established an outlier threshold, rather than establishing an absolute dollar amount in advance, until we were able to gain more experience with the model updates. For CY 2023, CMS reviewed bid submissions for OOPC differences between basic and EA PDPs. We communicated concerns at the 75th percentile, which corresponded to a 7.5 percent difference between PDP basic and EA plan(s). In other words, any EA plan that did not have an estimated OOPC value that was 7.5 percent better than its respective basic plan's estimated OOPC value needed to further enhance its benefit. For CY 2024, CMS again used an outlier approach at the same 75th percentile, corresponding to a 10.65 percent difference threshold between basic and EA plan(s).

Section 11201 of the Inflation Reduction Act of 2022 (IRA) made amendments to section 1860D-2 of the Act that impact Part D plan benefit design by capping enrollees' annual OOP costs, eliminating the coverage gap phase, and eliminating cost-sharing in the catastrophic phase. As a result of these changes to the benefit, CMS adopted a new approach to assessing meaningful difference between an EA plan and a basic plan for standalone PDPs in CY 2025. After consideration of the statutory changes under the IRA and the comments we received in response to the Draft CY 2025 Part D Redesign Program Instructions, we established an absolute percent threshold approach for evaluating PDP meaningful difference for CY 2025. This approach aligned with a longstanding CMS goal to move the meaningful difference evaluation from a variable absolute dollar differential to a static percent differential. Once established, a percent differential does not require annual updates for inflation and establishes a stable, consistent requirement from year to year. This approach also considers the richness of the

[24] See "Report to Congress: Medicare and the Health Care Delivery System," June 2022, MedPAC.

comparator basic plan in the evaluation; for instance, an EA plan will not need to meet the same dollar threshold when compared to basic plan with an estimated OOPC value of $100 as opposed to a basic plan with an estimated OOPC value of $150. This helps to alleviate the incentive to make the basic plan less rich to meet meaningful difference because a higher basic plan estimated OOPC value will result in a larger dollar threshold for the corresponding EA plan.

Specifically for CY 2025, CMS undertook an analysis of the historic threshold values used for the PDP meaningful difference requirements as shown in table II.D – 1. This analysis looked at the annual meaningful difference dollar thresholds and calculated the average percent differences between the basic and the lower valued EA plan (that is, the EA plan with the higher estimated OOPC value when two EA plans are offered in the same region) for each PDP sponsor. We then prepared distributions and evaluated the percentile that was used to establish the meaningful difference dollar threshold for each year. Averaging the years together, we determined that a meaningful difference threshold of eighteen percent between the basic and EA plans would align with the observed dollar differentials from previous years.

TABLE II.D-1: HISTORIC MEANINGFUL DIFFERENCE ANALYSIS

Threshold Contract Year	Bid Data Contract Year Used to Establish Threshold	Meaningful Difference Threshold	Percentile Used to Establish Meaningful Difference Threshold	Corresponding Percent Change Aggregated by PDP Sponsor
2015	2014	$20	95th	18 percent
2016	2015	$18	95th	15 percent
2017	2016	$23	50th	20 percent
2018	2017	$20	50th	20 percent
2019	2018	$22	50th	18 percent

Given the limited enhancements available to plans under Part D benefit redesign, we acknowledged that this may no longer be a reasonable expectation. For CY 2024, for example, all plans achieved close to a 12 percent difference without having an established threshold to target when preparing their bids. Therefore, for CY 2025, as a middle ground between these two

values of 12 percent and 18 percent, we required a 15 percent difference between a PDP sponsor's basic plan and EA plan(s) offered in the same region.

All PDP sponsors met or exceeded the 15 percent threshold for CY 2025. However, after careful consideration of concerns raised by PDP sponsors, and considering that the inclusion in the OOPC model of maximum fair prices (MFPs) for initial price applicability year 2026 would have a greater impact on basic plan estimated OOPC values, thus potentially making it slightly more difficult to meet meaningful difference, CMS lowered the meaningful difference threshold to 10 percent for CY 2026. At that time, CMS believed that lowering the OOPC differential between PDP basic and EA plans to 10 percent balanced the challenges PDP sponsors faced in differentiating between basic and EA plans, while continuing to ensure that the enhancements offered to beneficiaries in EA plans are meaningful. However, in evaluating the CY 2026 bids, CMS found that nearly all PDP sponsors achieved a 15 percent difference or better between their basic and EA plan(s). While the threshold remained at 10 percent for the subsequent CY 2027 bid submissions, all PDP sponsors met or exceeded a 15 percent difference.

2. Establishing Meaningful Differences Between Bids (§ 423.265(b)(2)(i)).

CMS proposes to modify the regulatory text at § 423.265(b)(2)(i) to codify that a bid would satisfy the requirement to be meaningfully different if it meets thresholds established by CMS through the OOPC model that CMS releases in advance of each contract year (and that CMS proposes to describe at § 423.104(f)(1)(ii)(D)(2)). The Part D OOPC model takes the drug utilization of a sample cohort of Part D beneficiaries and conducts a simulated processing of claims using each plan's bid submission, including formulary data, to estimate a monthly Part D OOPC value. The OOPC model release would additionally include a simulated Defined Standard (DS) benefit scenario. The Part D OOPC model would generate four values that CMS would use to evaluate meaningful difference, as shown in table II.D – 2. These outputs would include the estimated OOPC value of the basic plan (basic OOPC); the estimated OOPC value of the basic plan's formulary using a simulated DS benefit scenario (referred to as DS basic OOPC); the

estimated OOPC value of the EA plan (EA OOPC); and the estimated OOPC value of the EA plan's formulary using a simulated DS benefit scenario (referred to as DS EA OOPC). We are also proposing minor revisions to the regulatory text at § 423.265(b)(2)(i) to replace the term "significantly different" with "meaningfully different" which is the term CMS has adopted in historical guidance.

a. Overall Meaningful Difference Threshold (§ 423.265(b)(2)(i)(A))

CMS further proposes a meaningful difference calculation and threshold requirement for standalone PDPs that would establish that an EA PDP is meaningfully different from the basic plan offered by the same PDP sponsor within the same region. First, CMS would codify a calculation to establish the absolute value for meaningful difference by subtracting the EA OOPC from the basic OOPC. We would then calculate a percent difference by taking this difference, dividing it by the basic OOPC, and multiplying by 100. These calculations are shown in table II.D – 2. Second, given our experience with the OOPC model, described in section II.D.1.b. of this proposed rule (History of the Part D Out-of-Pocket (OOPC) Model), CMS would codify a requirement that a PDP sponsor must meet a 15 percent difference threshold to establish that an EA PDP is meaningfully different from the basic plan that it offers within a region. These proposals would be codified by revising § 423.265(b)(2)(i) and adding new paragraph (A).

b. Meaningful Difference Derived from Formulary Robustness Versus Benefit Design Thresholds (§ 423.265(b)(2)(i)(B))

In addition to proposing to codify the current meaningful difference threshold policy, CMS proposes to codify an ancillary threshold policy. The proposal would require that in order for an EA plan to meet the meaningful difference requirement, the share of meaningful difference attributed to formulary robustness must be greater than or equal to zero percent and the share of meaningful difference attributed to benefit design must be greater than 50 percent. Currently, CMS determines the proportion of meaningful difference derived from formulary robustness, which is distinct from benefit design (inclusive of tier placement parameters), for the

EA plan. We use the outputs from the DS benefit scenario to review these proportions. To determine the proportion of the estimated OOPC value provided by formulary robustness in a given EA plan, we subtract the DS EA OOPC from the DS basic OOPC, divide this difference by the meaningful difference, and multiply by 100. To determine the proportion of estimated OOPC value provided by benefit design, we subtract the formulary robustness proportion from 100. These calculations are also shown in table II.D – 2. We would codify our proposals by adding a new paragraph (B) to § 423.265(b)(2)(i).

CMS is proposing to codify the metrics for formulary robustness and benefit design, as compared to the DS benefit, so that we can compare plans that may use a wide range of different formulary designs and benefit structures. Based on past CMS experience in bid review, there were instances in which a PDP sponsor's EA plan within a region applied higher cost sharing to individual formulary tiers when compared to its basic plan in that region. Such PDP sponsors achieved an adequate OOPC differential by adding drugs to the formulary without offering a richer benefit (for example, lower deductible or lower copays) compared to the basic plan. CMS does not consider this type of enhancement to be entirely transparent to the beneficiary. We also note that such an enhancement is of limited scope, given that only beneficiaries who utilize the added drugs benefit from the enhancement. Further, in responding to CMS's meaningful difference review concerns, PDP sponsors often responded by simply adding drugs to their formularies, particularly those that are high cost but with low utilization, rather than improving the benefit.

Given these concerns, in the Final CY 2025 Part D Redesign Program Instructions,[25] we required that each metric—formulary robustness and benefit design—be no worse for the EA plan compared to the basic plan. All PDP sponsors met this requirement, with an average of 19.4 percent of the meaningful difference attributable to formulary robustness and 80.6 percent to

[25] Refer to the Final CY 2025 Part D Redesign Program Instructions.

benefit design. In the Final CY 2026 Part D Redesign Program Instructions,[26] CMS required the percentage attributed to formulary robustness be greater than or equal to 0 percent, and the proportion attributed to benefit design be greater than 50 percent.

In this rule, CMS's proposal to codify this ancillary threshold requirement to ensure EA plans offer a measurable enhancement would be consistent with the policy finalized in the Final CY 2026 Part D Redesign Program Instructions. Our proposed methodology is intended to prohibit PDP sponsors from relying on formulary robustness alone to achieve a meaningful difference value. At the same time, so as not to discourage PDP sponsors from adding Part D drugs to their formularies, this proposal ensures that they would still receive credit in the OOPC model for adding drugs to their formulary.

In summary, in this rule we propose to require that PDP sponsors meet a minimum 15 percent overall differential between PDP basic and EA plan(s), as calculated and represented in Table II.D – 2 as [H]. We are proposing to add this requirement at new § 423.265(b)(2)(i)(A). In addition, CMS proposes to require that the share of meaningful difference attributed to formulary robustness, as calculated and represented as [F], be greater than or equal to zero percent and the share of meaningful difference attributed to benefit design, as calculated and represented as [G], be greater than 50 percent. CMS proposes to add these requirements at new § 423.265(b)(2)(i)(B).

TABLE II.D-2: OUTPUT FROM THE PART D OOPC MODEL AND CALCULATIONS TO EVALUATE PDP MEANINGFUL DIFFERENCE

Value	Source	Description	Calculation	Requirement
[A] Basic OOPC	Output from the Part D OOPC model	Estimated OOPC value of basic plan (formulary and intended plan design)	Not applicable	Not applicable
[B] DS Basic OOPC	Output from the Part D OOPC model	Estimated OOPC value of the basic plan's formulary run through DS benefit	Not applicable	Not applicable
[C] EA OOPC	Output from the Part D OOPC model	Estimated OOPC value of EA plan (formulary and intended plan design)	Not applicable	Not applicable

[26] Refer to the Final CY 2026 Part D Redesign Program Instructions.

Value	Source	Description	Calculation	Requirement
[D] DS EA OOPC	Output from the Part D OOPC model	Estimated OOPC value of the EA plan's formulary run through DS benefit	Not applicable	Not applicable
[E] Meaningful Difference	Calculation	The differential in OOPC between the EA plan and the basic plan. This value must be positive, indicating the EA plan is better (that is, lower) than the basic plan	[A]−[C]	Not applicable
[F] Formulary Component (percent)	Calculation	The proportion of meaningful difference attributed to formulary robustness	([B] − [D])/[E] ×100	Greater than or equal to zero percent (§ 423.265(b)(2)(i)(B)(*2*))
[G] Benefit Component (percent)	Calculation	The proportion of meaningful difference attributed to benefit design	100 percent - [F]	Greater than 50 percent (§ 423.265(b)(2)(i)(B)(*3*))
[H] PDP Meaningful Difference (percent)	Calculation	The percent difference between the EA plan and the basic plan	([A] − [C])/[A]×100	Greater than or equal to 15 percent more value than the basic plan (§ 423.265(b)(2)(i)(A))

PDP sponsors are required to submit a bid for each Part D plan they intend to offer in their service area for the upcoming year. Section 423.265 governs the submission of bids and related information, and the burden associated with this provision is already captured in CMS-R-262, OMB 0938-0763. CMS would use the information that PDP sponsors already submit as part of their bids to evaluate compliance with revised § 423.265(b)(2)(i). Therefore, this proposed provision would not impose new burden requirements on PDP sponsors or change existing operational processes. We also do not anticipate that this provision would have additional measurable economic impact on PDP sponsors, beneficiaries, or the Medicare program, as it would only provide specificity to an existing requirement.

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

A. Using a CMS Approval Mechanism for Use of the Disaster/Emergency Special Enrollment Period and Other Technical Changes (§§ 422.62, 422.66, 423.32, 423.36 and 423.38)

1. Background and Proposed Provisions

Section 1851(c) of the Act provides the Secretary with the authority to establish a process by which MA enrollment elections (hereinafter referred to as "elections") are made and changed, including the form and manner in which they are changed. Section 1851(c)(2)(A) and (B) of the Act specifies that the election process shall permit individuals to make MA elections by filing an appropriate election form with an MA organization. Section 1851(e)(4)(D) of the Act authorizes the Secretary to create special enrollment periods (SEPs) for an individual to disenroll from an MA plan or elect another MA plan if the individual meets an exceptional condition provided by the Secretary.

Section 1860D–1(b)(1)(B) of the Act provides that in adopting the Part D enrollment process, the Secretary ''shall use rules similar to (and coordinated with) the rules for" MA plans under specified provisions of section 1851 of the Act, including section 1851(c) and (e) of the Act. Section 1860D–1(b)(3)(C) of the Act authorizes the Secretary to establish Part D SEPs for Medicare-eligible individuals to enroll in a Part D plan if they meet certain exceptional circumstances.

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

In 2020, we published a final rule (85 FR 33796) that codified the SEP for individuals affected by a government-entity-declared disaster or other emergency (hereinafter referred to as the "Disaster SEP") (§§ 422.62(b)(18) and 423.38(c)(23)), which was previously limited to Federal Emergency Management Agency (FEMA)-declared emergencies or disasters. In 2026, we published a final rule (91 FR 17384) to codify long-standing policy that certain SEPs required CMS approval for use through the use of CMS-operated mechanisms as determined by CMS, such as 1-800-MEDICARE or the Online Enrollment Center, or other means, such as the receipt of a notice of eligibility. In that rule, we established §§ 422.66(g), 423.32(k), and 423.36(g), which specified the SEPs with this limitation. Language was also added to the SEPs under §§ 422.62 and 423.38 to indicate that CMS approval was required for use and how approval would be provided. We codified these limitations in order to better oversee the use of SEPs which may not be appropriate for plans to use without prior CMS eligibility determination and approval. In that rule, we provided as examples the SEPs for individuals who are impacted by a contract violation or by conduct that was sanctioned by CMS. In these examples the organizations making the SEP eligibility determinations are not neutral arbiters of eligibility, as they have a financial interest in deeming the conduct of other organizations as a contract violation or they lack the complete information about the circumstances of the sanctioned conduct.

As explained in the contract year 2026 final rule, CMS developed this limitation because of concerns about the capacity of organizations to properly assess eligibility for SEPs where organizations do not or could not have complete context, or where they may have financial interests that cause them to not be neutral arbiters of eligibility. As discussed elsewhere in this rule, CMS is now proposing to extend this limitation to apply to another situation where additional CMS oversight over the utilization of a particular SEP may be appropriate, specifically, where there is evidence to suggest that the SEP is being misused. In such cases, we believe that it may be necessary to require CMS approval for use of a particular SEP, in order to

prevent misuse of the established election periods and the resulting enrollment abuses, including the potential for enrollment fraud.

To that end, we believe the Disaster SEP has been misused since it was codified and should require CMS approval prior to use. Shortly after the Disaster SEP was codified, we began to receive questions from external interested parties about the applicability of the SEP to various state and local disaster and emergency declarations. This was understandable since plans were adjusting to the new relevance of state and local declarations, given that the SEP previously was limited only to FEMA declarations. However, these inquiries soon became reports of suspected misuse of the SEP, which we started receiving in 2021 and continue to receive from plans, state departments of insurance, agents/brokers, and industry groups. In short, external interested parties report that some plans ignore the eligibility criteria of the SEP and treat disaster/emergency declarations as an open enrollment period, no matter the real or potential impact of the disaster/emergency on the individual utilizing the SEP. We have also received allegations that some plans are using this SEP for enrollment in areas where there has not been a disaster/emergency declaration.

This misuse of the Disaster SEP stems from an incorrect application of the eligibility criteria at §§ 422.62(b)(18)(iv) and 423.38(c)(23)(iv), which requires that eligible individuals did not make an election during another election period for which they were eligible "due to the emergency or major disaster." By its ordinary meaning, "due to the emergency or major disaster" requires that the individual was prevented from making another election as a result of that emergency or disaster, or that the effects of the emergency or disaster prevented the individual from taking advantage of another election period. The easiest example of such a disaster would be a major hurricane that resulted in evacuations, power outages, disruption to mail delivery, or property damage, such that the displacement of the individual along with other effects made them unable to submit an enrollment application during another valid election period, like the Annual Enrollment Period.

The principal policy justification for the Disaster SEP is that eligible individuals would have used the other election period but were prevented from doing so by something beyond their control that they could not have been expected to foresee. An SEP provides a remedy for eligible individuals impacted by an emergency or disaster by replacing the other election period that would have been used. Based on the reports of external interested parties, some plans were not assessing for eligibility based on the actual effects of the disaster, that is, that the disaster prevented the individual from making an election during another election period. These reports indicated that plans were either using any emergency or disaster declaration akin to an open enrollment period and/or were not checking that the individual was eligible for an election period at an earlier point in time and had been unable to make an election during the timeframe of that earlier election period because of the emergency or disaster. The Disaster SEP is not so broadly written and application in such a manner entirely defeats the purpose of an SEP meant to provide protection to a specific group of individuals and provide a remedy.

After receiving numerous reports of suspected misuse, we undertook an internal analysis of enrollments that were submitted using the Disaster SEP. As a starting point, we reviewed disaster declarations between 2022 and 2024 that were previously reported to us by external parties as questionable sources of SEP eligibility. Among these reports were the actual lists of disasters that certain plans had provided to their agents/brokers as eligible to the Disaster SEP. CMS reviewed these lists and it is our understanding, based on external reports, that these were to be used as a reference by agents and brokers when accepting enrollments and included every active declaration, regardless of the actual likelihood of that disaster causing someone to miss an enrollment period, thereby making them eligible for the Disaster SEP. CMS has received reports that these types of materials were frequently made available through online broker portals and typically included details about declared disasters, affected counties, and SEP start and end dates.

Using this information, we identified disaster declarations (during the above time period) that were the only active declaration at the time in a particular geographic area and, based on the

underlying circumstances, were unlikely to lead to an individual missing an election period as a result of the that disaster. We confirmed they were the only declared disaster by reviewing county, state, and federal disaster declarations in the same area to determine whether other declarations were active that could account for enrollments over the applicable period. We also found examples where enrollments were submitted in states and counties that had no active disaster declarations during part or all of the applicable period. The specific emergencies examined in our analysis included: a heat emergency (30 days of high temperatures); hurricanes that resulted in minimal damage; the death of former First Lady Rosalynn Carter; inflation; mpox and polio; and the 2024 solar eclipse. This analysis was intentionally limited to disaster declarations that were unlikely to have prevented an individual from using another election period and that CMS had received complaints or reports of possible misuse of the SEP.

Our analysis identified 55,642 enrollments occurring between January 2022 and August 2024 in our sample of eight states which were likely cases of misuse, either because there was no active disaster declaration in that area at that time or the disaster was unlikely to have impacted an individual's ability to make an election. Nationwide, there were 1,180,848 total enrollments using the Disaster SEP over the same time period. While the 55,642 inappropriate uses of the Disaster SEP represent only 4.7% of the total uses over the same timeframe, given the frequency with which the SEP is utilized and the volume of complaints we receive regarding misuse, we believe that our limited analysis confirmed that misuse is occurring, which is unlikely to be limited to the eight states in our analysis. Therefore, even though our analysis cannot be used to establish a nationwide error rate, we believe that there is widespread misuse of the Disaster SEP. Since our analysis, utilization of the Disaster SEP has only grown, with 777,898 elections in 2025 alone, highlighting the need for stronger oversight of this frequently used SEP given the observed evidence of misuse. CMS continues to receive reports of suspected misuse of the SEP from external interested parties, supporting our belief that the eligibility criteria for the SEP are being misapplied or misunderstood.

To address suspected and reported misuse of the Disaster SEP, we propose that use of the Disaster SEP would require prior CMS approval through the use of a CMS-operated mechanism. CMS is proposing that initially, this SEP would be restricted to use through 1-800-MEDICARE only, similar to other SEPs, though we may consider expanding this to other mechanisms, including the Online Enrollment Center, in the future. This requirement would allow for CMS to exercise oversight over the Disaster SEP and the election mechanism to ensure appropriate use prior to the election request being filed with the plan. This change would not limit an individual's ability to access the SEP if they are eligible but would ensure that the SEP is not being used inappropriately. Agents and brokers will still be able to assist individuals making elections using this SEP and have their involvement in the enrollment request captured by providing their National Producer Number, which is transmitted to the plan along with the enrollment request.

Consistent with our previous rulemaking (91 FR 17384), we propose to codify the requirement for CMS approval in the description of the SEP at §§ 422.62(b)(18)(ii) and 423.38(c)(23)(ii) and propose to include the Disaster SEP on the list of SEPs that require CMS approval at §§ 422.66(g)(2)(iv), 423.32(k)(2)(iv), and 423.36(g)(2)(iv). In response to our request for comments on the 2026 rule, a commenter even suggested that CMS limit the Disaster SEP to only CMS-operated mechanisms in the same way that we described the limitation for the other SEPs. We believe that implementing this limitation in a similar fashion to the other SEPs identified in the 2026 final rule provides a consistent framework for the process of making an election and the filing with the plan, without the need to create a new or unique verification processes for the Disaster SEP or future SEPs that might be misused.

We are proposing a limitation on the way in which this SEP is accessed by beneficiaries to create a more consistent enrollment process and application of eligibility criteria for the Disaster SEP. We are concerned that inconsistent application and misuse of the Disaster SEP creates an uneven playing field, undermining fair enrollment standards and contributing to

market instability. Specifically, this misuse can foster misleading or aggressive marketing, financial conflicts of interest, disruption in the continuity of care, and erosion of program integrity – all leading to increased administrative burden and Medicare program costs. Limiting the use of this SEP to a CMS-operated mechanism would level the playing field for organizations and should mitigate the negative consequences that can occur from the misuse of the Disaster SEP. Because of the higher level of oversight that we have over CMS-operated mechanisms, we can more easily ensure that the Disaster SEP is offered in cases where it is warranted, that is, in cases where the individual's unique circumstances clearly show that they were affected by a disaster and missed another opportunity to make an election, rather than the current state of the SEP where it is offered broadly and without regard to its eligibility criteria.

We conclude that the proposed changes to the regulatory text will not adversely impact agents and brokers, plan sponsors, or beneficiaries. During disasters, beneficiaries can be particularly vulnerable to high-pressure sales and marketing tactics. For those who have missed an enrollment period due to an emergency or disaster, it can be challenging to know which plans are available and best meet their coverage needs. For beneficiaries who want to utilize an agent or broker for assistance, this proposal supports that process. Beneficiaries can opt to contact their trusted agent or broker to perform the normal counseling functions, that is, reviewing the beneficiary's providers, prescriptions, pharmacies, costs, benefits, and available MA or Part D plans to help them to determine their best coverage options. When the beneficiary or the beneficiary and the agent call 1-800-MEDICARE to effectuate the enrollment, the beneficiary or the agent, as stated previously, can provide the agent/broker's National Producer Number for any due compensation. For those beneficiaries without existing agent/broker relationships, by contacting 1-800-MEDICARE, beneficiaries can ensure they will receive neutral comparisons across all eligible plans. This may help them make more informed decisions and protect their interests at a critical time.

Further, we conclude that the proposed regulatory change would not have a negative impact on the Medicare Trust Funds or result in a paperwork burden. All information impacts related to the procedural steps plans must take to receive and process election requests are currently approved by OMB under control numbers 0938-0753 (CMS-R-267) for Part C and 0938-0964 (CMS-10141) for Part D.

2. Alternative Considered

We considered an alternative proposal to address the suspected and reported misuse of the Disaster SEP. That alternative consideration is described in the following discussion:

Historically, CMS conveyed and effectuated disaster/emergency SEPs on an ad hoc basis specific to certain larger-scale disasters and emergencies via subregulatory guidance - the first appearing in our guidance manual, Chapter 2 of the Medicare Managed Care Manual, and Chapter 3 of the Medicare Prescription Drug manual in 2006 for Hurricanes Katrina, Rita, and Wilma. See also December 1, 2014, HPMS memo entitled "Enrollment Opportunities for Individuals Affected by the Winter Storms in Western New York," which described the availability of an SEP for individuals affected by winter storms that prevented them from using the Annual Enrollment Period (AEP). In 2018, CMS established the SEP for a FEMA-Declared Weather-Related Emergency or Major Disaster in Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Manual, which limited eligibility for this SEP to individuals affected by disasters and emergencies identified in FEMA declarations and did not include state and local government-entity declarations. In our 2020 rule (85 FR 9002), we proposed to codify the SEP for a FEMA-Declared Weather-Related Emergency or Major Disaster as it had existed in our subregulatory guidance. However, in response to public comments on that proposed rule, this was revised to include state and local government entities. In the final rule (85 FR 33796), we stated that based on comments requesting that the SEP be available for all government-entity disaster/emergency declarations, we would revise the SEP so it was not "solely contingent upon a FEMA declaration" and was consistent with our "goal of

providing an enrollment or disenrollment opportunity to an individual who missed an election period due to circumstances beyond his or her control" (85 FR 33868).

Based on reports of misuse of the Disaster SEP, which we started receiving in 2021 from plans, state departments of insurance, agents/brokers, and industry groups, as well as our own analysis of how often and under what circumstances this SEP is being used, we considered an alternative approach of limiting the use of the Disaster SEP to FEMA-declared events, which are formal, documented federal actions with clear start/end dates and geographic boundaries (by county/area). Using a FEMA-declared event as the basis for granting a disaster SEP would give CMS, plans, and agents an unambiguous basis for determining SEP eligibility, as using one federal standard ensures beneficiaries in similar emergency situations are treated the same way regardless of which state they live in, avoiding a patchwork of differing state/local definitions of "emergency." Broadening the SEP trigger to any state or local emergency declaration (which can be issued more frequently, with lower thresholds, or for a broader range of events such as minor weather events or localized incidents), creates more opportunities for agents/brokers to misuse the SEP to enroll or switch beneficiaries improperly (tying back to the "steering" concerns we discussed earlier) outside of normal enrollment periods.

We note that, in the event an individual is impacted by a state or local disaster/emergency event that is not a FEMA-declared event, CMS can allow an SEP, on a case-by-case basis, for exceptional circumstances related to enrollment into or disenrollment from an MA or Part D plan. Consistent with current practice, CMS will consider granting an enrollment or disenrollment opportunity in situations such as a circumstance beyond the individual's control that prevented them from submitting a timely request to enroll in or disenroll from a plan during a valid election period, or to ensure access to services, and when, without the approval of an enrollment exception, there could be adverse health consequences for the individual.

We welcome comments on the proposal to limit the use of the Disaster SEP to require CMS approval through the use of CMS-operated mechanisms such as 1-800-MEDICARE, as

well as the considered alternative approach to limit the Disaster SEP to FEMA-declared weather-related events or emergencies only.

3. Technical Correction

Separately, in the contract year 2027 proposed rule we inadvertently omitted two SEPs for which it is our longstanding guidance and practice to require that the beneficiary at issue have CMS approval for the use of that SEP through the use of a CMS-operated election mechanism, such as 1-800-MEDICARE or the Online Enrollment Center (OEC), or other means, such as receipt of a notice. To correct this oversight and ensure that regulations align with current subregulatory guidance, we propose to codify the same limitations for the following SEPs:

- SEP for individuals who are enrolled or not enrolled in Part D due to an error by a federal employee (§§ 422.62(b)(21) and 423.38(c)(3)).

CMS regulations at §§ 422.62(b)(21) and 423.38(c)(3) currently provide for an SEP for individuals whose enrollment or non-enrollment in an MA-PD or stand alone Part D plan was erroneous due to an action, inaction, or error by a Federal employee. Requiring CMS approval for the use of this SEP is consistent with CMS's longstanding application of this SEP. As articulated in CMS's current regulations, this SEP is only available upon a CMS determination that the SEP applies, meaning that a plan, broker, or beneficiary cannot independently declare that a federal employee made an error and thereby create an election period. In practice, CMS reaches such determinations based upon a review of CMS/federal records, as applicable incidents may involve what a 1-800-MEDICARE representative or another federal employee said or did, when it occurred, and whether that conduct actually caused the erroneous enrollment/non-enrollment. Additionally, requiring CMS approval protects enrollment integrity, as without centralized approval, plans could reach different conclusions about what constitutes a "federal employee error," potentially creating inconsistent or unauthorized corrective enrollment actions. Lastly, the approval itself starts the SEP clock. This is particularly important: unlike

many SEPs triggered automatically by an external event, this SEP begins with CMS approval, so there must be an authoritative CMS determination.

- SEP for individuals affected by a significant change in provider network (§ 422.62(b)(23)).

CMS regulations at § 422.62(b)(23) provide an SEP for individuals affected by a significant change in their plan's provider network. Requiring CMS approval for the use of this SEP is consistent with CMS's longstanding application of this SEP, which, as described in Chapter 4 of the Medicare Managed Care Manual, *Benefits and Beneficiary Protections*, section 110.1.2, entitled *Significant Changes to Networks*, involves a rigorous review by CMS of the totality of the circumstances to decide whether a termination is significant. The MA organization whose network changed should not be the final arbiter of whether its own network disruption is sufficiently significant to give members a right to leave. By requiring a CMS determination of "significance," this policy prevents different MA organizations from applying different definitions of "significant" and ensures that the SEP is applied consistently across plans and beneficiaries. Even after CMS finds a significant network change, the SEP is only available to those enrollees within the plan who are actually affected by the termination. Therefore, we are proposing to codify longstanding practice that this SEP should be granted under a CMS approval mechanism.

Consistent with our previous rulemaking (91 FR 17384), we propose to include these SEPs on the list of SEPs that require CMS approval by redesignating current § 422.66(g)(2)(iv) as § 422.66(g)(2)(viii) and adding § 422.66(g)(2)(vi) and (vii). We are also proposing to redesignate current § 423.32(k)(2)(iv) as § 423.32(k)(2)(vii) and adding § 423.32(k)(2)(vi), and redesignating § 423.36(g)(2)(iv) as § 423.36(g)(2)(vi) and adding § 423.36(g)(2)(v).

B. Start, End, and Effective Dates for Special Election Periods (§§ 422.62 and 423.38)

Special election periods (SEPs) provide opportunities for Medicare beneficiaries to make enrollment and disenrollment elections outside of the annual election period when specific life events or circumstances occur. SEPs ensure that beneficiaries maintain access to appropriate coverage when circumstances arise that could affect their enrollment options. These SEPs address a wide range of situations, including changes in eligibility status, loss of other coverage, plan terminations, disasters or emergencies, and other exceptional circumstances. Sections 1851(e), 1860D-1(b)(1)(B)(iii), and 1860D-1(b)(3) of the Act authorize CMS to establish SEPs.

Current regulations at §§ 422.62 and 423.38 establish the circumstances under which an individual is eligible to use an SEP. While §§ 422.68(d) and 423.40(c) provide a default effective date for SEP elections, the regulations do not consistently describe the start and end dates of SEP eligibility windows or the exceptions to the default effective date. Additional details about when specific SEPs begin and end, and when coverage becomes effective are currently described primarily in sub-regulatory guidance, specifically, the Medicare Advantage and Part D Enrollment and Disenrollment Guidance (the "Enrollment Guidance"), section 30.6. In addition, the availability of retroactive enrollment, where applicable, is not consistently reflected in regulatory text. To provide transparency, promote consistent administration of SEPs across MA and Part D programs, and provide beneficiaries and plan sponsors with a single regulatory source describing SEP availability and operation, we are proposing to codify timeframes and the availability of retroactive enrollment for certain SEPs. Because the proposed revisions reflect longstanding CMS policies and current operational practice, these changes would not alter beneficiary rights or plan responsibilities.

First, we are proposing to amend §§ 422.62 and 423.38 to specify the start and end dates of the following SEPs:

- The SEP for individuals whose plan or contract is non-renewed effective January 1, including service area reductions (nonrenewal) would be revised at §§ 422.62(b)(1) and

423.38(c)(6) to add subparagraph (i) to reflect that the SEP begins December 8 of the contract year and ends the last day of the following February.

- The SEP for individuals whose plan or contract is terminated (Termination or Modification by MA organization, Part D Sponsor, or Mutual Consent) would be revised at §§ 422.62(b)(1) and 423.38(c)(6)) to add paragraph (ii) to reflect that the SEP begins 2 months before the termination effective date and ends the month after the month of termination.

- The SEP for individuals whose plan or contract is terminated (CMS termination of contract) would be revised at §§ 422.62(b)(1) and 423.38(c)(6) to add paragraph (iii) to reflect that the SEP begins one month before the termination effective date and ends 2 months after the termination effective date.

- The SEP for individuals who change permanent residence would be revised at §§ 422.62(b)(2) and 423.38(c)(7) to reflect that the SEP begins the date of the change in permanent residence or the month before the change in permanent residence for an individual who notifies the MA organization or Part D sponsor in advance of the change. An individual who leaves an MA plan service area on a temporary basis for an extended period of time but continues to maintain a permanent residence in the service area must be disenrolled if the extended absence exceeds six consecutive months, or up to 12 months if the MA plan offers a visitor/traveler benefit. For Part D plans, this period of allowable temporary absence from the service area is 12 consecutive months. For tracking purposes, MA organizations and Part D plan sponsors typically consider a possible temporary absence from the service area to begin upon notification from the enrollee, receipt of non-urgent or non-emergent out-of-area claims, receipt of returned mail or similar indications that an enrollee is out of the service area. The SEP for an individual disenrolled for exceeding the aforementioned periods of allowable temporary absence from the service area begins the first day of the sixth month (or up to the 12^{th} month if a visitor/traveler benefit applies) for MA and, for Part D, the SEP begins the first day of the 12^{th} month, when the MA organization or Part D sponsor has not been able to confirm the

individual's residency status. The SEP would end 2 months following the month it begins or 2 months following the month of the move, whichever is later.

- The SEP for Contract Violations would be revised at §§ 422.62(b)(3) and 423.38(c)(8) to add paragraphs (b)(3)(iii) and (c)(8)(iv), respectively, to specify that the SEP begins once CMS determines that a violation occurred and ends 90 calendar days after CMS' determination.

- The SEP for individuals who involuntarily lose creditable prescription drug coverage would be revised at § 423.38(c)(1) to specify that the SEP begins the date the individual is notified of loss or reduction of creditable coverage and ends 2 calendar months after loss/reduction or receipt of notice, whichever is later.

- The SEP for individuals not adequately informed of loss of creditable coverage would be revised at § 423.38(c)(2) to specify that the SEP begins the month CMS determines individual is eligible and ends two calendar months following CMS determination.

- The SEP for individuals who disenroll from Part D to enroll in/maintain other creditable coverage would be amended at § 422.62(b)(14) to add paragraph (iii) and at § 423.38(c)(18) to specify that the SEP begins upon disenrollment from a Part D plan and ends on the 1st day of the following month in which disenrollment request is received by the plan.

- The SEP for other exceptional circumstances would be amended at redesignated §§ 422.62(b)(28) and 423.38(c)(37) to state the SEP begins upon CMS determination and notification to enrollee and ends on a case-by-case basis, as determined by CMS.

Second, under §§ 422.68(d) and 423.40(c), the default effective date for an enrollment election made during an SEP is the first day of the calendar month following the month in which the election is made. However, subregulatory guidance provides beneficiaries with a choice of prospective effective dates for certain SEPs. These exceptions are currently described in section 30.6 of the Enrollment Guidance and we are proposing to amend the following SEPs to align with our subregulatory guidance:

- The SEP for individuals whose plan or contract is non-renewed effective January 1, including service area reductions (nonrenewal) would be revised at §§ 422.62(b)(1) and 423.38(c)(6) to state in newly proposed paragraph (i) that enrollment requests received December 8 through December 31 will have an effective date of January 1, enrollment requests received in January will have an effective date of February 1 and enrollment requests received in February will have an effective date of March 1.

- The SEP for individuals whose plan or contract is terminated by the MA organization or Part D sponsor, or by mutual consent, would be amended at §§ 422.62(b)(1) and 423.38(c)(6) to add paragraph (ii) to allow an individual to request an effective date for the month after notice is given, or up to 2 months after the effective date of the termination, but the effective date may not be earlier than the date the applicable organization or sponsor receives the enrollment request.

- The SEP for CMS termination of contract would be amended at §§ 422.62(b)(1) and 423.38(c)(6) to add new paragraph (iii) to allow an individual to request an effective date for the month after notice is given, or up to three months after the effective date of the termination, but the effective date may not be earlier than the date the applicable organization or sponsor receives the enrollment request.

- The SEP for individuals who demonstrate a contract violation would be amended at §§ 422.62(b)(3)(iv) and 423.38(c)(8)(v) to provide that an individual may choose an effective date of the first day of the month after the month the new plan receives the completed enrollment request. The individual may also choose an effective date of enrollment in the new plan beginning any of the three months after the month in which the sponsor receives the completed enrollment request. However, the effective date may not be earlier than the date the applicable organization or sponsor receives the enrollment request.

While current guidance provides that the effective date for an enrollment or disenrollment made under the SEP for other exceptional circumstances may be either prospective or retroactive

based on the individual's circumstances, as determined by CMS, this is not currently reflected in regulatory text. We are proposing to revise §§ 422.62(b)(27) and 423.38(c)(36) to codify that the effective date of coverage under this SEP may be prospective or retroactive, consistent with current guidance and practice. We note that this codification does not limit CMS's discretion to evaluate individual circumstances; rather, it provides a clear regulatory basis for a determination that CMS already makes on a case-by-case basis. In determining whether a prospective or retroactive effective date is appropriate, CMS considers the individual's specific circumstances, including but not limited to, circumstances beyond the individual's control that prevented timely enrollment, situations involving misleading or incorrect information provided by a plan representative, or situations where access to care could be adversely affected without an enrollment exception. For example, CMS may consider a retroactive enrollment for a case in which an individual enrolled in a Medicare drug plan based on incorrect formulary information, such that there is no coverage for necessary medications under the current plan, and waiting for a prospective enrollment in a plan that meets the individual's needs would be problematic.

We note that the SEP for individuals who elect into or out of employer-sponsored coverage (§§ 422.62(b)(4) and 423.38(c)(11)) and the SEP for individuals who involuntarily lose creditable prescription drug coverage (§§ 422.62(b)(19) and 423.38(c)(1)) already include language in regulation reflecting the availability of a choice of prospective effective dates, and therefore no amendment is proposed for those SEPs with respect to this issue.

A summary of the proposed changes is provided in Table III.B-1 .

TABLE III.B-1 : PROPOSED CHANGES TO THE SPECIAL ELECTION PERIODS (SEPs)

SEP Name	CFR Citation	SEP Begins	SEP Ends
SEPs for individuals whose plan or contract is terminated or non-renewed, including service area reductions.			
A. Nonrenewal	§§ 422.62(b)(1); 423.38(c)(6)	December 8 of the contract year	The last day of the following February.

SEP Name	CFR Citation	SEP Begins	SEP Ends
B. Termination or Modification by MAO, Part D Sponsor, or Mutual Consent	§§ 422.62(b)(1); 423.38(c)(6)	2 months before termination effective date	One month after the month of termination
C. CMS Termination of Contract	§§ 422.62(b)(1); 423.38(c)(6)	One month before termination effective date	2 months after termination effective date
SEP for individuals who change permanent residence	§§ 422.62(b)(2); 423.38(c)(7)	The date of the change in permanent residence; The month before the change in permanent residence, for an individual who notifies the MA organization or Part D sponsor in advance of the change; or When the individual is being disenrolled because they have been out of the service area for over six months (Part C) or over 12 months (Part D) and the MA organization or Part D plan has not been able to confirm the residency status of the individual. See below for more information.	2 months following the month it begins; or 2 months following the month of the move, whichever is later.
SEP for Contract Violations	§§ 422.62(b)(3), 423.38(c)(8)	Once CMS determines that a violation occurred	90 calendar days after CMS' determination
SEP for individuals who involuntarily lose creditable prescription drug coverage	§§ 422.62(b)(19); 423.38(c)(1)	Date notified of loss or reduction of creditable coverage	2 calendar months after loss/reduction or receipt of notice, whichever is later
SEP for individuals not adequately informed of loss of creditable coverage	423.38(c)(2)	Month CMS determines individual is eligible	2 calendar months following CMS determination
SEP for individuals who disenroll from Part D to enroll in/maintain other creditable coverage	§§ 422.62(b)(14); 423.38(c)(18)	Upon disenrollment from Part D plan	1st day of following month in which disenrollment request is received by the plan
SEP for other exceptional circumstances	§§ 422.62(b)(28); 423.38(c)(37)	Upon CMS determination and notification to enrollee	Case-by-case, as determined by CMS

Lastly, two SEPs currently have regulatory support for start and end date provisions under Part C (§ 422.62) but lack parallel language under Part D (§ 423.38). Specifically, the SEP for individuals who involuntarily lose creditable prescription drug coverage (§ 423.38(c)(1)) and the SEP for individuals not adequately informed of a loss of creditable coverage (§ 423.38(c)(2)) do not have start and end date parameters that coordinate with the SEPs at § 422.62(b)(19) and (b)(20) and we are proposing to align the language. We believe this approach will ensure that beneficiaries enrolled in standalone Part D plans are afforded the same clarity and protections as those enrolled in MA-PD plans, and that plan sponsors administer these SEPs consistently across both programs.

The proposed changes are consistent with longstanding subregulatory guidance set forth in section 30.6 of the Enrollment Guidance and are intended to provide greater regulatory clarity and enforceability.

C. Request for Comment: *Seamless Continuation of Coverage for Newly Medicare-Eligible Individuals (§ 422.66)*

Section 1851(c)(3)(A)(i) of the Act provides that, in general, an individual who fails to make an election between Original Medicare and MA during their initial election period is deemed to have chosen Original Medicare. However, section 1851(c)(3)(A)(ii) of the Act provides the Secretary the authority to establish procedures under which an individual who is enrolled in a health plan (other than a MA plan) during their initial election period, and who fails to elect to receive other coverage may be deemed to have elected an MA plan offered by the organization that offers the individual's current non-MA plan. This second option is referred to as seamless continuation of coverage.

Consistent with this section of the Act, in 1998, we[27] published a final rule (63 FR 34968) to codify both the process of election of Original Medicare by default at 42 CFR 422.66(c) and the seamless continuation of coverage process at § 422.66(d). This initial codification implemented the seamless continuation of coverage process outlined in section 1851(c)(3)(A)(ii) of the Act, whereby individuals enrolled in a health plan offered by the organization may be deemed to have elected an MA plan offered by that same organization. In the 2005 final rule (70 FR 4588), CMS addressed the seamless continuation of coverage enrollment process and modified it to include MA-PD plans for the 2006 start of the Part D program. In 2018, we published the final rule (83 FR 16440) that revised the seamless continuation process to allow for the use of a new and simplified enrollment request mechanism by MA organizations and their members who wish to enroll in an MA plan offered by the same entity that offers the individual's pre-Medicare coverage.

The 2018 final rule also created a default enrollment process for MA dual eligible special needs plans, found at § 422.66(c)(2). Default enrollment allows for certain dual eligible individuals to be deemed to have elected an MA special needs plan. The requirements for

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[27] The Health Care Financing Administration, the predecessor agency to CMS.

default enrollment are codified at 42 CFR 422.66(c)(2). Not all D-SNP plans are eligible; the MA organization must have an affiliated Medicaid managed care plan and an approved D-SNP. Participating MA organizations are approved by both the state Medicaid agency and CMS, and MA organizations must be at least 3-star rated, a low enrollment contract, or a new MA plan. The 3-star rating requirement set a quality standard for plan participation in an auto-enrollment mechanism for Medicare Advantage for the first time. Participating plans must also not have any prohibition on new enrollment imposed by CMS. Dual eligibles receive advance notice of the intent to be default enrolled into a D-SNP and have the opportunity to opt out of the enrollment. As discussed further in this section, we are considering reestablishing the seamless continuation of coverage process with some modifications that are similar to the requirements in the existing default enrollment process.

Congress established seamless conversion in section 1851(c)(3) of the Social Security Act in the Balanced Budget Act of 1997. CMS addressed seamless conversion in rulemaking (CMS-4069-F) in 2005, and guidance was established that same year. CMS granted its first approval of an MA organization to offer seamless conversion in June 2005. The second approval was granted for March 2010 and the third for January 2012. In the 2018 final rule (83 FR 16440), we discussed the reasoning for changing seamless continuation of coverage from a default process, in which an individual would need to affirmatively opt out of automatic MA enrollment, to an opt in process. Specifically, we noted in the final rule that beneficiary advocates had requested additional consumer protections and that MA organizations found it difficult to comply with the opt out enrollment process and approval parameters. Advocates believed that automatic enrollment deprived beneficiaries of an active choice and cited cases in which beneficiaries alleged having been enrolled without their knowledge or consent. Advocates argued that a decision as important as choosing the way in which a newly Medicare-eligible individual receives Medicare should require an intentional “opt in” choice. Accordingly, we finalized an “opt in” policy in the 2018 final rule.

While we believe an "opt in" policy was previously appropriate, to improve outreach to newly eligible beneficiaries and ease the transition from commercial or Marketplace coverage to MA, we are considering a seamless continuation of coverage mechanism, similar to the opt-out process that existed prior to the 2018 final rule, but with several enhancements. Congress established seamless conversion in section 1851(c)(3) of the Act in 1997. We would modify § 422.66(d) to allow for the seamless continuation of coverage for enrollees of commercial or Marketplace plans into MA plans operated by the same organization, as provided in section 1851(c)(3)(A)(ii) of the Act. We believe this would address the administrative issues that led to the 2018 changes. Additionally, returning to an opt-out seamless continuation of coverage process would address prior beneficiary protection concerns by using the quality and notification requirements that, as discussed elsewhere in this rule, have proved successful in the default enrollment process. Further, we believe this change would result in the positive effects of maintaining coverage under the same organization, including continuity of care and simplicity for beneficiaries by preserving existing electronic health records, case management programs and approved prior authorizations, reducing the risk of temporary coverage losses during the transition to Medicare. Additionally, seamless continuation of coverage provides the newly Medicare-eligible individual with the option to transition to a Medicare health plan that is offered by the same organization the individual chose for their coverage prior to becoming eligible for Medicare. Since May 2020 CMS has made available to MA organizations a Medicare Beneficiary Identifier (MBI) lookup tool that can be used to process seamless continuation of coverage. This addresses some operational concerns that led to the 2018 changes, namely the transition at the time from health insurance claim numbers (HICNs), which no longer allowed plans to use an enrollee's SSN to determine their HICN. After the transition to HICNs but prior to release of the tool, plans had to wait for monthly CMS eligibility files to confirm when an enrollee was approaching Medicare eligibility, which made it difficult to meet the 60-day advance notice requirement for seamless continuation of coverage. The lookup tool gives MA

organizations direct, real time access to Medicare systems, allowing them to proactively search for an individual's Medicare status.

We have also benefited from our experience in implementing the default enrollment mechanism for D-SNPs currently described in 42 CFR 422.66(c)(2), which has shown that the additional protections included in the codification of default enrollment in 2018 were successful in responding to the concerns raised several years earlier. Prior to implementing default enrollment, CMS created a robust process for review of MA organizations' proposals for implementing default enrollment and also developed a centralized electronic repository for all proposal-related materials. Under this enhanced review process, MA organizations upload for CMS review a detailed description of their default enrollment process and all related enrollee notices and member materials. As part of this process, CMS reviews all member materials, including the advance notice, to ensure they are accurate and include all required elements, such as information on the individual's right to opt out of the enrollment, up to and including the day prior to the enrollment effective date, how to opt out and how to obtain information on other Medicare options. CMS maintains a record of communications between CMS and the MA organizations regarding any defects in the materials that need to be addressed, revised materials submitted to CMS and the final disposition of CMS' review. These technological advancements significantly enhanced CMS' oversight of the MA organization's plan for meeting the default enrollment requirements, just as CMS review of member materials has helped to ensure consistent and accurate messaging to beneficiaries regarding default enrollment across all MA organizations that choose to offer this enrollment mechanism.

Under the opt-out seamless enrollment process that CMS is considering, beneficiaries who do not opt out of seamless enrollment would also have access to enrollment periods, during which they could change their MA plan or return to Original Medicare. During the first 3 months of Medicare entitlement, all newly Medicare-eligible beneficiaries can use the MA Open Enrollment Period, as described in 42 CFR 422.62(a)(3)(ii), to switch to a different MA plan or

disenroll from MA to return to Original Medicare, with Medigap guaranteed issue rights from the Medigap Open Enrollment Period as outlined in section 1882(s)(2)(A) of the Act, which lasts for the first 6-months the individual is at least both aged 65 and enrolled in Medicare Part B. Additionally, under § 422.62(c), an MA eligible individual who elects an MA plan during their initial enrollment period that surrounds their 65th birthday may disenroll from MA and elect coverage under Original Medicare at any time during the first 12 months of their MA enrollment. This individual would have Medigap guaranteed issue rights as outlined in section 1882(s)(3)(B)(vi) of the Act. Depending on their individual circumstances, they may also be eligible for an SEP that could be used to change MA plans or return to Original Medicare. If an MA SEP is used to return to Original Medicare, the individual would also have Medigap guaranteed issue rights as outlined in section 1882(s)(3)(B)(ii) of the Act.

CMS is considering whether to model the seamless continuation of coverage enrollment process on the existing default enrollment process by: (1) requiring MA organizations to obtain CMS approval prior to engaging in use of the seamless enrollment mechanism; (2) requiring that approved MA organizations must meet quality standards by having at least a 3-star rating (or by meeting the definition of "low enrollment contract" or "new MA plan" if the MA organization does not have a star rating); and (3) requiring advance notice to the individual of the organization's intent to seamlessly enroll them into an MA plan, along with details about plan benefits and cost. To ensure that individuals are aware of the seamless continuation of coverage and their Medicare coverage options, the advance notice would be required to be issued no fewer than 60 calendar days before the proposed MA enrollment effective date, that is, the first of the month in which the individual is entitled to Part A and enrolled in Part B. The notice would include clear information on the MA plan, as well as instructions to the individual on how to opt out of (decline) the seamless continuation of coverage and how to enroll in Original Medicare or a different MA plan. (As with all communications, notices must comply with applicable anti-discrimination law, including laws requiring effective communication for individuals with

disabilities. *See for example* , 45 CFR 92.101 *et seq.* and 45 CFR 84.77.) We would require that MA organizations must submit enrollment transactions to CMS no fewer than 60 calendar days prior to the effective date of MA enrollment.

The process we are considering would specify that an MA organization may implement a seamless continuation of coverage enrollment process in which a newly Medicare-eligible individual enrolled in a commercial or Marketplace plan it offers may be deemed to have elected an MA plan offered by the same organization. It would require that MA organizations obtain CMS approval prior to participating in the seamless continuation of coverage process. CMS would require that the organization identify in its proposal each commercial or Marketplace plan (by contract/plan ID) for which it is requesting approval to implement a seamless continuation of coverage enrollment process. We would specify that for each such plan the organization must include in its identification and notification processes all of the eligible enrollees within that specific plan, that is, commercial or Marketplace plan enrollees who are approaching Medicare eligibility and reside in the service area of the MA plan into which they would be enrolled. Approval for MA organizations granted under this process would be for a period not to exceed 5 years and may be suspended or rescinded prior to the expiration of this period if the organization is not in compliance with the seamless continuation of coverage requirements. Additionally, we would require that MA organizations must send proposals to participate in seamless continuation of coverage to CMS and that the proposal to use a seamless continuation of coverage process must include details on the proper identification of eligible current enrollees, describe outreach activities, and acknowledge enrollment transaction processing requirements. MA organizations would need to have the means to identify eligible individuals 90 calendar days in advance of the date of their initial Medicare eligibility and must include all individuals, regardless of the reason for eligibility (age, disability, end-stage renal disease). MA organizations would be required to provide a description of outreach activities associated with seamless continuation of coverage and include a copy of the written notice. MA organizations would also be required, when

submitting a proposal to utilize seamless continuation of coverage, to acknowledge the requirement to send the appropriate enrollment transaction to CMS no fewer than 60 calendar days prior to the effective date of enrollment.

Additionally, MA organizations would have to have at least a 3-star rating (or meet the definition of "low enrollment contract" or "new MA plan," as those terms are defined in CMS's regulations at 42 CFR 422.252, if the MA organization does not have a star rating) and must not have any prohibition on new enrollment imposed by CMS to participate in seamless continuation of coverage.

Enrollment transaction submission requirements and notification requirements would specify that MA organizations would need to inform individuals who qualify for seamless continuation of coverage of the intent to enroll them in an MA plan. This notice would need to be sent at least 60 calendar days prior to the effective date of the enrollment and must include information on the differences in premium, benefits and other costs, including cost sharing, between the individual's current plan, Original Medicare, and the intended MA plan, and the process for accessing care under the MA plan. If the seamless conversion would result in the individual being enrolled in an MA plan type with more restrictive provider access and network rules, such as PPO to HMO, the notice would have to include an explanation of these differences. We would require that the notice must also include information on how to obtain information on the provider networks and prescription drug formularies of the commercial plan and the MA plan so that they may identify any differences. The notice would have to include information on how to opt out of the seamless continuation of coverage, the alternative options for Medicare health and drug coverage (for example, Original Medicare, other Medicare health and drug plan options), the availability of Medigap (Medicare Supplemental Plans) and consequences of enrolling in an MA plan if the individual later chose to change to Original Medicare and Medigap, whether or not guaranteed issue (GI) rights exist, and the MA trial right

period. MA organizations would be required to transmit the necessary enrollment information to CMS no fewer than 60 days prior to the effective date of the enrollment.

We remain invested in improving longitudinal care coordination and welcome input on other channels through which we could provide incentives for care continuity for both newly Medicare-eligible beneficiaries and existing MA plan enrollees. In other CMS programs, there are ongoing efforts to improve care coordination including the consideration of multi-year plan terms, for example, in the ACA market (91 FR 29526). We are interested in ideas that could improve longitudinal care coordination and provide a longer-term incentive for plans to manage members' health with preventive and follow-up care across multiple years rather than one enrollment cycle.

We are seeking public comment on a policy to return to an opt-out process for seamless continuation of coverage and on the expected administrative issues that plans would face in implementing the seamless continuation of coverage enrollment process. We also seek comment on the 90-day requirement to identify eligible individuals and the 60-calendar day notice and submission requirement for such an opt-out process, as described earlier in this section. We ask for comments on the feasibility of these timelines and whether a shorter requirement, or longer timeline, such as a 60-calendar day requirement for identification and a 30-calendar day requirement for notice and submission, would be more appropriate, or 120-calendar day and 90-calendar day respectively. We also seek public comment on ideas related to improving incentives for longitudinal care coordination in the MA program.

CMS is also seeking comment on whether additional eligibility criteria for MA organization participation in seamless enrollment would be appropriate. Specifically, adding a minimum length of time that an individual must have been enrolled in an MA organization's commercial plan offering as an additional eligibility criterion for seamless enrollment into their MA plan. A length of prior enrollment requirement could provide assurance that the individual both intended to enroll in the commercial plan and was satisfied enough with that organization

that they intended to remain enrolled. In such a case, we believe that continuation of coverage would be appropriate, due to the individual's existing relationship with that organization. This requirement would limit seamless continuation of coverage to only individuals who have been continuously enrolled in a plan offered by the same parent organization for a specified minimum period of time prior to the individual's Medicare entitlement date. We also seek comment on whether 12 or 24 months would be an appropriate minimum length of time for this requirement and whether this would be an effective means of protecting beneficiaries. If a requirement is finalized, it would be included in addition to the other eligibility criteria described previously. We also seek comment on what types of information might best ensure a beneficiary is able to compare their current commercial plan offering to the MA plan that they would be enrolled in through seamless enrollment, so that they are fully informed during the enrollment period. These would be potentially included in the notice to beneficiaries. While cost difference is a significant factor when considering new coverage, we are requesting comment on what other information should be required in the notice to beneficiaries that we could adopt in the forthcoming final rule.

CMS is also seeking comment on the inclusion of additional regulatory language to prohibit organizations from utilizing commercial health data to selectively include healthier individuals into their MA plans. We are considering adding an explicit prohibition on the use of historical utilization data, claims data, or risk scores in determining eligibility for seamless enrollment. Our intent in adding this would be to emphasize that the only permissible criteria for identifying enrollees for seamless conversion would be initial age/disability-based Medicare eligibility, current active enrollment in the organization's commercial plan and permanent residence in the MA plan service area.

Lastly, we also seek comment on limiting seamless continuation of coverage to only MA organizations with star ratings of 4 or higher and whether a 4-star rating requirement is an appropriate protection for beneficiaries enrolled through an opt-out process or whether this

would overly limit the pool of potential MA organizations that would utilize seamless continuation of coverage.

CMS is soliciting public comment on whether the additional and/or revised criteria noted previously may be appropriate. We also welcome comments on the following topics, to inform future rulemaking and policy efforts. We are interested in ways to increase early engagement for individuals newly eligible for Medicare. We seek public comments on ways to improve pre-enrollment outreach efforts for newly eligible beneficiaries. We seek comments on opportunities to simplify enrollment into MA for individuals approaching Medicare eligibility, including enrollment encouragement efforts to select the Medicare coverage option that is best suited for these individuals. We also seek comments on expanding opportunities for a streamlined transition from the individual's prior coverage to MA, similar to seamless and default enrollment, but for groups not captured by seamless or default enrollment. We also seek comments on ways to increase plan participation in programs such as seamless and default enrollment, particularly for dual eligible populations.

D. Cost Sharing Standards for Ground Ambulance and Emergency Services (§§ 422.100 and 422.113)

Per §§ 422.100 and 422.113, CMS currently has the following MA cost sharing limits for ground ambulance and emergency services:

- Ground ambulance: 50 percent coinsurance or an actuarially equivalent copayment (which may be based on the plan's total financial liability for the benefit).[28]
- Emergency services: $115 to $150 cost sharing[29] (based on maximum out-of-pocket (MOOP) type).

Section 1852(b) of the Act prohibits plan designs that have the effect of discriminating against or discouraging enrollment by beneficiaries based on their health needs. Sections 1856(b) and 1857(e) of the Act authorize CMS to set implementing standards for Part C and adopt additional requirements as necessary, appropriate and not inconsistent with Part C. Under this authority, for the reasons discussed in this section and section X.D.1. of this proposed rule, CMS is proposing the following:

- Ground ambulance: Be subject to, on an in-network basis, the range of cost sharing limits for professional services at § 422.100(f)(6)(iii).
- Emergency services: Be subject to dollar limits set by CMS that are actuarially equivalent to 15 to 20 percent of Original Medicare costs (based on the most recent Medicare FFS projections).

A comparison of the current ("baseline") and proposed cost sharing limits is available in Table III.D-1 and III.D-2 to illustrate the cost sharing limit changes considered by this proposal. Tables III.D-3 and III.D-4 contain the average ground ambulance and emergency services cost sharing amounts across different plan types. The illustrative proposed cost sharing limits from

[28] Currently, the 50% cost sharing standard (§ 422.100(f)(6)(i)) applies to ground and air ambulance services – however, this proposal only applies to ground ambulance services as discussed in this section.
[29] Per § 422.113(b)(2)(i), MA plans are financially responsible for emergency services regardless of whether the services are obtained within or outside the MA organization.

Tables III.D-1 and III.D-2 may be compared to the values in Tables III.D-3 and III.D-4 to understand how the proposed ground ambulance and cost sharing limits correspond to average cost sharing for these services across plan types. For example, the proposed $65 (Table III.D-1) increase to the emergency services cost sharing limit for a plan with a mandatory MOOP type (to $180) still retains a relatively low-cost sharing amount for emergency services as it is $60 less than the average cost sharing for this service in original Medicare ($240 as shown in Table III.D-3 based on contract year 2027 Medicare FFS data projections).

To illustrate the range of impact this proposal may have on average MA plan ground ambulance and emergency services cost sharing amounts, Tables III.D-5 and III.D-6 show (by MOOP type) the difference between average contract year 2026 MA plan cost sharing amounts and the illustrative proposed dollar limits for ground ambulance and emergency services, respectively, to illustrate this proposal's expected upward or downward pressure on average cost sharing for these service categories. In other words, on average MA enrollees may experience the cost sharing differences shown in Tables III.D-5 and III.D-6 if this proposal is finalized and plans (including those that are already meeting the proposed standard): (1) retain the same MOOP type from the prior contract year[30], and (2) fully use this proposal's flexibility to increase cost sharing for emergency services, and (3) fully incorporate this proposal's illustrative minimum necessary decrease to ground ambulance services cost sharing. While this is possible, CMS also refers readers to Table III.D-7 for greater insight into the potential ground ambulance cost sharing changes that may result from this proposal. Table III.D-7 shows CMS's calculation of the expected average contract year 2028 MA plan ground ambulance cost sharing change (ranges between about ($38) – ($126) decreases, based on MOOP type). Table III.D-7 differs from Table III.D-5 because it only considers contract year 2026 MA plans whose cost sharing

[30] As discussed in section X.C.1 and X.D.1, while CMS expects that this proposal may maintain or improve upon the cost sharing incentives tied to lower MOOP type adoption, at this time, CMS cannot predict the extent to which the proposed cost sharing standard changes in combination may influence MA plans to adopt lower MOOP types. Thus, the assumption of MOOP type continuance in Tables III.D-5 and III.D-6 may be a limitation; however, per Table X.3, only 35 MA plans chose to switch their plan's MOOP type to a lower type between contract year 2025 and 2026.

already exceeds the proposed limit (still assumes MOOP type continuance). In essence, Table III.D-7's calculation assumes that MA plans already in compliance with this proposal will not change their cost sharing values. However, CMS includes Table III.D-5 to clarify the flexibility offered by this proposal and Table III.D-7 to provide a more nuanced expectation of average MA plan ground ambulance cost sharing changes if this proposal is finalized.

Based on the information in Tables III.D-1 through III.D-7 and X.9, if finalized CMS currently projects that this proposal will: (1) increase emergency services dollar cost sharing limits (by $65 to $90, based on MOOP type) and (2) decrease average[31] MA plan ground ambulance cost sharing by about $75 (or between about $38 to $126, based on MOOP type, per Table III.D-7) for 65% of MA plans. From another perspective – the ability of this proposal to increase or decrease the average combined MA plan cost sharing for these services – CMS expects this proposal, based on the sum of "difference" figures from Tables III.D-5 and III.D-6, will allow for (in the case of increases) or require (in the case of the decrease) the following changes to average combined MA plan ground ambulance and emergency services cost sharing, by MOOP type, for contract year 2028 (based on contract year 2026 MA plan data):

- Lower MOOP: $155 increase (from about $385[32] to $540[33])
- Intermediate MOOP: $34 increase (from about $416[34] to $450[35])
- Mandatory MOOP: ($56) decrease (from about $416[36] to $360[37])

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[31] As shown in Table III.D-7, this average assumes MOOP type continuance and reflects all MOOP types. For example, plans with a mandatory MOOP are expected to have a more significant, $126 decrease in ground ambulance cost sharing if this proposal is finalized (as the illustrative $180 limit for the mandatory MOOP type is $126 less than the contract year 2026 MA plan weighted average cost sharing for the same benefit, of plans with a cost sharing amount currently in excess of the $180 limit).

[32] Reflects the sum of average ground ambulance and emergency services cost sharing amounts of MA plans with a lower MOOP amount from Tables III.D-5 and III.D-6.

[33] Reflects the sum of the illustrative proposed ground ambulance and emergency services dollar limits (based on contract year 2027 Medicare FFS data projections) for the lower MOOP type.

[34] Reflects the sum of average ground ambulance and emergency services cost sharing amounts of MA plans with an intermediate MOOP amount from Tables III.D-5 and III.D-6.

[35] Reflects the sum of the illustrative proposed ground ambulance and emergency services dollar limits (based on contract year 2027 Medicare FFS data projections) for the intermediate MOOP type.

[36] Reflects the sum of average ground ambulance and emergency services cost sharing amounts of MA plans with a mandatory MOOP amount from Tables III.D-5 and III.D-6.

[37] Reflects the sum of the illustrative proposed ground ambulance and emergency services dollar limits (based on contract year 2027 Medicare FFS data projections) for the mandatory MOOP type.

For comparison, based on Tables III.D-3 and III.D-4, Original Medicare's combined weighted average ground ambulance and emergency services cost sharing amount is $360 (reflecting the sum of $240 cost sharing for emergency services and $120 cost sharing for ground ambulance services). Under this proposal, average combined cost sharing for MA plans with a mandatory MOOP would align closely with this Original Medicare benchmark, while average combined cost sharing for MA plans with a lower or intermediate MOOP may remain above it — consistent with how CMS establishes cost sharing flexibilities for the lower MOOP types for other service categories. Because MA plan bids must remain actuarially equivalent to Original Medicare per § 422.100(j)(2), CMS expects any such changes would be accompanied by offsetting adjustments elsewhere in the bid, resulting in a neutral total financial impact on enrollees in the aggregate (as discussed in section X.C.1. of this proposed rule, on a per member per month basis).

With these changes, CMS expects that contracted provider reimbursement rates and enrollee utilization of services may also change. For example, MA plans may increase contracted provider reimbursement rates for ground ambulance services if they are responsible for a larger proportion of the benefit cost under the range of cost sharing limits. In contrast, CMS expects potentially decreased contracted provider reimbursement rates for emergency services. For example, if an MA plan increases their emergency services cost sharing amount because of this proposal, then the plan may seek to negotiate lower contract rates with the provider (given increased cost sharing compensation) and thus have less total financial liability for emergency services. This proposal may also influence beneficiary decision making about where to receive care. For example, CMS expects some beneficiaries may consider going to an urgent care center rather than an emergency room.

TABLE III.D-1: COMPARISON OF CURRENT ("BASELINE") AND ILLUSTRATIVE PROPOSED CONTRACT YEAR 2028 MA "EMERGENCY SERVICES" SERVICE CATEGORY COST SHARING LIMITS

Description	Lower MOOP	Intermediate MOOP	Mandatory MOOP

Baseline[1]	$150	$130	$115
Illustrative Actuarially Equivalent Dollar Limits to Proposed Limits[2]	$240	$210	$180
Difference	$90 increase allowed	$80 increase allowed	$65 increase allowed

[1] Baseline cost sharing limits that currently apply to "Emergency Services" are currently codified in § 422.113(b)(2)(v)(B).

[2] These values are illustrative based on contract year 2027 Medicare FFS data projections from the Office of the Actuary (OACT). The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (per § 422.100(f)(7)). If finalized, CMS would set the contract year 2028 emergency services cost sharing limits at actuarially equivalent values to the proposed standard based on the most recent Medicare FFS data projections available. At the time of publishing this proposed rule, these illustrative limits are actuarially equivalent to 15 to 20 percent of Original Medicare costs – based on the projected weighted average Medicare FFS allowed amount. Under this proposal, CMS retains the authority from § 422.100(f)(7) to choose among the available actuarial approaches (such as, weighted average or median) to calculate actuarially equivalent dollar limits.

TABLE III.D-2: COMPARISON OF BASELINE AND ILLUSTRATIVE PROPOSED MA "GROUND AMBULANCE SERVICES" SERVICE CATEGORY CONTRACT YEAR 2028 COST SHARING LIMITS

Description	Lower MOOP	Intermediate MOOP	Mandatory MOOP
Baseline[1]	50%	50%	50%
Illustrative Proposed Limits[2]	50% / $300	40% / $240	30% / $180

[1] Baseline cost sharing limits that currently apply to ground ambulance services are codified in § 422.100(f)(6)(i). Currently, CMS has not set an actuarially equivalent copayment limit to the 50 percent coinsurance limit. CMS may set an actuarially equivalent copayment limit to the current standard through the annual subregulatory guidance process under § 422.100(f)(7)(iii) for a future contract year if this proposal is not finalized. For comparison purposes, the actuarially equivalent copayment to the current 50 percent coinsurance limit based on contract year 2027 Medicare FFS data projections is $300.

[2] The coinsurance limits reflect CMS's proposal to apply a range of cost sharing limits from § 422.100(f)(6)(iii). Under this proposal CMS intends to set actuarially equivalent copayment limits to the coinsurance percentages shown, based on the most recent Medicare FFS data projections. The copayment values shown are illustrative of this intention, based on contract year 2027 Medicare FFS data projections. The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (per § 422.100(f)(7)). If finalized, CMS would set the contract year 2028 emergency services copayment limits based on the most recent Medicare FFS data projections available. At the time of publishing this proposed rule, these illustrative limits are actuarially equivalent to the coinsurance percentages shown – based on the projected weighted average Medicare FFS allowed amount. Under this proposal CMS retains the authority from § 422.100(f)(7) to choose among the available actuarial approaches (such as, weighted average or median) to calculate actuarially equivalent dollar limits.

TABLE III.D-3: COMPARISON OF WEIGHTED AVERAGE "EMERGENCY SERVICES" SERVICE CATEGORY COST SHARING AMOUNTS (ACROSS ORIGINAL MEDICARE, MA, AND EMPLOYER PLANS)

Plan Type	Weighted Average Emergency Services Cost Sharing Amounts (Coinsurance/Copayment)
Original Medicare[1]	20% / $240
MA (Excluding Employer, D-SNP, and MSA plans)[2]	20% / $130
Employer – Overall[3]	21% / $217
Employer – Small Firms[3]	24% / $259
Employer – Large Firms[3]	20% / $200

[1] Average Original Medicare cost sharing is weighted based on utilization and is based on contract year 2027 Medicare FFS data projections.

[2] Cost sharing averages for MA plans are weighted by enrollment, include $0 copayment and 0 percent coinsurance values, and are based on contract year 2026 plan benefit package data (the result is the same based on data from either minimum or maximum cost sharing fields). While MA plans may choose to establish a coinsurance for emergency services, it must be capped at the applicable dollar limit and is therefore not directly comparable to Original Medicare's 20 percent coinsurance amount for the same benefit.

[3] Per KFF, employer plan averages are weighted by covered workers. KFF Employer Health Benefits Survey, 2023. Accessed from: *https://www.kff.org/health-costs/2023-employer-health-benefits-survey/#figure743*.

TABLE III.D-4: COMPARISON OF WEIGHTED AVERAGE "GROUND AMBULANCE SERVICES" SERVICE CATEGORY COST SHARING AMOUNTS (ACROSS ORIGINAL MEDICARE AND MA PLANS[1])

Plan Type	Weighted Average Ground Ambulance Cost Sharing Amounts (Coinsurance / Copayment)
Original Medicare[2]	20% / $120
MA (Excluding Employer, D-SNP, and MSA plans)[3]	$275

[1] Employer plan data was unavailable for ground ambulance services.
[2] The $120 figure is actuarially equivalent to 20 percent coinsurance based on CY 2027 Medicare FFS data projections.
[3] Based on contract year 2026 MA plan data, 93.5 percent of MA plans (excludes employer, D-SNP, and MSA plans) use copayment for ground ambulance services, so CMS reports only weighted average copayment instead of weighted average coinsurance. This weighted average cost sharing average includes $0 copayment and 0% coinsurance values.

TABLE III.D-5: GROUND AMBULANCE SERVICES - DIFFERENCE BETWEEN AVERAGE CONTRACT YEAR 2026 MA PLAN COST SHARING AMOUNTS AND ILLUSTRATIVE PROPOSED DOLLAR LIMITS

Metric	Lower MOOP	Intermediate MOOP Plans	Mandatory MOOP Plans
CY 2026 Average MA Plan Cost Sharing[1]	$247	$287	$301
Illustrative Proposed Dollar Limit	$300	$240	$180
Difference	$53 increase allowed	$47 decrease required	$121 decrease required

[1]Based on maximum cost sharing values of contract year 2026 MA plans (excluding employer, D-SNP, and MSA plans) and this weighted average cost sharing average includes $0 copayment values.

TABLE III.D-6: EMERGENCY SERVICES - DIFFERENCE BETWEEN AVERAGE CONTRACT YEAR 2026 MA PLAN COST SHARING AMOUNTS AND ILLUSTRATIVE PROPOSED DOLLAR LIMITS

Metric	Lower MOOP	Intermediate MOOP Plans	Mandatory MOOP Plans
CY 2026 Average MA Plan Cost Sharing[1]	$138	$129	$115
Illustrative Proposed Dollar Limit	$240	$210	$180
Difference	$102 increase allowed	$81 increase allowed	$65 increase allowed

[1]Based on maximum cost sharing values of contract year 2026 MA plans (excluding employer, D-SNP, and MSA plans) and this weighted average cost sharing average includes $0 copayment values.

TABLE III.D-7: CALCULATION OF EXPECTED AVERAGE CONTRACT YEAR 2028 MA PLAN GROUND AMBULANCE COST SHARING CHANGE IF PROPOSED RANGE OF COST SHARING STANDARD IS FINALIZED (BASED ON CONTRACT YEAR 2026 MA PLAN DATA[1])

MOOP Type	Column A: Proposed Ground Ambulance Cost Sharing Limit	Column B: Contract Year 2026 Weighted Average Ground Ambulance Copayment (of MA Plans with a Copayment Greater than Proposed Limit Based on MOOP Type)	Column C: Expected Average Contract Year 2028 MA Plan Ground Ambulance Cost Sharing Change if Proposed Limits Apply (The Difference between Column A and Column B)[2]
Lower	$300.00	$337.53	($37.53)
Intermediate	$240.00	$299.13	($59.13)
Mandatory	$180.00	$305.78	($125.78)

[1] Based on maximum cost sharing values of contract year 2026 MA plans (excluding employer, D-SNP, and MSA plans).

[2]The dollar differences in this column assume that MA organizations would only lower their existing ground ambulance cost sharing amount (which may be based on the plan's total financial liability for the benefit) by the minimum amount necessary to come into compliance with the proposed limits – without changing their plan's MOOP type. These values are a rough parameter to assess the potential impact of this proposal on the average MA plan ground ambulance cost sharing amount based on MOOP type. The weighted average of this column is ($75.30) and represents the expected average decrease to average MA plan ground ambulance cost sharing (across all MOOP types) if this proposal is finalized with the limitations noted throughout this section and section X.D.1. of this proposed rule.

1. Background

Based on CMS's analyses (including analyses of contract year 2026 MA plan cost sharing data and contract year 2027 Medicare FFS data projections), CMS is concerned that the existing ground ambulance and emergency room cost sharing standards may be resulting in: (1) inadequate cost sharing for MA plans in connection with emergency services compared to the cost to provide the benefit and (2) high cost sharing for ground ambulance services for MA enrollees and uncollectable bad debt concerns for ground ambulance providers.

First, the current dollar limits for emergency services were based on contract year 2021 Medicare FFS data projections and do not reflect recent trends in increasing Original Medicare costs to provide these services (as shown in Table X.8, based on contract year 2027 Medicare FFS data projections). For example, the $150 emergency services dollar limit was actuarially equivalent to 20 percent of the contract year 2021 Medicare FFS median projection ($755); in comparison an updated actuarially equivalent value based on the most recent Medicare FFS median data projection (CY 2027, $973) would equate to $195. If MA organizations are also

experiencing an increase in their total financial liabilities for emergency services over this time period, without a corresponding increase to the cost sharing limit, the cost sharing could be inadequate for this benefit[38].

CMS analyzed contract year 2026 MA plan data to determine if MA plans were establishing emergency services cost sharing at the maximum allowable amount. Based on the information in Tables III.D-1, III.D-3, III.D-6, and III.D-8, most contract year 2026 MA plans established cost sharing for emergency services at the highest allowable amount for the plan's MOOP type. In brief, the weighted average MA plan emergency services cost sharing amount is $130 (Table III.D-3) and this correlates to how 45 percent of MA plans have an intermediate MOOP type (Table III.D-8) and are currently subject to a $130 emergency services dollar limit.

CMS compared the MA emergency services cost sharing information (based on contract year 2026 MA plan data) with other available data in Original Medicare and certain types of private health insurance plans. For example, based on the information in Table III.D-3, contract year 2026 MA plans have on average cost sharing for emergency services that is $110 to $87 less than comparable industry figures (the difference between the weighted average MA plan copayment for emergency services and the cost sharing for the same service in Original Medicare and employer plans – the "overall" row). This data point highlights how MA organizations are not, on average, receiving cost sharing for emergency services at amounts that are on par with the most recent cost sharing for this service in Original Medicare or employer plans under the current regulations.

CMS also considered the effect of the statutory requirement (Section 1852(a)(1)(B)(i) of the Act) for MA organizations to submit bids that are at least actuarially equivalent to coverage in Original Medicare. Specifically, if MA organizations are experiencing a financial impact in one area of their benefit design then they may increase cost sharing for other benefits to achieve actuarial equivalence with Original Medicare on a per member per month basis (as required by §

[38] As noted in this section, the overall bid must remain actuarially equivalent to original Medicare.

422.100(j)(2)). As a result, it is possible that the current emergency services cost sharing limits may in combination with § 422.100(j)(2)'s requirement be resulting in cost sharing increases or benefit reductions elsewhere – solely to make up for the potential financial loss received in emergency services cost sharing.

TABLE III.D-8: PERCENT OF MA PLANS BY MOOP TYPE AND YEAR (EXCLUDING EMPLOYER, D-SNP, AND MSA PLANS)

Contract Year	Lower MOOP	Intermediate MOOP	Mandatory MOOP
2022	26%	Not Available[1]	74%
2023	28%	41%	31%
2024	31%	43%	26%
2025	33%	45%	22%
2026	29%	45%	26%

[1] The intermediate MOOP type was not established until contract year 2023.

Second, MA organizations may be increasing cost sharing costs for non-emergency benefits, such as ground ambulance services, to: (1) make up for any potential financial loss due to the current cost sharing limit for emergency services and (2) maintain actuarial equivalence with Original Medicare overall per § 422.100(j)(2). While CMS analyzed average MA plan cost sharing for other service categories, MA plans may be particularly incentivized to raise cost sharing for ground ambulance services because: (1) there is significant flexibility in the current 50 percent coinsurance limit (for which CMS has not set an actuarially equivalent copayment limit) and (2) contract year 2026 MA plans established cost sharing amounts for ground ambulance services that are significantly in excess of cost sharing for that service in Original Medicare. In comparison, as shown in Tables III.D-9 and III.D-10, for other service categories (including air ambulance services), CMS is not finding potentially excessive cost sharing. As shown in Table III.D-10, for most of the other service categories subject to a 50 percent coinsurance limit (without an actuarially equivalent copayment limit set by CMS) on average MA plans have coinsurances around 20 percent, the cost sharing standard under Original Medicare. For example, CMS found MA plans are establishing cost sharing for air ambulance services on average at 20 percent while their cost sharing amounts for ground ambulance services (on average, $275) significantly exceeds cost sharing in original Medicare for those services (20% or $120 based on contract year 2027 projections). However, due to a lack of data, CMS cannot determine the level to which MA plans' average copayments in Table III.D-10 are aligned with Original Medicare for these categories.

TABLE III.D-9: CONTRACT YEAR 2026 MA PLAN WEIGHTED AVERAGE[1] COST SHARING COMPARED TO CMS SET CONTRACT YEAR 2026 COST SHARING LIMITS BY SERVICE CATEGORY

Service Category	Weighted Average Contract Year 2026 MA Plan Cost Sharing	Contract Year 2026 Cost Sharing Limits (Range Based on Limits for Mandatory – Lower MOOP)
IP Acute – 60 days	$1,793	$4,200 to $6,171
IP Acute – 10 days	$1,790	$2,721 to $3,401
IP Acute – 6 days	$1,698	$2,445 to $3,056
IP Acute – 3 days	$946	$2,230 to $2,787
IP Psych – 60 days	$1,609	$3,380 to $4,200
IP Psych – 15 days	$1,609	$2,255 to $2,819
IP Psych – 8 days	$1,603	$2,080 to $2,600
SNF – First 20 days	$2	$0 to $20/day
SNF – Days 21 – 100	$197	$218/day
Cardiac rehabilitation	$12	$30 to $50
Intensive cardiac rehabilitation	$13	$40 to $65
Pulmonary rehabilitation	$12	$25 to $40
SET for PAD	$12	$20 to $30
Emergency services	$130	$115 to $150
Urgently needed services	$39	$40 to $65
Partial hospitalization	$51	$105 to $175
Intensive outpatient services	$57	$110 to $180
Primary care physician	$1	$40 to $70
Chiropractic care	$14	$15 to $20
Occupational therapy	$27	$35 to $60
Physician specialist	$32	$55 to $95
Mental health specialty services	$24	$50 to $85
Psychiatric services	$25	$55 to $90
Physical therapy and speech-language pathology	$28	$55 to $95
Therapeutic Radiological Services	$74	$85
DME – Diabetic Shoes or Inserts	$8	$10 to $30
Dialysis Services[2]	20%	$70 or 20%
Part B Drugs – Insulin	$16	$35
Part B Drugs – Chemo/Radiation[2]	20%	$395 or 20%
Part B Drugs – Other[2]	20%	$340 or 20%

[1] Weighted average MA plan cost sharing (including no cost sharing) is based on the plan's maximum cost sharing for that service category and considers both plan coinsurance and copayment amounts.
[2]Approximately 98 to 99 percent of MA plans use coinsurance for these categories so CMS reports weighted average coinsurance instead of weighted average copayment.

TABLE III.D-10: CONTRACT YEAR 2026 MA PLAN AVERAGE[1] COST SHARING FOR SERVICE CATEGORIES SUBJECT TO THE 50 PERCENT COINSURANCE LIMIT (WITHOUT A COPAYMENT LIMIT SET BY CMS)

Service Category	Weighted Average Contract Year 2026 MA Plan Cost Sharing (Coinsurance/Copayment)
Podiatry	20% / $31
Other health care professional	29% / $32
Opioid treatment program services	19% / $20
Outpatient Diagnostic Procedures/Tests	19% / $62
Outpatient Lab Services	20% / $17
Diagnostic Radiological Services	19% / $263
Outpatient X-ray Services	19% / $50
Outpatient Hospital Services	22% / $326
Outpatient Hospital Services – Observation Services	23% / $315
Ambulatory Surgical Center (ASC) Services	20% / $262
Outpatient Substance Abuse Services	20% / $28
Outpatient Blood Services[2]	20%
Ground Ambulance Services[3]	$275

Service Category	Weighted Average Contract Year 2026 MA Plan Cost Sharing (Coinsurance/Copayment)
Air Ambulance Services	20% / $303
DME-Equipment[2]	20%
DME-Prosthetics[2]	20%
DME-Medical Supplies[2]	20%
DME – Diabetes Monitoring Supplies[2]	21%
Kidney Disease Education Services[2]	20%
Glaucoma Screening[2]	20%
Diabetes Self-Management Training[2]	20%
Digital Rectal Exams[2]	20%
EKG following Welcome Visit[2]	20%
Medicare Dental Services	20% / $35
Eye Exams	21% / $19
Eyewear[2]	20%
Hearing Exams	21% / $21

[1] Weighted average MA plan cost sharing (including no cost sharing) is based on the plan's maximum cost sharing for that service category and considers both plan coinsurance and copayment amounts.
[2]Approximately 98 to 99 percent of MA plans use coinsurance for these categories so CMS reports only weighted average coinsurance instead of weighted average copayment.
[3] Based on contract year 2026 MA plan data, 93.5 percent of MA plans use copayment for ground ambulance services, so CMS reports only weighted average copayment instead of weighted average coinsurance.

Without an actuarially equivalent copayment limit set by CMS, MA organizations have been allowed to establish copayments for ground ambulance services up to an actuarially equivalent value to 50 percent coinsurance based on their total financial liability for the benefit. This flexibility has allowed MA organizations to establish ground ambulance cost sharing amounts in significant excess of cost sharing in Original Medicare for this benefit ($120 based on contract year 2027 Medicare FFS data projections). For example, based on CY 2026 MA plan data, ground ambulance copayments ranged widely (from $0 to $560) with the highest copayment ($560) being $440 more than cost sharing in Original Medicare for the same benefit. In addition, as shown in Table III.D-4, MA plans are on average charging $155 more for ground ambulance services than Original Medicare ($275 minus $120). In comparison, as previously discussed and based on the information in Table III.D-3, contract year 2026 MA plans have on average cost sharing for emergency services that is $110 to $87 less than comparable industry figures.

With cost sharing for ground ambulance services being significantly higher for enrollees in MA plans, CMS is concerned that ground ambulance providers may face a significantly greater risk of uncollectable bad debt when providing ambulance services to MA enrollees over

beneficiaries in Original Medicare. This is because in general, as cost sharing amounts increase, the chance of the beneficiary being unable to afford the cost sharing typically also increases.[39] In summary, based on Table III.D-4, CMS is concerned that MA enrollees being charged on average $155 more for ground ambulance services compared to beneficiaries in Original Medicare (the difference between $275 and $120) may be resulting in additional uncollectable bad debt for ground ambulance providers.

CMS notes that this concern over uncollectable bad debt for MA ground ambulance providers has been echoed by those in the industry. For example, CMS has received feedback suggesting that the CMS-established emergency services cost sharing limits are artificially low and MA plans are raising cost sharing for ground ambulance services to make themselves whole on the emergency services cost sharing loss. For example, an industry association and members of Congress have shared concerns that a substantial portion of MA enrollees are unable to afford the current level of cost sharing for ground ambulance services, leaving ambulance providers with unpaid cost sharing amounts, and have requested that CMS take action to reduce ground ambulance cost sharing in MA.

These concerns over potentially excessive ground ambulance services are especially pertinent for CMS to consider given Section 1852(b)(1) of the Act. Specifically, MA plan practices, including benefit design, that are likely to substantially discourage enrollment by certain MA-eligible individuals are prohibited by Section 1852(b)(1). As discussed, CMS is concerned that because MA enrollees are being charged on average $155 more for ground ambulance services compared to beneficiaries in original Medicare, the increased cost sharing responsibility for this service is significant enough to potentially steer beneficiaries with health-status concerns that may require ground ambulance services from enrolling in MA plans with that level of cost sharing.

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[39] With an exception for dual-eligible MA enrollees, as their cost sharing is typically paid for by the State Medicaid program.

2. Proposed Ground Ambulance and Emergency Services Cost Sharing Standards

CMS considered several alternatives when developing this proposal. Those alternatives are discussed in detail in section X.D.1. of this proposed rule. In brief, CMS considered options that would:

- Address potential financial incentives MA organizations may have under the current cost sharing standards to raise cost sharing for benefit categories that are not emergency services, such as ground ambulance services, to make up for the current cost sharing limit for emergency services.
- Address concerns raised by interested parties, including ground ambulance providers, regarding excessive MA cost sharing for ground ambulance services.
- Maintain or improve upon the existing cost sharing incentives for MA organizations to adopt lower MOOP amounts.[40]
- Use the most recent Medicare FFS data projections to set copayment and dollar limits for ground ambulance and emergency services that align with industry trends for that benefit.

After considering the options described in section X.D.1. of this proposed rule, CMS decided to propose the changes identified under "alternative three" in section X.D.1.c.(3) of this proposed rule, as reflected by the following proposed amendments:

- Amend § 422.113(b)(2)(v) to allow CMS to annually set dollar limits for emergency services that are actuarially equivalent to the following based on MOOP type and the most recent Medicare FFS data projections:

++ Mandatory MOOP: 15 percent

++ Intermediate MOOP: Numeric midpoint between the dollar limits for the lower and mandatory MOOP types.

++ Lower MOOP: 20 percent

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[40] As discussed in section X.D.1. of this proposed rule, based on contract year 2026 and prior year plan data, the existing emergency services dollar limits may have incentivized some MA organizations to switch their plans from mandatory to a lower or intermediate MOOP type.

- Amend §§ 422.100(f)(6)(ii) and 422.113(b)(2)(v) to apply the $5 rounding rule and actuarial requirements from § 422.100(f)(6)(ii) and (f)(7) on the proposed methodology to set emergency services dollar limits to maintain consistency with the approach for setting copayment limits for other service categories (including professional services).

- Amend § 422.113(b)(2)(v) to remove the "lower of" clause (which requires MA plans to establish emergency services cost sharing amounts that are the lower of: (A) CMS dollar limits or (B) the cost sharing established by the MA plan if the emergency services were provided by the organization) – to simplify the standard.

- Amend § 422.113(a) to apply the range of cost sharing limits from § 422.100(f)(6)(iii) on ground ambulance services.

If finalized, these regulatory changes would apply beginning with contract year 2028.

As discussed in section X.D.1. of this proposed rule, CMS is currently approaching the calculation of actuarial equivalent dollar limits to the proposed standard for ground ambulance and emergency services by using the most recent weighted average Medicare FFS allowed amount (versus the median). For example, the OACT determined that the mean (weighted average) rather than the median of the distribution of the cost of ground ambulance trips was more appropriate to use for purposes of setting an actuarially equivalent copayment limit because the cost per trip is close to a bell-shaped curve (normal distribution). As a result, CMS used the most recent (contract year 2027 projections at the time of issuing this proposed rule) weighted average Medicare FFS allowed amount for each category to calculate illustrative cost sharing limits. These illustrative cost sharing limits (in Tables III.D-1 and III.D-2) can be used to clarify the potential impact of this proposal. For example, as shown in Table III.D-1, this proposal is expected to result in an approximate $90 increase to the emergency services dollar limit for the lower MOOP type (from $150 to $240). As discussed previously in this section, contract year 2026 MA plans have on average cost sharing for emergency services that is $110 to $87 less than comparable industry figures. As a result, this proposal could adequately address the potential

financial shortfall MA organizations may experience in emergency services cost sharing. While CMS expects the actual impact to the dollar limits would be different based on using updated Medicare FFS data projections (contract year 2028 projections when available), the illustrative dollar limits shown in Tables III.D-1 and III.D-2 are sufficient for purposes of estimating impact.

If this proposal is finalized, CMS would update the actuarially equivalent copayment and dollar limits for ground ambulance and emergency services annually through the subregulatory guidance process codified at § 422.100(f)(7)(iii). CMS may solicit comment through this subregulatory guidance process if CMS is considering, for example, a change to the actuarial approach taken to set these copayment and dollar limits (such as using the median or weighted average Medicare FFS allowed amount to calculate the dollar limit) for a future contract year, consistent with the discretion described in § 422.100(f)(7)(i)(A). Alternatively, CMS may choose not to set an actuarially equivalent copayment or dollar limit for ground ambulance and emergency services for a future contract year. In this case, MA organizations would be required to establish copayment or dollar cost sharing amounts that do not exceed the proposed limits, which may be based on the plan's total financial liability for the benefit. For example, if CMS does not set an actuarially equivalent copayment for ground ambulance services in a future contract year, then a plan with a mandatory MOOP type would be allowed to establish a dollar cost sharing amount for these services that is equal to or less than an actuarially equivalent value to the proposed 30 percent coinsurance standard for that MOOP type (under the range of cost sharing limits), based on the plan's total financial liability for the benefit.

CMS takes this opportunity to reiterate that the cost sharing limits under § 422.100(f)(6) apply in addition to any other limits and rules applicable to MA cost sharing, including a plan's MOOP limit, and therefore apply separately. CMS proposes to add language to § 422.100(f)(6) to further emphasize this existing requirement. Therefore, under this example, in the absence of a CMS-set copayment or dollar limit, the plan must establish cost sharing for ground ambulance services that does not exceed 30 percent coinsurance on a pre-MOOP actuarially equivalent

basis. CMS emphasizes that a plan's cost sharing amounts must meet the regulatory standard prior to consideration and application of the plan's MOOP amount because the cost sharing limits in § 422.100(f)(6) are in addition to any other cost sharing limits and rules, including a plan's MOOP amount.

CMS also considered whether to apply this proposal to Section 1876 Cost Plans (Cost Plans). As shown in Table III.D-11, based on contract year 2026 plan data, Cost Plans have lower cost sharing on average for emergency and ground ambulance services compared to MA plans. For example, the weighted average contract year 2026 Cost Plan cost sharing amount for emergency services is approximately $92, which is $38 less than the weighted average cost sharing amount for that service in MA plans ($130) and $88 less than the lowest proposed emergency services standard for the mandatory MOOP type ($180, which is actuarially equivalent to 15 percent of Medicare FFS costs, based on contract year 2027 Medicare FFS data projections). In comparison, the weighted average Cost Plan cost sharing for ground ambulance is approximately $200, which is $75 less than weighted average cost sharing amount for that service in MA plans ($275); but $20 more than the lowest proposed ground ambulance standard for the mandatory MOOP type ($180, which is actuarially equivalent to 30 percent of Medicare FFS costs, based on contract year 2027 Medicare FFS data projections). Based on this data, Cost Plans are maintaining reasonable cost sharing amounts for emergency and ground ambulance services. As a result, CMS is not proposing to change Cost Plan cost sharing standards for these services.

TABLE III.D-11: CY 2026 WEIGHTED AVERAGE SECTION 1876 COST PLAN COST SHARING AMOUNTS FOR GROUND AMBULANCE AND EMERGENCY SERVICES

Service Category	Weighted Average Cost Plan Cost Sharing (Copayment/Coinsurance)	Minimum Cost Plan Copayment	Maximum Cost Plan Copayment
Emergency Services	$92.37 / 0%	$50	$140
Ground Ambulance	$200.55 / 20%	$50	$350

3. Statutory and Regulatory Limitations on Benefit Design Changes

Plan benefit design changes may be made in response to multiple factors, including new cost sharing requirements. If this proposal is finalized, MA organizations will have the flexibility to offset any potential cost changes related to providing ground ambulance services (if they were not already establishing cost sharing amounts equivalent to or below the illustrative amounts from Table III.D-2). For example, MA organizations may choose to increase their emergency services cost sharing amount up to the illustrative amounts from Table III.D-1. In addition to or in lieu of making changes to cost sharing for emergency services, MA organizations that have to reduce their ground ambulance cost sharing amounts may make other changes to their benefit designs to meet the overall actuarial equivalence requirement from § 422.100(j)(2). For example, MA organizations may change MOOP amounts or cost sharing for other services.

MA organizations may make changes to their plan benefit design that comply with existing statutory and regulatory requirements. This includes sections 1852(a)(1)(B)(i), 1852(b)(1), and 1854(a)(5) and (6) of the Act. Section 1852(a)(1)(B)(i) of the Act provides that the MA organization must cover, subject to limited exclusions, the benefits under Parts A and B (that is, basic benefits as defined in § 422.100(c)(1)) with cost sharing that does not exceed or is at least actuarially equivalent to cost sharing in Original Medicare in the aggregate; this is repeated in a bid requirement under section 1854(e)(4) of the Act. CMS has addressed and implemented this requirement in several regulations, including §§ 422.100(j)(2), 422.101(e), 422.102(a)(4), and 422.254(b)(4).

Section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. Section 1854(a)(5) and (6) of the Act provide that CMS is not obligated to accept every bid submitted and may negotiate with MA organizations regarding the bid, including benefits. Under section 1854(a)(5)(C)(ii) of the Act, CMS is also authorized to deny a plan bid if the bid proposes too significant an increase in enrollee costs or

decrease in benefits from one plan year to the next. This proposal would not limit CMS' negotiation authority under section 1854 of the Act and § 422.256 but would provide cost sharing standards for an acceptable benefit design for CMS to apply in reviewing and evaluating bids.

MA organizations must also comply with applicable Federal civil rights laws that prohibit discrimination. None of the proposals in this proposed rule limit application of applicable anti-discrimination requirements. These existing statutory antidiscrimination requirements, regulatory actuarial equivalence requirements, the competitive nature of the MA program, and the additional proposed flexibility for emergency services cost sharing are sufficient guardrails to prevent MA organizations from making discriminatory changes to their benefit designs in response, if this proposal is finalized. However, as discussed in the following section, CMS solicits comment on whether implementing this proposal beginning in contract year 2028, if finalized, sufficiently protects enrollees from potentially disruptive changes in cost sharing and benefits from one year to the next.

4. Comment Solicitations

As shown in Tables III.D-7 and X.9., if the proposed ground ambulance services cost sharing standard is finalized, CMS expects (based on contract year 2026 MA plan bid data and contract year 2027 Medicare FFS data projections) that approximately 65 percent of MA plans will decrease their ground ambulance cost sharing amounts by $75 on average. As a result, given the actuarial equivalence requirement at § 422.100(j)(2), CMS also expects those MA plans would increase cost sharing amounts for other service categories or make other adjustments to their benefit design that, at a minimum, result in actuarial equivalence. In other words, on average, CMS expects 65 percent of MA plans will make the following changes to their benefits from contract year 2027 to 2028:

- Decrease the enrollee's liability for ground ambulance services by $75 on average.

- Increase the enrollee's liability in other ways that would result in an actuarial change of $75 on average.

As discussed previously in section III.D. of this proposed rule, from another perspective (the ability of this proposal to increase or decrease the average combined MA plan ground ambulance and emergency services cost sharing amount), CMS expects different impacts based on MA plan MOOP type. Specifically, CMS expects this proposal will allow for increases up to $155 (for MA plans with a lower MOOP) and $34 (for MA plans with an intermediate MOOP) and require a decrease of about $56 (for MA plans with a mandatory MOOP type) to average MA plan combined ground ambulance and emergency services cost sharing (based on contract year 2026 MA plan data). CMS expects these potential changes to average combined MA plan ground ambulance and emergency services cost sharing amounts would also be accompanied by offsetting adjustments elsewhere in the bid to maintain actuarial equivalence per § 422.100(j)(2). As a result, CMS expects a neutral total financial impact on MA enrollees from this proposal (as discussed in section X.C.1 of this proposed rule, on a per member per month basis).

We are proposing to apply these new cost sharing standards for ground ambulance and emergency services beginning with contract year 2028. However, CMS acknowledges that this proposal could impact some plans and enrollees more significantly. For example, the maximum ground ambulance cost sharing of contract year 2026 MA plans is $560. Based on the illustrative cost sharing limits for ground ambulance services (as shown in Table III.D-2, $180 to $300 based on MOOP type) this would mean a minimum $260 decrease to that plan's ground ambulance cost sharing amount (based on the assumption of a lower MOOP type to receive the most ground ambulance cost sharing flexibility). In addition, enrollee impact is expected to be neutral on a per member per month basis. This means that for some enrollees, the impact may be greater. Specifically, based on an enrollee's utilization of services, individual enrollees may have increased or decreased cost liability (comparing year over year) if this proposal is finalized.

Given the potential for this proposal to impact some plans and enrollees more significantly (than the neutral assessment as discussed in section X.C.1 of this proposed rule), CMS solicits comment on whether CMS should:

- Pursue one of the alternatives discussed in section X.D.1 of this proposed rule instead of the proposed approach for ground ambulance and emergency services.
- Apply a transition period from the existing contract year 2027 ground ambulance or emergency services cost sharing limits to the finalized cost sharing standard and if so, how long the transition should be.

5. Proposed Regulation Changes

Thus, CMS proposes the following changes to §§ 422.100 and 422.113:

- Modify § 422.100(f)(6) to emphasize the existing requirement that the cost sharing limits in §§ 422.100(f)(6), 422.100(j), and 422.113(b)(2) apply in addition to any other limits and rules applicable to MA cost sharing.
- Add references to § 422.113(b)(2)(v) at § 422.100(f)(6)(ii) and (f)(6)(ii)(A) to reflect the applicability of the $5 copayment rounding rules on emergency services.
- Apply the proposed range of cost sharing limits for ground ambulance services, beginning with contract year 2028, at § 422.113(a) with a cross reference to § 422.100(f)(6)(iii)(F).
- Modify § 422.113(b)(2)(v) to apply the proposed emergency services cost sharing standard, between 15 percent to 20 percent of the most recent Medicare FFS data projections without a “lower of” clause, beginning with contract year 2028.
- Modify § 422.113(b)(2)(v)(A) to specify the emergency services cost sharing limit that applies to MA plans with a mandatory MOOP type.
- Modify § 422.113(b)(2)(v)(B) to specify the emergency services cost sharing limit that applies to MA plans with an intermediate MOOP type.

- Add new § 422.113(b)(2)(v)(C) to specify the emergency services cost sharing limit that applies to MA plans with a lower MOOP type.

- Remove § 422.113(b)(2)(v)(B)*(1)* through *(4)* to remove references to the previous emergency services cost sharing limits that applied in contract year 2023 through 2026 and to remove the $150 to $115 dollar limits applicable to emergency services for contract year 2028 and subsequent contract years.

- Move existing § 422.113(b)(2)(vi) language regarding the cost sharing limit for urgently needed services to new paragraph (vii)[41].

- Revise § 422.113(b)(2)(vi) to clarify the applicable emergency services cost sharing dollar limit that would apply (based on the estimated total MA plan financial liability) if CMS does not set an actuarially equivalent dollar limit (based on the most recent Medicare FFS data projections).

- Add § 422.113(b)(2)(viii) to clarify and apply the rounding rules from § 422.100(f)(6)(ii) and requirements (such as application of generally accepted actuarial principles and practices) from § 422.100(f)(7) to ground ambulance services, emergency services, and urgently needed services.

[41] New paragraph § 422.113(b)(2)(vii) retains a January 1, 2023, effective date as CMS is not proposing changes to the cost sharing standard for urgently needed services.

E. Enrollee Notification Requirements for Provider Terminations, Continuity of Care, and SEP Notice Consolidation §§ 422.62, 422.111, 422.112, and 422.2267

1. Summary of Proposals

CMS is proposing several changes to regulations regarding provider network terminations. First, CMS is proposing to revise the enrollee notification and continuity of care requirements applicable to MA organizations under §§ 422.111(e), 422.112(b), and 422.2267(e)(12). These changes would revise the timing and content of required enrollee notices for provider terminations and establish new minimum continuity of care standards to protect enrollees during provider network transitions. CMS is also proposing to modify §§ 422.2267(e)(12)(ii)(D) and 422.62(b)(23)(iii) to require MA organizations to include special election period (SEP) eligibility information in the provider termination notice when CMS has determined that the affected enrollee is eligible for the SEP described at § 422.62(b)(23).

Finally, CMS is proposing to codify longstanding criteria used to identify whether a provider termination constitutes a significant change in a plan provider network at § 422.112(d), thereby triggering eligibility for the SEP at § 422.62(b)(23), and to align the SEP lookback period at § 422.62(b)(23)(ii) with the lookback period used for the provider termination notice.

2. Introduction

MA organizations have considerable discretion to select the providers with whom they contract in order to build high-performing, cost-effective provider networks. They may make changes to those networks at any time during the contract year, provided they continue to furnish all Medicare-covered services in a nondiscriminatory manner, meet established access and availability standards and timely notice requirements, and ensure continuity of care for enrollees. This flexibility is supported by section 1854(a)(6)(B)(iii) of the Social Security Act (the Act), which prohibits CMS from requiring MA organizations to contract with a particular provider.

MA organizations must provide enrollees notice when a network provider's contract terminates. CMS established these enrollee notification requirements at § 422.111(e) in the

"Medicare Program; Medicare+Choice Program" final rule, which appeared in the Federal Register on June 29, 2000 (65 FR 40170). More recently, in the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule (88 FR 22120), hereinafter referred to as the "April 2023 final rule", CMS established specific enrollee notification requirements for without-cause and for-cause provider contract terminations and added specific and more stringent enrollee notification requirements when primary care and behavioral health provider contract terminations occur. CMS also revised § 422.2267(e)(12) to specify the required content of the provider termination notice.

Under current regulations at § 422.111(e), CMS codified distinct time periods, by provider type, as part of the enrollee notification requirements regarding changes to provider networks. MA organizations are required to provide enrollees with advance notice (30 to 45 days depending on the provider type) when a provider is terminated from the MA plan's network. This advance notice is intended to allow enrollees sufficient time to identify a new in-network provider or, where applicable, exercise a SEP to change MA plans.

However, CMS has observed that provider contract negotiations frequently continue after advance notices are issued, and that in many cases terminations do not ultimately occur. As a result, enrollees may make unnecessary changes to their care arrangements (including switching providers or disenrolling from their current plan). Additionally, current regulations do not include standardized continuity of care requirements following an actual provider termination, leaving a potential gap in enrollee protections during the transition period.

The requirement for written notification to enrollees regarding their eligibility for the SEP for Significant Change in Provider Network (§ 422.62(b)(23)(iii)) is currently separate and distinct from the requirement that MA plans provide enrollees advance notice of routine provider terminations (§§ 422.111(e) and 422.2267(e)(12)). MA organizations must comply with different

notice standards, timing requirements, and recipient populations. As a result, MA plans may be required to send multiple notices regarding related provider network changes and, in some cases, more than one notice to the same enrollee.

To address the gaps identified above, CMS is proposing changes to §§ 422.111(e), 422.112(b), 422.2267(e)(12), and 422.62(b)(23)(iii) that will reduce operational complexity and compliance risk for MA organizations and streamline communications for enrollees.

Under § 422.62(b)(23), individuals affected by a significant change in a plan provider network are eligible for a SEP that permits disenrollment from the MA plan that has changed its network. CMS has not codified the criteria it uses to identify a significant change in a plan provider network for purposes of triggering this SEP. This has resulted in inconsistent plan reporting, potentially uneven application of enrollee protections, and a lack of transparency regarding when affected enrollees are eligible for a SEP. Therefore, CMS is proposing to codify the process, including establishing notification requirements, evaluation criteria, and applicable timeframes.

Finally, CMS is proposing to revise the application of "affected enrollee" at § 422.62(b)(23)(ii) to align it with the enrollee population already identified in the provider termination notice requirements at § 422.111(e). This would more effectively target the enrollee population with an active and meaningful relationship with their provider and support the consolidation of the provider termination notice and the SEP eligibility notice into a single communication to affected enrollees.

3. Proposed Regulatory Changes

a. Identification of Affected Enrollee: Provider Termination Notification (§ 422.111(e))

Prior to the April 2023 final rule, CMS addressed the meaning of "affected enrollee" through subregulatory guidance in Section 110.1.2.3 of Chapter 4 of the Medicare Managed Care Manual, which identified affected enrollees as those "assigned to, currently receiving care from,

or have received care within the past three months from a provider or facility being terminated." That three-month lookback standard applied uniformly across all provider types.

In the April 2023 final rule, CMS codified the enrollee notification requirements at § 422.111(e) and established distinct lookback periods to identify affected enrollees based on the provider type. For primary care and behavioral health provider terminations, CMS codified a 3-year lookback period at § 422.111(e)(1)(iii). For all other specialty types, CMS retained the 3-month lookback standard at § 422.111(e)(2)(iii). Additionally, the April 2023 final rule included in § 422.111(e)(1)(iii) a separate category of enrollees "currently assigned" to the terminating primary care provider, which was designed primarily for HMO-model MA plans in which enrollees are required to designate a primary care provider as a condition of enrollment.

To identify affected enrollees, CMS is proposing to replace the existing provider-type-specific lookback framework with a uniform 12-month lookback for all provider types. The three-month lookback for specialty provider terminations does not reliably capture enrollees with a meaningful care relationship with the terminating provider. Enrollees may see specialists on a routine annual or semiannual basis, and under the current standard, those enrollees are not recognized as affected enrollees for purposes of receiving a provider termination notice. A uniform 12-month lookback captures enrollees with a meaningful, active care relationship with a terminating provider of any type (including specialists seen on a semiannual or annual basis who are missed by a 3-month window), while avoiding the overly broad 3-year lookback period, which could extend to enrollees who do not have an ongoing care relationship with a terminated provider. Moreover, the current framework requires MA organizations to run separate lookback queries and maintain two separate enrollee populations for a single provider contract termination. A uniform 12-month lookback period would allow the MA organization to identify all affected enrollees using a single standard applied to the same contract termination.

Therefore, CMS proposes to modify § 422.111 by removing the existing provider-type-specific lookback framework and adding a paragraph at § 422.111(e)(3) that establishes a

notification requirement for all enrollees who are currently receiving care, or have received care within the past 12 months, from a contracted provider being terminated. Under the proposed rule, MA organizations would identify affected enrollees through a single query, maintain one list, and issue one notice. A uniform standard also supports the consolidation of the provider termination notice and, where applicable, the significant provider termination SEP eligibility notice into a single communication directed to a single, consistently defined enrollee population.

CMS is also proposing to remove the "currently assigned" category described at § 422.111(e)(1)(iii). Primary care physician (PCP) assignment is a structural feature of plan design in HMO-model MA plans, in which enrollees are required to designate a PCP as a condition of enrollment. In PPO and other plan structures, formal PCP assignment is not a standard feature. As a result, whether an enrollee falls within the "currently assigned" category depends not on the nature of their care relationship with the provider but on the type of MA plan in which they are enrolled. CMS does not consider MA plan structure to be an appropriate basis for determining which enrollees are entitled to a provider termination notice. Furthermore, § 422.111(e)(1)(iii) does not define what it means to be "currently assigned" to a provider, or how MA organizations should identify which enrollees fall within this category. The absence of a regulatory definition has produced inconsistent application by MA organizations regarding who is actually eligible as an affected enrollee. The proposed 12-month lookback would replace this ambiguous category with a clear standard that applies consistently across all MA plan structures.

CMS believes that a uniform 12-month lookback would capture enrollees who have a meaningful, active care relationship with a terminating provider of any type, while excluding those whose relationship with the provider is too far back in time to warrant notification. It eliminates the need for separate lookback queries per provider type and supports the consolidation of the provider termination notice and, where applicable, the significant provider termination SEP eligibility notice into a single communication.

CMS solicits public comment on whether a uniform 12-month lookback period is the appropriate standard for identifying affected enrollees to receive the provider termination notice under § 422.111(e)(3). CMS is interested in whether this period appropriately captures enrollees with a meaningful, active care relationship with a terminating provider of any type, whether the lookback period should vary depending on the type of provider being terminated, or whether CMS should consider an alternate timeframe, such as a 6-month lookback. CMS also invites comment on whether removing the "currently assigned" category would exclude enrollees with an active care relationship with a terminating primary care provider, and whether any additional protection is warranted for enrollees who are formally assigned to a provider but have not had a clinical encounter within the past twelve months.

b. Timing for Enrollee Notification Requirements for Provider Terminations and Continuity of Care (§§ 422.111(e) and 422.112(b))

CMS proposes to require MA organizations to send a notification to affected enrollees of a provider termination within 5 business days of the effective date of the termination, rather than in advance of the termination. This change is intended to ensure that enrollees receive accurate and final information before taking action (such as changing MA plans or switching providers), thereby reducing unnecessary disruptions to care arrangements caused by premature or speculative notices. Based on CMS's experience, provider negotiations frequently result in a contract agreement; however, a final agreement may not be reached until shortly before the effective termination date. Therefore, at § 422.111(e), CMS is proposing to revise paragraph (2) to indicate MA organizations must provide enrollees notice of a termination of a contracted provider within 5 business days of the termination effective date regardless of whether the termination was for cause or without cause. CMS is proposing to remove the good faith effort standard for for-cause terminations because MA organizations would be required to notify enrollees within five business days of the termination, rather than 30 or 45 days in advance of the termination. CMS expects this later timeline to be feasible for both types of terminations. This

proposed rule would shift the timing of required enrollee notifications of provider terminations and establish new minimum continuity of care standards to protect MA enrollees during provider network transitions that result from provider terminations.

Because CMS is proposing to revise the provider notification timing, CMS is also proposing a new continuity of care period designed to give affected enrollees sufficient time to transition to a new in-network provider without interruption to their coverage or an increase in their cost-sharing obligations. CMS expects that if an organization mails the notice within 5 business days of the termination date, it will arrive in a reasonable amount of time for enrollees to make any applicable changes or take action based on the contents of the notice.

These continuity of care requirements would be additional standards to implement the statutory requirement under section 1852(a) of the Act that MA organizations provide to their enrollees (by furnishing directly or through contracted providers, arranging for, or paying for) basic benefits (that is, all Part A and Part B benefits with limited exceptions) and such supplemental benefits the MA organization elects to offer. CMS has authority to adopt standards to carry out the applicable MA provisions in Title XVIII of the Act and to add new contract terms as necessary, appropriate, and not inconsistent with the statute in sections 1856(b) and 1857(e)(1) of the Act. Consistent with that authority, CMS is proposing to add to the current continuity of care regulations at § 422.112(b) by creating a new paragraph (9) to require that upon the termination of a contract between an MA organization and a provider or facility, the MA organization must continue to provide coverage for basic benefits, including items and services furnished by the terminated provider to affected enrollees at the applicable in-network cost-sharing rate for a minimum coverage period of 90 days beginning on the termination effective date. The MA organization would be required to pay the provider pursuant to the requirements at § 422.214 for out-of-network providers. CMS would consider enrollees to have been affected by the provider termination if, per § 422.111(e)(3), the enrollees are currently receiving care from, or have received care within the past 12 months from, the terminated

provider. This will ensure operational consistency between the notice and continuity of care requirements and will allow time for enrollees to transition to a new, in-network provider without disruption to coverage or an increase in cost-sharing. This continuity of care requirement does not extend to payments to providers that have been terminated for cause, including where the provider is excluded by the OIG or included on the preclusion list as described at §§ 422.222 and 422.224.

CMS requests comment on whether the proposed shift to notification within 5 business days of the termination, regardless of whether the termination was for cause or without cause, is appropriate, and whether MA organizations have operational constraints that would affect their ability to issue the provider termination notice within 5 business days of the effective date of the termination. CMS invites comments on whether the proposed 90-day continuity of care period is appropriate, or alternative timelines should be adopted, and whether MA organizations have operational constraints that would affect their ability to implement the proposed continuity of care requirements at § 422.112(b)(9) for the enrollee population defined at § 422.111(e)(3).

c. Technical Cross-Reference Corrections (§§ 422.111(e) and 422.2267(e)(12))

CMS is also making several additional technical changes to the provider termination notice requirements. CMS is proposing to add an exception to § 422.2267(e)(12)(ii)(C) for situations when an individual provider has died. Current CMS regulations require MA organizations to explain how an enrollee can request continuation of care with their current provider, but that instruction does not make sense when the provider is deceased. In those cases, CMS is proposing that the provider termination notice content communicate to the enrollee how to identify a new in-network provider, how to transfer their records, and how any applicable continuity of care protections would work if the termination were due to the death of the provider.

CMS is also proposing to remove the telephonic notice requirement at § 422.111(e)(1)(i) in its entirety, retaining only the requirement to provide written notice. Currently,

§ 422.111(e)(1)(i) requires MA organizations to provide written notice and make one attempt at telephonic notice to affected enrollees who have not opted out of calls regarding plan business as described in § 422.2264(b). CMS is proposing to remove both the telephonic notice requirement and the cross-reference to § 422.2264(b). With respect to the telephonic notice requirement, CMS received feedback indicating that the requirement added operational burden and enrollee confusion without a meaningful benefit.

Finally, CMS is proposing to update the content requirements at § 422.2267(e)(12)(ii) so that the provider termination notice reflects the effective date of the termination as proposed above. The provider termination notice would continue to include the same information currently required. CMS believes that the current advance notice framework imposes unnecessary operational burden on MA organizations by requiring the issuance of enrollee notifications while contract negotiations remain active, often resulting in notices that must be later retracted when a termination is averted. Aligning notification with the termination effective date eliminates this duplicative work and reduces administrative burden without compromising enrollee protections. Where continuity of care protections under § 422.112(b)(9) apply, MA organizations must include in the notice the minimum coverage period beginning on the termination effective date, that coverage is provided at the applicable in-network cost-sharing rate, and that coverage applies to basic benefits furnished by the terminated provider. As a conforming change, CMS is also proposing to remove § 422.2267(e)(12)(iii). That paragraph specifies that the telephonic notice required under § 422.111(e)(1)(i) must relay the same information as the written provider termination notice. Because CMS is proposing to remove the telephonic notice requirement from § 422.111(e)(1)(i), § 422.2267(e)(12)(iii) would no longer serve its original purpose and would be removed. CMS is also correcting an incorrect cross-reference in § 422.2267(e)(12)(ii)(D). That subparagraph currently directs enrollees to request consideration for a SEP "as specified in § 422.62(b)(26)," but that provision is being renumbered to § 422.62(b)(28) in this proposed rule. CMS is proposing to revise § 422.2267(e)(12)(ii)(D) to cite the correct regulation.

CMS solicits comment on all proposed technical changes to the provider termination notice requirements in this section.

d. SEP Eligibility Information in the Provider Termination Notice (§§ 422.2267(e)(12)(ii)(D) and 422.62(b)(23)(iii))

Currently, the written notice required to inform enrollees of their eligibility for the SEP based on a Significant Change in Provider Network (§ 422.62(b)(23)(iii)) operates separately from the advance notice MA organizations must provide for routine provider terminations (§§ 422.111(e) and 422.2267(e)(12)). Each notice obligation carries its own standards, timing, and intended recipients. Accordingly, MA organizations may need to issue more than one notice concerning related provider network changes, including multiple notices to the same enrollee where applicable.

To streamline these communications, CMS proposes to modify §§ 422.2267(e)(12)(ii)(D) and 422.62(b)(23)(iii) to require an MA organization to include information about SEP eligibility in the provider termination notice in cases where CMS has determined that the affected enrollee is eligible for the SEP described at § 422.62(b)(23), that is, if the termination has been determined by CMS to be a significant change in the MA plan's provider network under the new § 422.112(d) as proposed in section III.E.3.e of this proposed rule. Specifically, CMS is proposing to require under § 422.62(b)(23)(iii) that when CMS has determined that a provider termination is significant, MA organizations include information regarding an enrollee's eligibility for a SEP in the provider termination notice required under § 422.111(e), and how to use the SEP as described in § 422.2267(e)(12)(ii)(D).

Effectively, this means that for any provider termination, affected enrollees will only receive a single notification from the MA organization. If CMS determines that a provider termination is significant, that notification will inform the enrollees that they are eligible for a SEP. This change is intended to reduce operational burden and compliance risk for MA organizations while simplifying and clarifying communications for enrollees.

Not every enrollee who receives a provider termination notice is eligible for the significant provider termination SEP under § 422.62(b)(23). For cases in which the termination has been determined not significant in accordance with § 422.112(d), the MA organization would not include significant provider termination SEP content in the notice. Nonetheless, all enrollees may also request access to the exceptional circumstances SEP under § 422.62(b)(28), which provides a separate pathway for enrollees facing coverage disruptions. That SEP is not automatic; it depends on an individual's unique circumstances and is determined on a case-by-case basis and is available regardless of whether the provider termination qualifies as significant. The criteria and process for the significance determination are being proposed in this rule under § 422.112(d), as addressed in section III.E.3.e.(2) of this proposed rule.

CMS solicits comment on whether MA organizations have any operational constraints that would affect their ability to integrate the provider termination notice and the significant SEP notice into a single communication when applicable.

e. Significant Change in Plan Provider Network (§ 422.112(d) and § 422.62(b)(23)(ii))

(1) Background

When a mid-year provider termination constitutes a "significant" change in a plan's provider network, affected enrollees are eligible for a SEP that allows them to enroll in another MA plan or to disenroll to Original Medicare. CMS is authorized to establish SEPs under section 1851(e) of the Act, including section 1851(e)(4) of the Act, which authorizes the Secretary to establish SEPs for individuals who meet other exceptional conditions specified by the Secretary, and § 1852(b)(1) of the Act, which governs MA organization obligations regarding enrollment and disenrollment.

The SEP for Significant Change in Provider Network was established in CY 2015 in response to significant mid-year network disruptions affecting MA enrollees and was subsequently codified at § 422.62(b)(23) in the Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit

Program, and Medicare Cost Plan Program Final Rule (85 FR 33796). In that final rule, CMS specified that significant changes in provider networks are those that go beyond individual or limited provider terminations that occur during the routine course of plan operations, and that have the potential to substantially impact a large number of the MA plan's enrollees, such as terminated relationships with multispecialty group practices or hospital systems.

Under the current framework, when CMS determines that a change in an MA plan's provider network is significant, affected enrollees are eligible for the SEP and may use it to request enrollment in another MA plan or to disenroll to Original Medicare from the MA plan that has changed its network. As described at § 422.62(b)(23)(ii), enrollees are "affected" by a significant network change and eligible for this SEP when they are assigned to, are currently receiving care from, or have received care within the past three months from a provider or facility being terminated from the MA plan's provider network. The SEP begins the month the individual is notified of eligibility and extends an additional two calendar months thereafter under § 422.62(b)(23)(i).

CMS has provided subregulatory guidance on significant network changes in Chapter 4 of the Medicare Managed Care Manual. Under that guidance, MA organizations have been directed to notify CMS of any provider termination that the MA organization deems to be a significant provider termination at least 90 days prior to the effective date. After receiving such notification, CMS reviews to determine whether the change in provider network is significant. The timeframe for CMS determinations has varied depending on the circumstances of each case. If CMS determines that a provider termination represents a significant change in the MA plan's provider network, the CMS Account Manager for the MA organization notifies the MA organization of the determination and of the requirement to issue written notification to affected enrollees of their eligibility for the SEP for significant change in provider network, the start and end dates of the SEP, how to make use of the SEP, and Medigap guaranteed issue rights in accordance with section 1882(s)(3)(D) of the Act. CMS provides model language regarding the

SEP and Medigap guaranteed issue rights for the MA organization to use in its notice to affected enrollees.

As a separate requirement, MA organizations must notify affected enrollees of any changes in a provider network resulting from a termination (with or without cause) of a contract with a provider organization pursuant to §§ 422.111(e) and 422.2267(e)(12). Currently, the requirement for written notification to enrollees regarding their eligibility for the SEP for Significant Change in Provider Network (§ 422.62(b)(23)(iii)) is separate and distinct from the requirement that MA organizations provide enrollees advance notice of routine provider terminations (§§ 422.111(e) and 422.2267(e)(12)). As discussed in section III.E.3.d of this preamble section, CMS is proposing to consolidate these two notice requirements into a single communication to affected enrollees; the proposals in this section are designed to support and streamline that consolidation.

Despite the existence of this SEP framework, CMS has not previously codified in regulation the specific criteria it uses to evaluate whether a provider termination is significant. This approach has created a significant operational gap with material consequences for beneficiaries and program administration. MA organizations exercise discretion when deciding whether a change is significant and, accordingly, whether to notify CMS. Because CMS has not codified the criteria it uses to evaluate significance, MA organizations apply varying internal standards—some may not report a termination to CMS because they do not believe it meets the significance threshold, while others may apply different or inconsistent criteria. This inconsistency means that CMS may not be evaluating all terminations that meet its significance threshold, and that some enrollees who are eligible for a SEP are not appropriately notified of their eligibility and thus unable to use this protection.

Therefore, CMS proposes to codify the criteria used to identify a significant change in a MA plan provider network. This approach preserves the distinction between routine provider

terminations and those that are sufficiently disruptive to warrant SEP eligibility, while providing transparency, consistency, and accountability.

(2) Notification Thresholds and Timeline (§ 422.112(d))

CMS is proposing to establish notification thresholds for significant provider terminations at new § 422.112(d). The proposal would require an MA organization to notify CMS of a contracted provider termination that meets either of the following thresholds at least 60 days prior to the effective date of the termination for without-cause terminations and when practicable for for-cause terminations: (i) at least 10 percent of the MA plan's enrollees would be affected by the provider termination under § 422.62(b)(23)(ii); or (ii) the provider termination would constitute at least 10 percent of the MA plan's network for a given specialty type under §§ 422.116(b)(1) or (2). When a termination meets either threshold, it would be deemed "significant." Upon notification, CMS would inform the MA organization of the requirement to issue written notification to affected enrollees of their eligibility for a SEP, the start and end dates of the SEP, how to make use of the SEP, and Medigap guaranteed issue rights in accordance with § 1882(s)(3)(D) of the Act. CMS would provide model language for the MA organization to use when notifying affected enrollees of their SEP eligibility in accordance with § 422.62(b)(23)(iii) and § 422.2267(e)(12)(ii), as addressed in section III.E.3.d of this proposed rule.

The first threshold, enrollee impact, focuses on the direct effect of the termination on the MA plan's enrollee population. A termination that affects at least 10 percent of an MA plan's enrollees, in accordance with the definition of "affected enrollee" at § 422.62(b)(23)(ii), represents a disruption that merits CMS's awareness and the award of a SEP. This threshold is directly tied to the beneficiary protection rationale underlying the SEP: when a substantial portion of a plan's enrollees lose access to a provider with whom they have an established care relationship, those enrollees should have the opportunity to seek coverage from a plan that includes their provider.

The second threshold, specialty network, focuses on enrollee access limitations due to changes to the plan's provider network. A termination that eliminates 10 percent or more of a plan's contracted network for a given specialty type under § 422.116(b)(1) or (2) represents a material reduction in enrollee access to covered services in that specialty. This threshold fits within CMS's existing framework under § 422.116, under which CMS already evaluates networks by specialty category and provider counts. The specialty network threshold recognizes that substantial contraction in a specialty network may impair access to medically necessary services, especially for beneficiaries in smaller MA plans, for which the loss of a single provider or practice group can represent a disproportionate share of available contracted capacity. Applying the enrollee impact threshold alone may miss these types of terminations, for which the enrollee impact is significant due to diminished access to a given specialty.

CMS believes a 10 percent threshold represents a balanced approach that appropriately distinguishes material network changes from routine contracting activity, while providing greater transparency, consistency, and predictability for beneficiaries, MA organizations, and CMS oversight operations. CMS chose percentage-based thresholds, as opposed to fixed provider counts, because percentage-based thresholds account for variation in plan enrollment size, network size, geography, and specialty concentration. A fixed provider count that is appropriate for a large urban network may be wholly inadequate to capture a significant disruption in a rural specialty market. For example, the loss of nine providers may be insignificant in a large urban network with hundreds of contracted specialists but devastating in a rural specialty market where those nine providers represent the majority of available contracted capacity. A percentage-based threshold scales appropriately across these varying contexts.

The 10 percent threshold represents the point at which a network change transitions from routine contracting activity to a disruption of sufficient scale to merit CMS awareness and enrollee notification. A lower threshold would be overinclusive, capturing routine contracting fluctuations that do not rise to the level of a significant network change and imposing

unnecessary administrative burden on MA organizations and CMS. A higher threshold would be under-protective, permitting substantial network disruptions to proceed without CMS review or enrollee notification. A 10-percent threshold reasonably balances these competing concerns and is consistent with CMS's longstanding internal practice for evaluating significance.

CMS solicits comment on whether 10 percent is the appropriate threshold for the enrollee impact under proposed § 422.112(d)(1)(i). CMS is interested in whether a lower threshold would better protect beneficiaries in markets where even a smaller percentage of affected enrollees represents a significant disruption, or whether a higher threshold would more appropriately limit the significance determination to truly material network changes. CMS also invites comment on whether the threshold should vary based on plan size, market type, or other factors. Additionally, CMS solicits comment on whether 10 percent is the appropriate threshold for the specialty network under proposed § 422.112(d)(1)(ii). CMS is interested in whether this threshold appropriately captures network disruptions that impair access to covered services in a given specialty, and whether it should be calibrated differently for different specialty types, geographic markets, or plan types.

The proposed 60-day advance notification requirement for without-cause terminations aligns with the existing § 422.202(d)(4) provider notification timeframe, making it feasible for MA organizations and consistent with existing operational practice. Because the proposed rule codifies objective, quantitative thresholds, MA organizations will already have confirmed that they have met the threshold before notifying CMS, which will streamline CMS's internal review process. The 60-day window would be sufficient for CMS to review a significance determination and provide model language to the MA organization before the termination takes effect. This approach is expected to reduce burden on MA organizations relative to the current subregulatory guidance, which directs MA organizations to notify CMS 90 days in advance. CMS understands that for-cause terminations may occur without 60-days advanced notice, and therefore, MA plans

may not be able to notify CMS 60 days before the termination date. Accordingly, CMS proposes to codify that MA plans notify CMS when practicable for for-cause terminations.

CMS maintains the right to inquire about provider terminations that were not reported by an MA organization when external information (including congressional inquiries, beneficiary complaints, or other sources) suggests that a significant termination may have occurred. The proposed codification of significance determination criteria does not limit CMS's existing oversight authority; it supplements that authority by establishing clear, enforceable reporting obligations. Because the significance determination criteria would now be codified in regulation, MA organizations would be on notice of the circumstances under which they are required to report a provider termination to CMS. Failure to report a qualifying termination in accordance with proposed § 422.112(d) would be subject to compliance action. MA organizations have previously requested clarity regarding reporting thresholds; codification would provide both the clarity they have sought and the accountability that the program requires.

CMS solicits comment on whether the proposed 60-day advance notification requirement for MA organizations to notify CMS of without-cause significant provider terminations and when practicable for for-cause terminations under § 422.112(d) is appropriate, and whether MA organizations have operational constraints that would affect their ability to notify CMS within these timeframes.

(3) Identification of "Affected Enrollee" for the SEP (§ 422.62(b)(23)(ii))

Current § 422.62(b)(23)(ii) provides that an enrollee is affected by a significant network change when the enrollee is assigned to, currently receiving care from, or has received care within the past 3 months from a provider or facility being terminated from the provider network. CMS is proposing to replace this framework with a uniform 12-month lookback for all provider types and to remove the "assigned to" category, for the same reasons CMS is making those changes to the provider termination notice requirement at proposed § 422.111(e)(3): the 3-month lookback does not reliably capture enrollees with a meaningful care relationship with the

terminating provider for SEP purposes. A uniform 12-month lookback would capture enrollees with a meaningful, active care relationship with a terminating provider of any type, including specialists seen on a semiannual or annual basis who would be missed by a three-month window.

CMS believes this proposed change would provide particular benefit to beneficiaries in rural areas, beneficiaries with complex care needs, and beneficiaries who depend on continuity with a specific provider. In rural markets, provider networks are often smaller, and the loss of a single provider or practice group can represent a disproportionate share of available contracted capacity. A significant termination in a rural market may leave beneficiaries with few or no in-network alternatives, making timely SEP notification critical to protecting their access to medically necessary services. Similarly, beneficiaries with complex care needs who have established ongoing treatment relationships with a specialist are particularly vulnerable to disruptions caused by mid-year provider terminations, and the proposed framework is designed to ensure that those affected beneficiaries are identified and notified appropriately.

CMS is also proposing to remove the "assigned to" category from § 422.62(b)(23)(ii). As discussed in section III.E.3.a of this proposed rule, PCP assignment is a structural feature of HMO-model MA plans and does not apply consistently across PPO and other plan structures.

Under the current framework, the enrollee population identified as "affected" for SEP purposes under § 422.62(b)(23)(ii) differs from the enrollee population identified for provider termination notice purposes under § 422.111(e), even though both determinations are made by the MA organization using the same underlying data. This inconsistency requires MA organizations to identify and manage two separate enrollee populations for what is, in effect, a single network disruption event. A uniform standard would eliminate the need for MA organizations to run separate queries and maintain separate enrollee populations by provider type and would directly support the consolidation of the provider termination notice and the SEP eligibility notice into a single communication—a consolidation that is only operationally feasible when both notices are directed to the same enrollee population.

CMS solicits comment on the proposed uniform 12-month lookback period to determine whether an enrollee is affected by a significant network change at § 422.62(b)(23)(ii). CMS invites comment on whether this period appropriately captures enrollees with an established care relationship with the terminated provider, and whether alternative lookback periods would better serve the purposes of the SEP. Finally, CMS invites comment on any other aspects of the proposals described in this section, including the alignment of the affected enrollee definition with the enrollee populations identified in § 422.111(e)(3).

F. Network Adequacy Exception Request Rationales (§ 422.116)

In the Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly which appeared in the **Federal Register** on December 10, 2024 (89 FR 99340), hereinafter referred to as the December 2024 proposed rule, CMS proposed to codify its long-standing network adequacy exception request rationales, with one change. CMS proposed to eliminate the rationale that the "provider does not contract with any organization or contracts exclusively with another organization" (meaning MA organization) as a basis for an exception. In the proposed rule, CMS indicated that in removing this rationale, CMS's intent was to limit the reasons that an organization would be able to bypass the established network adequacy criteria for a given specialty/county and provide greater incentives for MA organizations to establish contracts with providers that are located within the established time and distance standards. Based on comments received through the comment process for the December 2024 proposed rule, CMS has decided to reconsider this proposal and is proposing to codify all existing exception request rationales, including the rationale: "provider does not contract with any organization or contracts exclusively with another organization."

Under CMS's authority to set standards to implement and carry out the MA statute (in section 1856(b)(1) of the Act), CMS codified network adequacy standards at § 422.116 under the final rule, Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program, which appeared in the **Federal Register** on June 2, 2020 (85 FR 33796), hereinafter referred to as the June 2020 final rule. CMS has also adopted specific access requirements in §§ 422.100(b), 422.112, 422.113, and 422.114 to ensure that MA enrollees in various types of MA plans have access to covered services.

In the June 2020 final rule, CMS codified regulations allowing MA organizations to submit exceptions to the network adequacy standards in § 422.116, including the circumstances under which an MA organization may request an exception (§ 422.116(f)(1)) and the factors that CMS considers when evaluating an MA organization's request for an exception (§ 422.116(f)(2)) as well as examples of how those factors are applied. An MA plan may request the exception permitted under § 422.116(f)(1)(i) if (A) certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type and (B) the MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

The Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance[42], and exception request template[43] indicates that organizations may request exceptions using the following valid rationales:

- Provider is no longer practicing (for example, deceased, retired).
- Provider does not provide services at the office/facility address listed in the supply file.
- Provider does not provide services in the specialty type listed in the supply file.
- Provider has opted out of Medicare.
- Provider does not contract with any organizations or contracts exclusively with another organization.
- Sanctioned provider on List of Excluded Individuals and Entities.
- Provider is at capacity and is not accepting new patients.
- Use of Original Medicare telehealth providers or mobile providers.
- Specific patterns of care in a community.

[42] https://www.cms.gov/files/document/medicare-advantage-and-section-1876-cost-plan-network-adequacy-guidance-12-09-2024.pdf
[43] https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202412-0938-004

CMS explained in the Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance that while the time and distance standards vary by county and specialty type, and are generally attainable across the country, there are unique instances where a given county's supply of providers/facilities is such that an MA organization would not be able to meet the network adequacy criteria. The exceptions process allows MA organizations to provide evidence to CMS when the health care market landscape has changed or is not reflected in the current CMS network adequacy criteria. The organization must include conclusive evidence in its exception request that the CMS network adequacy criteria cannot be met because of changes to the availability of providers/facilities, resulting in insufficient supply.

Per § 422.116(f)(1)(i), an MA plan may request an exception to network adequacy criteria when both of the following occur: (A) certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type; and (B) the MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

As part of CMS's evaluation of MA networks using § 422.116, MA organizations must first submit their Health Service Delivery (HSD) tables, containing all their network providers, to CMS. CMS processes and reviews the network submissions against its established regulatory standards through use of an automated system located in the Health Plan Management Systems (HPMS) network management module. This automated module within HPMS evaluates the networks based on CMS's current network time and distance standards. Once the evaluation is complete, CMS, through HPMS, provides MA organizations with an Automated Criteria Check (ACC) report. The ACC report contains CMS's determination of whether the standards in § 422.116 have been met or not met, and the report displays where the MA organization's specific county/specialty combinations, within the given service area, are passing and failing

those standards. MA organizations may decide to submit an exception request for those parts of their network submission that were found to be failing CMS's network time and distance standards by using the exception request template found in HPMS, in accordance with CMS procedural instructions.

After submission, CMS evaluates exception requests based on the criteria noted in § 422.116(f)(2), including whether the current access to providers and facilities is different from the HSD reference and Provider Supply files for the year (see § 422.116(a)(5)), whether the MA organization demonstrates that network access is consistent with or better than the original Medicare pattern of care, and whether approval of the exception is in the best interest of beneficiaries. The exception request is then either approved or denied. Once the CMS exception request review is complete, the results of CMS's determination are uploaded into HPMS with an approval or denial status for MA organizations to view. If an exception request is denied, CMS will provide feedback with the exception disposition, including, as applicable, a sampling of the providers that CMS lists in the Provider Supply File that are available for the MA organization to contract with that would allow the MA organization to meet the time and distance standards for the specific county/specialty type. MA organizations must resubmit all previously approved exception requests whenever CMS requests an organization to upload its HSD tables to review an MA organization's network(s).

CMS received mixed feedback regarding the proposal to codify exception request rationales with one change to remove the rationale, "provider does not contract with any organization or contracts exclusively with another organization" in the December 2024 proposed rule. With regard to the portion of the proposal related to removing the "provider does not contract" rationale, supporters noted that the change would improve both network adequacy reviews and oversight of MA organizations' networks, while other commenters indicated that eliminating the exception rationale would decrease flexibility for MA organizations and make it harder to assemble provider networks in rural areas or areas with limited providers. Commenters

on this portion of the proposal also noted that MA organizations cannot force contractual relationships with providers so having this rationale provides latitude in building networks and maintains enrollee choice. Finally, commenters argued that with the proposal to remove the rationale, CMS would be inappropriately inserting itself into contracting negotiations between MA plans and providers. Otherwise, commenters were largely supportive of the overall proposal for CMS to codify the long-standing network adequacy exception request rationales.

CMS agrees that codifying the exception request rationales will improve network adequacy reviews, making them more consistent and based on codified standards. Additionally, CMS agrees that MA organizations should retain flexibility in contracting, which the rationale "provider does not contract with any organization or contracts exclusively with another organization" gives in the network review process. Therefore, based on comments received on the initial proposal and to continue to strengthen CMS's network adequacy review process and rules related to exception requests, CMS is proposing to codify the following (including the rationale, "provider does not contract with any MA organization or contracts exclusively with another MA organization") as valid rationales when an MA plan submits substantial and credible evidence, in the form and manner requested by CMS, to demonstrate that an exception request meets the requirements under § 422.116(f)(1)(i):

- Provider is no longer practicing (for example, deceased, retired).
- Provider does not provide services at the office or facility address listed in the Provider Supply file in paragraph (a)(5)(ii) of this section.
- Provider does not provide services for the specialty type listed in the Provider Supply file in paragraph (a)(5)(ii) of this section.
- Provider has opted out of Medicare (in compliance with § 422.204(b)(4)).
- Provider does not contract with any MA organizations or contracts exclusively with another MA organization.

- Provider is a sanctioned provider on the List of Excluded Individuals and Entities (in compliance with § 422.204); or provider is on the CMS preclusion list (in compliance with § 422.222).
- Provider has the potential to cause beneficiary harm.
- Provider is at capacity and is not accepting new patients.

One, or more, of the listed rationales may be used to explain the reason that an MA plan has failed to demonstrate that its network meets the minimum requirements of § 422.116(a) through (e) but MA organizations should provide CMS with as comprehensive of an explanation as possible, including supporting documentation, regarding why an exception should be granted under the standards in § 422.116(f).

As discussed in the December 2024 proposed rule, current subregulatory guidance[44] states that CMS considers certain exception rationales under an "other" category. This guidance indicates that MA organizations may use the "other" category to request other exceptions, for example, "provider does not contract with any organization," "the provider has the potential to cause beneficiary harm," or "the provider is inappropriately credentialed." CMS is proposing to eliminate the "other" category, but to codify certain examples listed as permissible rationales. As described previously, CMS is proposing to codify the exception rationale "provider does not contract with any organization." CMS is also proposing to codify the exception rationale, "provider has the potential to cause beneficiary harm", as this exception rationale serves to safeguard the best interests of beneficiaries against any potential risks posed by providers. Finally, CMS is not proposing to codify the exception rationale "the provider is not properly credentialed" currently permitted in the "other" category. CMS regulations under § 422.204 place the responsibility for credentialing and recredentialing of providers on MA organizations and not CMS. While a provider's lack of proper credentials may support a rationale based on

[44] https://www.cms.gov/files/document/medicare-advantage-and-section-1876-cost-plan-network-adequacy-guidance-12-09-2024.pdf

potential to cause beneficiary harm, CMS is not proposing to codify a separate, formal exception rationale specific to credentialing.

CMS's current subregulatory guidance also includes an exception rationale for "use of Original Medicare telehealth providers and mobile providers". CMS is not proposing to codify the "use of Original Medicare telehealth providers and mobile providers" as an available exception rationale because the use of Original Medicare telehealth providers and mobile providers is an available avenue for fulfilling network adequacy requirements, rather than a means of satisfying the exception requirements under § 422.116(f)(1)(i)(A) and § 422.116(f)(1)(i)(B). MA organizations may contract with Original Medicare telehealth providers and mobile providers to meet network adequacy requirements, so they may be submitted in their HSD tables. CMS's guidance states that for organizations using Original Medicare telehealth providers, services must meet the requirements for "telehealth services" under section 1834(m) of the Act (for example, provider types, eligible originating sites, geography, and currently approved list of Medicare telehealth services), as well as the requirements for "communication technology-based services" not subject to the section 1834(m) of the Act limitations (brief communication technology-based service/virtual check-in, remote evaluation of pre-recorded patient information, and inter-professional internet consultation). The MA organization must demonstrate that it meets all applicable requirements. CMS's guidance also states that if an MA organization uses mobile providers (for example, mobile x-ray suppliers, orthotics and prosthetics mobile units), they must be qualified and furnish services through scheduled appointments.

As CMS has indicated in subregulatory guidance, for purposes of the exception described in § 422.116(f)(1)(i), CMS will not accept an MA organization's assertion that it cannot meet current CMS network adequacy criteria because of a general "inability to contract" that is not reflected in one of the exception request rationales. CMS does not require an MA organization to contract with any particular provider or facility, and MA organizations have significant

discretion in how they meet network adequacy standards. But MA organizations must establish a sufficient network to ensure enrollee access to appropriate providers as required by section 1852(d)(1) of the Act. CMS does not consider a general representation that an MA organization is unable to contract with otherwise available providers to be a sufficient basis for allowing an exception to network adequacy criteria.

With this proposal, CMS is codifying long-standing rules related to network adequacy exception request rationales; therefore, CMS does not believe there is any additional paperwork burden to be considered. However, CMS will submit these proposed changes through PRA CMS-10636 under control number 0938-1346 for OMB review. CMS welcomes comment on these proposals, including the exhaustive list of exception request rationales proposed here, and whether there are additional rationales to consider that are in the best interest of beneficiaries. In addition, CMS is soliciting comment on potential unintended consequences from this proposal, including potential changes in the provider landscape, that could limit MA plan choice and/or availability in certain areas of the country.

G. Enrollment Capacity Limits (§§ 422.60, 422.62, 422.254 and 423.38)

Section 1854(a)(1)(A)(iii) of the Act specifies that MA organizations may submit the enrollment capacity (if any) in relation to the plan and area they are serving as part of the initial bid submission. In 1998, CMS first codified this policy in regulation for the Medicare+Choice program (the predecessor of Medicare Advantage) in 42 CFR 422.306, later reorganized to 42 CFR 422.254(c)(4) for coordinated care plans and MA private fee-for-service plans, and 42 CFR 422.254(e)(1) for MA Medical Savings Account (MSA) plans (63 FR 35094).

Historically, Medicare+Choice plans commonly requested enrollment capacity limits during their bid submission. Once the program shifted from Medicare+Choice to Medicare Advantage, the number of requests declined as MA plans gained a larger market share. Moreover, prior to the CY 2027 bid submission, CMS had not received any requests for an enrollment capacity limit as part of the bid over the last decade.

Until recently, CMS had not issued specific instructions related to submission of an enrollment capacity limit as part of a plan's bid submission in the Health Plan Management System (HPMS) platform. In the Preliminary Contract Year 2027 Standards for Part C Benefits, Bid Review, and Evaluation memo, CMS reminded MA organizations of the option to submit a proposed enrollment capacity limit and included instructions for how to submit this request in HPMS with their bid. Following the preliminary bid guidance, multiple parties inquired about factors that CMS would use to evaluate and accept the proposed limit. However, section 1854(a)(1)(A)(iii) of the Act and 42 CFR 422.254(c)(4) and (e)(1) do not provide specific requirements or criteria by which CMS should review limits submitted as part of a bid. Given this, CMS provided additional information on how CMS would review these requests and addressed questions in the Final Contract Year 2027 Standards for Part C Benefits, Bid Review, and Evaluation memo. For 2027, CMS received 66 bid submissions with proposed enrollment capacity limits and accepted all limits as meeting the minimum threshold for acceptance based

on the bid guidance. Here, CMS proposes to codify a process for how it will review enrollment capacity limits submitted as part of the bid.

CMS is proposing to codify procedures for submitting an enrollment capacity limit in HPMS consistent with the way MA plans submitted these requests in CY 2027. That is, for CY 2028 and beyond, interested plans must submit their proposed limit, along with a short narrative explaining the basis for the identified limit for CMS review, with their annual bid. Requesting an enrollment capacity limit is entirely voluntary. Enrollment capacity limits accepted as part of the bid submission process would be in effect for the duration of the calendar year and MA organizations would be prohibited from disenrolling existing members to reach an approved limit (42 CFR 422.74(a)). Under this proposal, CMS would only accept enrollment capacity limits at or above current enrollment as of June 1st of the year preceding the contract year for the planned service area (for example, the plan's current enrollment as of June 1, 2027, would be the minimum enrollment capacity limit allowable in CY 2028 bids for the planned service area). This approach allows plans to determine what increase in enrollment they could reasonably accommodate and address concerns about unexpected large enrollment increases due to competitors exiting the service area. CMS expects that MA organizations should have the ability to maintain their current enrollment if they are operating in good standing and provide quality care to enrollees. Under this proposal, requesting an enrollment capacity limit is optional and may be requested at or above current enrollment as of June 1st of the year preceding the contract year for the planned service area. CMS encourages, but is not proposing to require, plans to factor in projected enrollment growth between June 1 and the start of the plan year when determining what enrollment capacity number to request, if any.

Of note, the majority of enrollment capacity limits submitted in the CY 2027 bids were significantly higher than the minimum threshold (only 15 of the 66 plans requested an enrollment limit representing 0–10% growth over current enrollment, with many plans setting a limit that would represent significant growth in enrollment if it were met). This indicates that some plans

are utilizing enrollment capacity limits to protect against an unexpected increase in enrollment rather than limiting any additional enrollment beyond their current enrollees. For CY 2027, CMS provided guidance that new plans, which do not have current enrollment, interested in including an enrollment capacity limit in their bid should utilize the assumptions on their plan's projected enrollment used in the Bid Pricing Tool to inform their proposed limit.

For CY 2028 and subsequent years, CMS is proposing a similar approach, with some modifications. If an MA organization is submitting a bid for a new plan benefit package (PBP) for a new contract, the plan should use its projected enrollment and bid assumptions to propose an enrollment capacity limit. Similarly, if an MA organization adds a new PBP to an existing contract, while all other PBPs of the same type within the contract continue to operate for the upcoming year, the plan can use their projected enrollment and bid assumptions to propose a limit. CMS will consider two or more PBPs to be the same type when they are both the same type of special needs plan (SNP) or the same type of non-SNP. For example, two PBPs are the same type if they are both C-SNPs that focus on diabetes or if they are both facility-based I-SNPs. Of note, all PBPs within a single contract are either health maintenance organizations, preferred provider organizations, cost plans, or medical savings account plans by default.

For an MA organization that is closing a PBP and also opening a new PBP (or PBPs) of the same type under the same contract, CMS will only approve an enrollment capacity limit that is at least as high as the current June enrollment for the proposed service area for the existing PBP(s) that are non-renewing. Take for example a 2027 contract with four health maintenance organization PBPs: a D-SNP, C-SNP and two non-SNPs. For 2028, the MA organization plans to non-renew the C-SNP PBP and one of the non-SNP PBPs, and create a new non-SNP PBP. The minimum threshold for the new non-SNP PBP in this example would be the June 1, 2027, enrollment for the proposed service area from the non-renewing non-SNP PBP only. This approach will also apply to new PBPs where MA organizations are seeking to cross-walk

enrollees from a non-renewing PBP into the new PBP. However, acceptance of an enrollment capacity limit is not contingent on CMS allowing the proposed cross-walk exemption.

In instances where an MA organization is non-renewing multiple PBPs and opening a new PBP of the same type under the same contract, the minimum threshold for the new PBP should be the current June 1st enrollment for the proposed service area in aggregate. Conversely, if there are two new PBPs with one non-renewing plan, CMS would compare the June enrollment for the non-renewing plan to the aggregate of limit(s) requested in the two new PBPs as the minimum threshold that would be accepted. In each of these scenarios, it is important to note that the minimum threshold is based on the current June 1st enrollment for the proposed service area for the upcoming bid year. This means that if an MA organization is opening a new PBP for an existing contract in one service area and closing a PBP of the same type in an entirely different service area, there would be no minimum threshold for that new PBP. This proposed update would avoid incentivizing MA organizations to close existing plans and open new plans in the same service area under the same contract in order to avoid the minimum threshold proposed by CMS and would promote similar access to new plans for individuals enrolled in non-renewing MA plans.

For the 2027 contract year, CMS encouraged plans to consider projected enrollment growth between the timing of the bid submission and the start of the plan year on January 1, 2027, when proposing an enrollment capacity limit in their bid. CMS is soliciting comments on the proposed minimum threshold of June 1st enrollment preceding the contract year or whether a higher minimum should be established (for example, a specified percentage higher than current enrollment) for what CMS may approve. Setting a higher minimum threshold could prevent plans exceeding their approved enrollment capacity limit for the upcoming year prior to the Annual Enrollment Period (AEP), thus essentially being closed to beneficiaries who would like to switch plans (for example, to a higher-rated plan or one with a specific in-network provider). CMS encouraged plans to take this potential scenario into account for the CY 2027 bid

submission by suggesting plans incorporate some buffer in their enrollment capacity limit requests. CMS could formalize this recommendation by setting a higher numerical limit necessary for approval (for example, 5 percent, 10 percent, or another growth percentage above the current enrollment as of June 1st for the preceding plan year). CMS also seeks comment on the approach to new PBPs and how the minimum threshold is applied in the different scenarios articulated above.

Beyond the numerical minimum threshold, CMS received several inquiries regarding whether additional factors would be used to evaluate and accept the proposed limit after issuing the CY 2027 guidance. Section 1854(a)(1)(A)(iii) and 42 CFR 422.254(c)(4) and (e)(1) do not provide specific requirements or criteria by which CMS should review enrollment capacity limits. For CY 2027, there were no other factors used to evaluate acceptance of proposed limits beyond confirmation that the requested limit was at or higher than the minimum threshold and submission of a supporting narrative. Because CMS has an obligation to ensure that there is access to care for enrollees and beneficiary choice, CMS is proposing to codify that plans would be required to provide a written narrative explaining how they arrived at the requested limit (for example, their current enrollment, provider networks, available access to care or other metrics). Under this proposal, if an MA organization submits an enrollment capacity limit with their bid that is lower than the minimum threshold or fails to provide the required written narrative, CMS would offer the MA organization a chance to cure their submission prior to making a final determination.

CMS is seeking comment on what additional criteria, if any, CMS should use to evaluate limits proposed by MA organizations in bid submissions and may consider incorporating additional criteria from public comments in the final rule. In developing this proposal, CMS considered defining additional requirements for qualifying justifications that the plan would need to demonstrate in their submitted narrative. For example, CMS could require that MA plans provide a summary of current enrollment, capacity of the anticipated provider networks,

timeliness in care for current enrollees, quality performance, and any current and anticipated operational challenges (for example, challenges hiring sufficient care managers, IT infrastructure) as part of their rationale to demonstrate how additional enrollment beyond their proposed limit could potentially jeopardize quality of care. Under this scenario, CMS could then base approval decisions on the strength of the submitted rationale. Further, CMS could put forward criteria that would allow CMS to reject a proposed enrollment capacity limit, such as if there are limited MA offerings in a particular area and multiple plans request enrollment capacity limits at or near the minimum threshold.

CMS recognizes that MA plans already make business decisions as part of their bid and employ marketing strategies that might impact enrollment. CMS also believes that enrollment capacity limits submitted with the bid should be considered another tool for plans to ensure that they are able to provide high-quality care and ensure provider access for their current enrollees and these proposed procedures to align with this understanding.

In summary, CMS is proposing to codify procedures regarding enrollment capacity limits submitted in the bid in recognition that these submissions are permitted by statute and appropriate as a formal component of the bid submission process. To effectuate these changes, CMS is proposing to revise § 422.254(c)(4) and § 422.254(e)(1) to establish criteria for CMS review of requests submitted as part of the bid by inserting the following language under each section: "(i) Proposed enrollment capacity limits must not be below the current enrollment as of June 1 of the year preceding the contract year for the planned service area. (ii) Plans submitting a proposed enrollment capacity limit must include a supporting narrative that describes how the limit was derived. (iii) For a plan in a new contract or a new plan to be offered under an existing contract without any non-renewing plans in the proposed service area for the contract year, there is no minimum limit for acceptance. (iv) For a new plan to be offered under an existing contract, the proposed enrollment capacity limit must not be below the aggregate current enrollment as of

June 1 of the year preceding the contract year for the planned service area for any non-renewing plans of the same plan type within the contract."

1. Enrollment Capacity Limits Submitted Outside the Bid via 42 CFR 422.60(b)(3)

Currently, MA plans may also request an enrollment capacity limit outside of the bid submission process. In 2000, CMS finalized a regulation at 42 CFR 422.60(b)(3) that it would consider "enrollment limit requests for an M+C plan service area, other than those submitted with the adjusted community rate proposal, or for a portion of the plan service area, only if the health and safety of beneficiaries is at risk, such as if the provider network is not available to serve the enrollees in all or a portion of the service area" (65 FR 40170). CMS noted that this change was spurred by the bid submission deadline moving several months earlier due to the Balanced Budget Refinement Act of 1999 and in recognition that there may be other reasons Medicare+Choice plans may want to submit these requests outside of the bid submission. The preamble language did not further describe how CMS would define the health and safety standard but did state that "the circumstances under which a capacity limit will be approved after the ACRP date would likely occur when a portion of a provider network that furnishes an M+C plan becomes unavailable during the course of a contract year." In 2005, CMS updated the language to the current text: "CMS considers enrollment limit requests for an MA plan service area, or a portion of the plan service area, only if the health and safety of beneficiaries is at risk, such as if the provider network is not available to serve enrollees in all or a portion of the service area" (70 FR 4588). When proposing the update, CMS noted that there could be several scenarios when an MA organization may need to restrict enrollment for capacity reasons because their ability to serve the potential number of enrollees it previously estimated it could would be significantly impacted, such as when a plan loses a sizable contract with a health system or physician group (69 FR 46866). In the final rule (70 FR 4588), CMS stated that the "ability to request a capacity limit is an important element of the MA program that helps ensure that plan enrollees will have sufficient access to needed providers and services. CMS's approval of a

capacity limit request indicates that CMS agrees with the requesting MA organization that its defined network of providers is sufficient to deliver health care only to a limited number of plan members." However, CMS did not define or provide additional examples of scenarios when the health and safety of beneficiaries is at risk, or how to objectively evaluate plans' capacity to absorb additional enrollees with their current provider networks. For example, if one large competitor leaves a market, and there are many available plans, enrollees may be dispersed across multiple plans, thus avoiding any potential shocks and any resulting harm that may be experienced by the receiving plans and their enrollees.

Since these rules were promulgated, CMS has received very few enrollment capacity limit requests outside of the bid submission. In fact, the few that were received in 2025 were the first in many years. When reviewing the 2025 requests, CMS reviewed the materials shared by MA organizations for their specific plans to determine whether the health and safety standard at § 422.60(b)(3) was met. CMS interprets the health and safety standard at § 422.60(b)(3) to be based on present and documented risk to enrollees. Where an MA organization seeks a post-bid enrollment capacity limit based solely on anticipated challenges and the projected downstream impact to enrollees, these rationales are inherently speculative. Such requests cited concerns related to large organizations exiting markets or reducing plan offerings, anticipated operational challenges, expected increases in enrollment, provider network capacity, and potential effects on quality measures and Star Ratings. To date, CMS has denied all of these requests because the supporting evidence was speculative in nature, relying on projected market fluctuations and hypothetical enrollment shifts. In reviewing the market exits, CMS noted the impacted service areas had a variety of plans that could receive displaced enrollees. Moreover, none of the requesting plans demonstrated a concrete risk to beneficiary health and safety.

Since § 422.60(b)(3) was first promulgated, additional tools and policies have been developed within the MA program to address the concerns around provider access and protecting enrollees that were the impetus for this policy. CMS has broad authority to impose intermediate

sanctions under 42 CFR part 422 Subpart O for a variety of reasons. CMS also has flexibility to determine which sanctions are imposed, with discretion on whether to prohibit marketing by a plan, impose an enrollment sanction, and/or impose civil money penalties. When an MA organization fails to comply with program requirements, including requirements related to access to providers and services, CMS may, where appropriate, impose intermediate sanctions, restrict new enrollment into the plan, and allow current enrollees to switch plans via a special election period (SEP) (42 CFR 422.62(b)(5), 42 CFR 423.38(c)(12)). The availability of intermediate sanctions provides protection for enrollees, without placing undue constraints on enrollee plan choices and access.

Moreover, CMS is concerned that allowing requests for enrollment capacity limits outside of the formal bid process and based on projected risk to enrollees has the potential for introducing contract gaming and limiting fair competition between plans. CMS is cognizant of ensuring that any enrollment capacity limit, if granted, is structured in a way that avoids creating or exacerbating opportunities for contract gaming: plans with approved capacity limit requests may potentially have an easier time managing a smaller enrollment base which may allow them to stem any financial losses from increased utilization compared to bid projections or other unanticipated negative impacts to plan margins in a given contract year compared to plans that endeavor to maintain broad MA network access and serve larger enrollee populations despite smaller or negative margins. CMS believes that risk is increased for requests made outside of the bid process. While § 422.60(b)(3) provides that such requests may only be granted where the health and safety of beneficiaries is at risk, CMS is concerned that plans may view these requests as a potential financial tool—allowing plans to use these mid-year capacity limits as a mechanism to make business decisions outside of the bid period, and with information about the landscape they would not have had during the plan year. Several of the requests CMS received in prior years either directly or indirectly indicated the request was driven by financial concerns,

rather than any risk to beneficiary health and safety. In light of these potential gaming concerns, CMS is proposing to limit the availability of enrollment capacity limits to the bid process.

Because CMS currently only considers an enrollment limit request outside of the bid submission process if there are present and documented risks to enrollee health and safety as set forth in § 422.60(b)(3), and CMS has other more robust tools available to intervene in these instances, CMS is proposing to remove the paragraph at § 422.60(b)(3) and revise § 422.60(b)(1) to make the request process applicable to enrollment capacity requests submitted as part of bid submission. These changes would remove the ability of plans to submit a capacity limit request outside of the bid submission. If a plan is concerned about the capacity of their provider network in delivering quality and timely care or other concerns about beneficiary outcomes, it can reach out to its CMS Regional Office account manager about these challenges. Where appropriate, CMS may issue intermediate sanctions, which can include suspending the plan's enrollment of Medicare beneficiaries and other actions.

Enrollees in plans subject to enrollment sanctions are eligible for a SEP that would allow them to choose another MA plan or Original Medicare. In addition, one of the primary rationales for allowing MA organizations to request enrollment limits outside of the bid process was to provide relief in the event of significant changes in provider networks, as reflected in the language of § 422.60(b)(3) identifying a lack of provider network availability as a potential basis for granting a request. It is important to note that CMS currently provides a SEP when there is a significant provider termination, as allowed under § 422.62(b)(23). Therefore, CMS has other protections in place to address the motivating concerns that prompted CMS to allow post-bid enrollment requests based on beneficiary health and safety risks. CMS also notes that extremely few requests of this nature were received prior to 2025, when some national MA organizations reduced their service areas. Even if such requests were a common occurrence, multiple plans identifying concerns that would be significant enough to meet the threshold of risk to health and safety would raise broader compliance concerns for the overall MA program. For example, if

numerous MA organizations report that large provider groups have terminated their network contracts, and such terminations pose a sufficient risk to beneficiary health and safety, CMS could use existing compliance mechanisms to investigate the underlying circumstances. Such an investigation may examine compliance with network adequacy standards or the plan's obligation for arranging for and covering any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs.

For these reasons, CMS is proposing to remove § 422.60(b)(3), thus removing the ability for plans to request an enrollment capacity limit outside of the bid process based on a risk to beneficiary health and safety. For further clarification of this point, CMS also proposes to revise § 422.60(b)(1) to indicate that all requests for enrollment capacity limits must be submitted with the bid with the following language: "(1) MA organizations may submit information on enrollment capacity of plans as part of the annual bid submission described at § 422.254(c)(4) or § 422.254(e)(1), as applicable."

2. Enrollment Processes for Plans with a CMS-approved Capacity Limit

As part of the CY 2027 bid process, CMS received several questions about the enrollment processes for plans with a capacity limit. The final CY 2027 bid guidance noted that all plans must accept valid requests to enroll during all election periods until an established enrollment capacity limit is met.[45] This guidance is consistent with the requirements in 42 CFR §§ 422.60(a)(1) and 422.62(a), which CMS is not proposing to modify and would continue to be required. That is, a plan with an established enrollment capacity limit must accept all valid enrollments in the order they are received until the capacity limit is reached. For example, if the plan's enrollment exceeds the enrollment capacity limit submitted in the bid and accepted by CMS for CY 2028 at the start of the AEP in October 2027, it may not accept AEP enrollments

[45] The requirement to accept enrollment requests during all election periods unless a capacity limit has been reached does not apply to MA organizations that have chosen to be closed to new enrollments during the MA Open Enrollment Period and the Open Enrollment Period for Institutionalized Individuals per 42 CFR 422.60(a)(2).

for the January 1, 2028, enrollment start date. However, the plan must accept election requests using other election periods with 2027 effective dates (with the last possible effective date December 1, 2027). If the plan's enrollment is below the enrollment capacity limit before or at any point during the AEP, it must accept valid enrollment requests in the order they are received until the limit is met. When a plan is closed to new enrollment due to an enrollment capacity limit, the plan must remain closed to all prospective enrollees until space becomes available through natural attrition. If a plan receives valid enrollment requests after an enrollment capacity limit has been reached, the plan would deny those requests. If denied, an individual who wishes to enroll in the plan would need to wait until the plan is once again open and submit a new enrollment request. The individual would need to be eligible for an election period at the time of this subsequent request. Up until the enrollment capacity limit is reached, the plan must accept individuals based upon enrollments received in chronological order and in a manner that does not discriminate on the basis of any factor related to health as described in § 422.110.

CMS now discusses in greater detail its proposal for how plans would be required to operationalize an accepted enrollment capacity limit. Given that bid capacity limits would only be available when requested in connection with the bid submission under the proposed revisions to § 422.60(b), the proposed enrollment process requirements applicable to enrollment capacity limits obtained through the bid submission process would be codified at § 422.60(b)(2). Currently, § 422.60(b)(2) sets forth a rule for how a plan must prioritize accepting enrollment requests if the plan's enrollment falls below their enrollment capacity limit after previously having reached the capacity limit and being closed to new enrollment. Under this proposed rule, a plan would know well in advance of a contract year if they have an approved capacity limit and would have the ability to proactively manage their new enrollment closely. Plans with an established enrollment capacity limit would be responsible for maintaining a constant awareness of whether enrollment has met that limit, as they would need to determine the point in time at which they would cease accepting new enrollment requests. As a matter of course, plans are

responsible for following CMS regulations on enrollment and submitting enrollments to CMS via MARx. Plans receive real-time responses from CMS for enrollment transactions submitted through MARx's user interface (UI) and Medicare Daily Transaction Reply Reports (DTRRs). Plans must monitor their enrollment data and should proceed cautiously when they are nearing their enrollment capacity limit to ensure they reach but do not exceed it. Once a plan is nearing its enrollment capacity limit, it may need to break batches of enrollments into smaller units so as not to exceed the enrollment capacity limit. If a plan receives several enrollment requests on one day, such that accepting all of them would exceed its enrollment capacity limit, the plan would accept and process to completion, as it would any other enrollment request, only those enrollment requests that were received while the plan's enrollment capacity limit had not yet been reached. The plan would deny any enrollment requests that, based on the time and date they were initially received by the plan, were received after the capacity limit had been reached. If a plan, during the processing of enrollments on a given day, determines that its enrollment capacity limit has been reached, the plan must continue processing those enrollment requests it received before the capacity limit was reached and may not disenroll those additional individuals. Only those enrollment requests that are received by the plan after the enrollment capacity limit has already been reached would be directly impacted by the capacity limit by having the enrollment request denied.

There may be circumstances in which an individual submits a valid enrollment request when there are still spaces available in the plan, but the plan reaches the enrollment capacity limit prior to submitting the enrollment transaction to CMS. Similarly, a plan may receive an incomplete application when the plan has not reached the enrollment capacity limit but then subsequently reach the capacity limit before the missing (but required) information is obtained. CMS would expect plans to accept these applications and process them to completion, including submitting the enrollment transaction to CMS as appropriate. Again, beneficiaries enrolled in excess of an approved enrollment capacity limit may not be disenrolled.

To conform with this approach, CMS is proposing to revise § 422.60(b)(2) to be "MA organizations must deny enrollment applications at the point of initial receipt once their CMS-approved enrollment capacity limit has been reached" and to remove 2(i) and 2(ii).

Under proposed § 422.60(b)(2), when individuals apply to an MA plan with an approved enrollment capacity limit, they would receive a denial notice if the enrollment capacity limit has been reached at the time the enrollment request is initially received by the plan. Currently, as described in the MA and Part D Enrollment and Disenrollment Guidance, section 50.4, plans must send denial notices within 10 calendar days of receipt of an enrollment request, or the expiration of the time for a request for additional information from the applicant, if applicable. It is therefore possible that an individual who applies late in an election period may not receive the denial notice before the end of their election period or may receive the notice without sufficient time to find and apply to a new plan. Although all individuals have the option of calling 1-800-MEDICARE to request a SEP for other exceptional circumstances, CMS is including in this proposal a new SEP to address this potential scenario and ensure that these individuals are not prevented from making an election through no fault of their own.

Section 1851(e)(4)(D) of the Act provides the Secretary with the authority to establish SEPs for exceptional conditions, during which an individual may request enrollment in, or disenrollment from, an MA plan. Therefore, CMS proposes to create a new SEP at 42 CFR 422.62(b)(27) to ensure that individuals denied enrollment because of an enrollment capacity limit have the opportunity to make an election into an available health plan. This SEP would require that the individual was eligible for an election period, attempted to enroll in an MA plan during that election period, was denied enrollment because of a CMS-approved capacity limit, received the enrollment denial notice, and was then unable to make another election during that original election period, because that election period had expired. CMS also proposes to renumber the existing SEP for other exceptional conditions at § 422.62(b)(27) as (b)(28). Because individuals who would be denied enrollment in a particular MA plan because of an

enrollment capacity limit may prefer a standalone Part D plan instead of a different MA plan, CMS also proposes an analogous Part D SEP for other exceptional conditions at § 423.38(c)(36). The eligibility criteria for this SEP would be identical to that of the proposed new SEP at § 422.62(b)(27). CMS proposes to renumber the existing Part D SEP for other exceptional circumstances at § 423.38(c)(36) to (37). To conform with the proposed renumbering of existing § 422.62(b)(27) to (28) CMS is proposing to update the cross reference at § 422.66(g)(2)(iv). Similarly, to conform with the proposed renumbering of existing § 423.38(c)(36) to (37), CMS is proposing to update cross references at newly redesignated § 423.32(k)(2)(v) (as discussed in section III.A) and § 423.36(g)(2)(v).

At redesignated §§ 422.62(b)(27) and 423.38(c)(36) CMS proposes that the new SEP would begin the date the individual is notified of the enrollment denial and ends two calendar months after notification.

CMS proposes to limit use of this SEP to a CMS-operated mechanism, like 1-800-MEDICARE, consistent with the reasoning described in previous rulemaking (91 FR 17384, 17433) and in the proposal for section III. A. Using a CMS Approval Mechanism for Use of the Disaster/Emergency Special Enrollment Period at §§ 422.62 and 423.38 that is also included in this proposed rule. In the case of the proposed capacity limit SEP, this is a situation where it would be inappropriate for the receiving MA organization to evaluate the applicant's eligibility because the receiving plan would not have the information it would need to determine eligibility for the SEP, such as details of the approved capacity limit, at what point the limit was reached, whether enrollment has subsequently dropped below the limit, whether the applicant was eligible for an election period when they requested enrollment in the capacity-limited plan, whether the applicant was denied enrollment due to the plan having reached the capacity limit, and whether there was insufficient time for the applicant to request enrollment in a different plan after having been denied enrollment. In this case, only CMS has all the necessary information to consider an individual's eligibility for this proposed new SEP. CMS proposes to include this limitation to

CMS-operated mechanisms in both the requirements of the proposed SEP at § 422.62(b)(27) and in the list of SEPs that require prior CMS approval at § 422.66(g)(2). CMS is also proposing to specify that the SEP specified in the new proposed § 423.38(c)(36) would require CMS approval before an individual can use the SEP to make an election for Part D.

CMS is seeking public comment on alternatives to the standard for SEP eligibility described in our proposal, given that some individuals who are denied enrollment in an MA plan due to a capacity limit may be notified of the denial late in the election period they used to request enrollment in that plan and, as such, may not have sufficient time to identify and request enrollment in another plan prior to the expiration of that election period. CMS seeks comment on whether our consideration of this scenario is warranted and, for someone who receives a denial notice late in an election period, what would be the appropriate amount of time prior to the end of the election period to establish the SEP start date.

For CY 2027, CMS has encouraged plans with an accepted enrollment capacity limit to publicly post on their website when their plan has reached their limit to avoid potential beneficiary frustration if they try to enroll in a plan that does not have additional capacity. Therefore, CMS is considering whether to add additional regulatory language to require plans to post their accepted enrollment capacity limits and/or a notice when the limit has been reached on their public websites as part of marketing regulations at 42 CFR Part 422 Subpart V and 42 CFR 422.2265. For example, the MA plan would be required to display a message on its website that informs potential enrollees that enrollment in the plan has reached capacity and that it is no longer open for new enrollments. CMS seeks comment on this topic.

This proposal maintains the statutory framework allowing MA organizations to determine their capacity to accept new enrollees when submitting bids, while protecting against contract gaming concerns and challenges in CMS's ability to fairly and accurately determine whether to approve enrollment capacity requests outside of the bid process. The proposed approach also ensures the MA organization's ability to request an enrollment capacity limit on a level playing

field across organizations through the bid submission process, while reducing the complexity of CMS review.

As CMS is proposing to maintain the ability for plans to request an enrollment capacity limit in the bid, plans would be expected to carefully assess their ability to absorb additional growth considering current market volatility when determining whether to include a proposed enrollment capacity limit in the plan's bid submission. This would ensure that, in the event a large MA organization exits a market unexpectedly, remaining plans in the market have proactively established an upper bound for the number of new enrollees they could realistically accommodate.

The estimated financial impact of this proposal is expected to be minimal. While there may be an increased number of plans submitting, and ultimately being approved for, an enrollment capacity limit as part of their bid submission, any added administrative burden on CMS (to review and approve/deny the request) or MA organizations (to make the request and then track enrollment) would be negligible and can likely be achieved using existing resources. Further, CMS is also removing the ability for plans to request a capacity limit outside of the bid process. However, because this was not a common occurrence as noted earlier, there is no burden reduction from this change. CMS requests comments on this proposal, including the proposed approach for CMS to review requests for enrollment capacity limits submitted during the bid and the removal of the ability to request a limit outside of the bid submission process. CMS is interested in comments about this proposal's impact on MA organizations' decision-making regarding offering plan benefit packages in specific service areas and other market implications, particularly on whether it supports competition and avoids contract gaming. Commenters should also note any anticipated impact to beneficiary access, choice, and outcomes.

H. Use of Existing Interoperability API for Prior Authorization Transactions (§ 422.202)

Non-standardized prior authorization processes in MA can contribute to administrative burden for providers, delays in beneficiary access to care, and inefficient use of program resources. In June 2025, both MedPAC and the Medicare Trustees (in their respective reports to Congress) raised concerns about physician payment adequacy, administrative burden, and beneficiary access to clinicians.[46,47] Later that month, the U.S. Health and Human Services (HHS) Secretary Robert F. Kennedy, Jr. and CMS Administrator Dr. Mehmet Oz convened dozens of payers across health insurance markets, including MA organizations, who voluntarily pledged their cooperation as CMS works to mend a fractured prior authorization system to reduce administrative costs and improve timely access to care.[48] This effort is critical to the longevity of the Medicare program, and particularly important to the MA program, which is predicted by the Medicare Trustees to cover 57.8% of all Medicare-eligible people by 2034.[49]

In a report, some payers noted that electronic prior authorization can reduce administrative burden for providers and minimize delays in care. These payers also stated that continued reliance on manual processes negates the efficiencies electronic prior authorization is designed to offer and emphasized that hospitals and other providers must invest in capabilities that will allow them to benefit from electronic prior authorizations. According to a 2024 survey conducted by America's Health Insurance Plans (AHIP), nearly half of prior authorization requests for medical services (45%) are submitted by providers manually, using phone, fax or

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[46] June 2025 Report to Congress: Medicare and the Health Care Delivery System. MedPAC. Published June 12, 2025. https://www.medpac.gov/document/june-2025-report-to-the-congress-medicare-and-the-health-care-delivery-system/

[47] 2025 Annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds [Medicare Trustees]. The Boards of Trustees[….]. Published June 18, 2025. https://www.cms.gov/oact/tr/2025

[48] HHS Secretary Kennedy, CMS Administrator Oz Secure Industry Pledge to Fix Broken Prior Authorization System. U.S. Department of Health and Human Services. Published June 23, 2025. https://www.hhs.gov/press-room/kennedy-oz-cms-secure-healthcare-industry-pledge-to-fix-prior-authorization-system.html

[49] 2025 Annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds [Medicare Trustees]. The Boards of Trustees[….]. Published June 18, 2025. https://www.cms.gov/oact/tr/2025

traditional mail. The report also cited a study that estimated that twenty-five percent (25%) of health care spending is considered unnecessary and occurs due in part to outdated technology.[50]

Provider-side concerns are no less prevalent. To emphasize the urgency and severity of the issue from the provider perspective, the American Medical Association conducted a physician survey in 2025 and found that more than 1 in 4 physicians reported that prior authorization led to a serious adverse event for a patient in their care.[51] In addition, research published by the Journal of the American Medical Association (JAMA) in 2019 separated cost estimates for unnecessary spending into six waste domains, with administrative complexity (the domain that captures administrative burden for both payers and providers) generating more waste than any other category.[52] For comparison, administrative complexity accounted for three and a half times more waste than fraud and abuse according to figures presented in the research; the research also pointed to interoperability initiatives by CMS and the Office of the National Coordinator for Health Information Technology (ONC) as a promising means to alleviate burden as prior authorization processes become more streamlined.

The impact of inefficient prior authorization processes also continues to increase for hospital systems. The American Hospital Association (AHA) recently reported that between 2022 and 2023, care denials increased by an average of 55.7% for MA claims alone; in the same report, the AHA revealed that administrative costs now account for more than 40% of total expenses hospitals incur when delivering care to patients.[53] CMS also notes that a 2018 HHS Office of Inspector General (OIG) report on MA denials estimated that 75% of MA organization

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[50] Improving Prior Authorization for Patients & Providers. AHIP. Published June 23, 2025. https://www.ahip.org/resources/improving-prior-authorization-for-patients-providers

[51] 2025 AMA prior authorization physician survey. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

[52] Shrank WH, Rogstad TL, Parekh N. Waste in the US Health Care System: Estimated Costs and Potential for Savings. JAMA. 2019;322(15):1501–1509. doi:10.1001/jama.2019.13978. https://jamanetwork.com/journals/jama/fullarticle/2752664

[53] Skyrocketing Hospital Administrative Costs, Burdensome Commercial Insurer Policies Impacting Patient Care. AHA. Published September 2024. https://www.aha.org/guidesreports/2024-09-10-skyrocketing-hospital-administrative-costs-burdensome-commercial-insurer-policies-are-impacting

denials were overturned during the appeal process in the period reviewed by OIG.[54] Faster, more efficient, and more responsive prior authorization systems could minimize the strain on hospital and provider resources and reduce the delay that MA enrollees experience when attempting to access items and services they are entitled to under the MA program.

In February 2024, CMS finalized the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program rule (89 FR 8758), hereafter referred to as the "2024 CMS Interoperability and Prior Authorization final rule". The rule included a series of interoperability requirements for MA organizations, some of which pertain to prior authorizations. Specifically, beginning January 1, 2027, each MA organization must implement and maintain a Prior Authorization API, as defined in § 422.122, to support electronic prior authorization that, among other things: (1) is populated with the MA organization's list of covered items and services (excluding drugs) that require prior authorization; (2) can identify all documentation required by the MA organization for approval of any items or services that require prior authorization; and (3) has the capability to send and receive Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant prior authorization requests and responses. In an industry survey tracking readiness for the Prior Authorization API requirements from early 2026, most providers viewed the API as extremely important, and the majority of payers had started implementing the API requirements.[55]

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[54] Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials. HHS Office of the Inspector General. Published September 25, 2018. https://oig.hhs.gov/reports/all/2018/medicare-advantage-appeal-outcomes-and-audit-findings-raise-concerns-about-service-and-payment-denials/

[55] WEDI Survey Finds Payers and Providers Making Progress Complying with Interoperability and Prior Authorization Final Rule. Published March 10, 2026. https://www.wedi.org/2026/03/11/wedi-survey-shows-progress-in-implementing-cms-interoperability-and-prior-authorization-final-rule/

In early 2026, CMS proposed the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges (91 FR 19890), hereafter referred to as the "2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule". The rule proposed that under the Administrative Simplification provisions of the HIPAA (Part C of Title XI of the Act), HHS would adopt the FHIR standards and implementation guides that comprise the Prior Authorization API as the standards for prior authorization-related transactions. If finalized as proposed, and upon the compliance date, when HIPAA covered entities conduct electronic prior authorization for items, services, or drugs covered under a medical benefit, they would be required to use a Prior Authorization API. In the same rule, CMS also proposed that impacted payers, including MA organizations, support prior authorization for drugs covered under a medical benefit through their Prior Authorization API with a proposed compliance date of October 1, 2027. Should that proposal be finalized before this rule is finalized, CMS proposes to expand the requirements proposed here, as needed for consistency with the standards applicable to the Prior Authorization API under § 422.119.

There are separate National Council for Prescription Drug Programs (NCPDP) prior authorization standards that Medicare Part D sponsors (including MA organizations that offer a Medicare Advantage Prescription Drug plan) are already required to support as part of their electronic prescription drug programs. Per regulations at 42 CFR 423.160(b)(1) and 45 CFR 170.205(b), prescribers and dispensers are required to use the same NCPDP standards when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D-eligible individuals.[56]

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[56] Prior authorization standards for Part D drugs were previously addressed in the final rule titled "Medicare Program; Medicare Prescription Drug Benefit Program; Health Information Technology Standards and Implementation Specifications," which appeared in the June 17, 2024, **Federal Register** (89 FR 51238).

As part of the agency's efforts to relieve administrative burden on MA enrollees and their providers, CMS proposes to require MA organizations to add a contract requirement that contracted providers use existing interoperability tools, namely the Prior Authorization API codified in regulation at § 422.122(b), to reduce the costly and unnecessary layers of administrative complexity in the prior authorization process. As drafted, this proposal pertains only to prior authorizations for non-drug items and services under the MA program, including non-drug supplemental benefits where applicable, consistent with § 422.119(b)(1)(iv), which requires MA organizations to support electronic prior authorization only for non-drug items and services.

Specifically, CMS proposes to add a new requirement under § 422.202(c) that would apply to MA organizations when contracting with a provider for participation in the MA organization's network. If an in-network provider furnishes non-drug items or services for which prior authorization is required, the MA organization must include a contractual requirement that the provider use the Prior Authorization API to transmit information pertaining to a prior authorization request for those non-drug items or services to the MA organization.[57]

MA organizations would also be required to include a term in each contract with a provider for participation in the MA organization's network that if the provider furnishes non-drug items or services for which prior authorization is required, the provider must annually participate in testing with the MA organization. The purpose of this testing is to ensure that the Prior Authorization API features are bi-directionally functional, useable, and accessible for both the MA organization and the contracted provider. In other words, the annual end-to-end testing would ensure the provider is able to submit a prior authorization request to the MA organization and the MA organization is able to respond through the Prior Authorization API. CMS invites

[57] As discussed previously in this preamble, should the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule be finalized to include drugs in the Prior Authorization API requirements at § 422.119 before this rule is finalized, CMS proposes to similarly expand the requirements proposed here, as needed for consistency with the standards applicable to the Prior Authorization API under § 422.119.

public comment on whether additional guidance would help ensure compliance with the proposed annual testing requirement.

CMS reminds MA organizations of their obligation to ensure that all first tier, downstream, and related entities (FDRs) conduct activities in a manner that is consistent and compliant with the MA organization's contractual obligations to CMS pursuant to § 422.504(i). Accordingly, when an MA organization delegates to an FDR the responsibility of contracting with a provider on the MA organization's behalf, the MA organization remains responsible for ensuring that the resulting contract between the FDR and the provider complies with the proposed requirements.

To implement these requirements, the agency cites its authority at section 1856(b)(1) of the Act to promulgate regulations that adopt standards consistent with, and to carry out, Part C of Title XVIII of the Act (such as section 1852(d)(1)(A) of the Act) and its authority under section 1857(e)(1) to adopt new contract terms and conditions for MA organizations, not inconsistent with Part C, that the Secretary finds "necessary and appropriate." Section 1852(d)(1)(A) of the Act requires MA organizations to, as a condition of using a network of providers, make covered benefits available and accessible to enrollees with reasonable promptness and in a manner that assures continuity in the provision of benefits. In implementing section 1852(d)(1)(A) of the Act, CMS previously adopted a regulation, at § 422.112(b), that requires MA organizations to ensure the continuity of care and integration of services through arrangements with providers that include procedures to ensure that the MA organization and the contracted providers have access to the information necessary for effective and continuous patient care.

With solutions such as the Prior Authorization API in place and requirements to ensure MA organizations and their contracted providers use it to their fullest advantage, CMS can help to address the issue of outdated and non-standardized prior authorization practices that drive up administrative costs, burden the MA program with needless layers of administrative complexity, and delay enrollees receiving necessary covered services. Should these proposals be finalized,

the new requirements would apply beginning January 1, 2028. CMS welcomes public comment on these proposals.

In connection with this proposal, CMS recognizes that rural hospitals, small groups, and individual providers face unique challenges that may affect their ability to implement these requirements. As such, CMS is specifically soliciting input from health providers and hospitals to better understand current capabilities, identify barriers to adoption, and explore ways the agency can provide meaningful support throughout the transition process. CMS invites commenters, including rural, small groups, and individual health providers, to respond to the following areas of inquiry, and may revise the proposed provisions based on responses received:

- Do the current systems of rural, small group, and individual health providers and hospitals support data exchange with MA organizations, payers, and other providers, including current electronic health record (EHR) capabilities in general; and to what extent are rural health providers and hospitals, small group, and individual providers operating on outdated or legacy systems that would require significant upgrades or replacement to meet the proposed requirements?

- CMS is interested in information regarding the physical and technical infrastructure required to support API-based prior authorization, including whether providers have sufficient existing hardware and systems; access to reliable broadband internet access; IT staff resources; and any physical infrastructure limitations (for example, server capacity, power reliability) that could impede implementation.

- Are there specific financial vulnerabilities unique to rural hospitals, critical access hospitals (CAHs), rural health clinics (RHCs), or small independent or individual practices that CMS should consider in finalizing these proposals?

- What types of financial assistance (for example, grants, low-interest loans, enhanced reimbursement) would most effectively support rural, small group, and individual providers in

meeting the proposed requirements, and are there existing federal or state funding programs that could be leveraged?

● What types of educational materials, webinars, or toolkits would help rural, small group, and individual providers understand and prepare for these requirements?

● Are there existing partnerships with state health departments, State Offices of Rural Health, regional extension centers, or health information exchanges that could be leveraged to support rural, small group, and individual providers?

● Should CMS consider providing in-network rural, small group, and individual providers with additional time to implement these requirements, and what factors (for example, infrastructure, workforce, cost) should CMS consider when establishing a compliance deadline?

● Should CMS adopt a rural, small group, and individual provider hardship exception for the requirements, or a broader hardship exception? If so, what criteria should qualify a provider for such an exception and how should the hardship exception work?

Additionally, CMS is committed to advancing interoperability across the health care ecosystem to improve care coordination, reduce administrative burden, and enhance quality of care for MA beneficiaries. The 21st Century Cures Act (Pub. L. 114-255) amended section 3000 of the Public Health Service (PHS) Act (42 U.S.C. 300jj(9)) to provide a statutory definition of interoperability. It states that interoperability with respect to health information technology, means such health information technology that — (A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; (B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and (C) does not constitute information blocking as defined in section 3022(a) of the PHS Act (42 USC 300jj–52(a)).

As part of its ongoing efforts to modernize health information exchange, CMS solicits comments on three key areas to advance interoperability between providers and MA

organizations, seeking input on the following topics: (1) strategies to advance the adoption of interoperable health IT tools; (2) the extent to which interoperability can help reduce clinically inappropriate duplicate imaging and laboratory testing; and (3) opportunities to strengthen interoperability for administrative, payment, and operational functions. CMS may consider feedback received in response to this request for information in the development of future policy and rulemaking, as appropriate.

First, the CMS Office of Health Technology and Products (OHTP) and ONC have proposed and finalized regulations to improve the electronic exchange of health care data and streamline processes related to prior authorization by increasing the interoperability of systems used in MA and across the health care industry. While CMS seeks to advance interoperability, CMS recognizes that readiness to adopt interoperability tools varies across practice types and MA organizations. These differences in readiness can affect the pace and consistency of implementation across the MA program. Therefore, CMS solicits comments on the following:

- What factors affect provider and MA organization interoperability readiness?
- What technical assistance, shared services, or policy flexibilities would support providers and MA organizations in successfully adopting tools to improve interoperability?
- What additional APIs, interoperability standards, or data exchange frameworks should CMS consider to improve the flow of information between providers and MA organizations?

Second, CMS is interested in exploring whether interoperable health information exchange can help reduce clinically inappropriate duplicate imaging and laboratory testing which may pose a risk to MA enrollee safety and/or raise program integrity concerns. Currently, diagnostic imaging and laboratory testing are often stored within the electronic systems in which they are performed and may not be easily accessible to physicians and other healthcare providers who use a different electronic system. This fragmentation may lead to unnecessary repeat testing and avoidable patient safety risks. Pursuant to § 422.121(a) MA organizations are required to implement a Provider Access API beginning in 2027 that makes individual claims, certain

encounter data, and specified prior authorization information available. CMS is particularly interested in whether FHIR-based data exchange infrastructure such as the Provider Access API could reduce duplicative testing by making prior results accessible at the point of care. CMS simultaneously solicited comments through the Calendar Year 2027 Medicare Physician Fee Schedule proposed rule on strategies to reduce duplicate imaging and laboratory testing in Original Medicare.

CMS recognizes that, unlike in Original Medicare, the agency does not pay providers directly in the MA program, and that the agency is not permitted to interfere with contractual pricing arrangements between MA organizations and their network providers. Accordingly, the questions below are directed at understanding what providers and MA organizations are doing or could do to advance interoperability for imaging and laboratory testing, and what CMS could do through its contracts and program requirements with MA organizations to support these efforts. Therefore, CMS solicits comments on:

- Whether CMS should propose to require MA organizations to include contractual provisions in their network provider agreements requiring the use of the Provider Access API to access patient data and avoid unnecessary repeat testing?
- If providers, MA organizations or other stakeholders have identified clinically inappropriate duplicate imaging and laboratory testing, what barriers have been faced implementing programs to address this issue and how might CMS address these challenges?
- What processes, policies, and technologies do providers, and MA organizations use to identify and prevent unnecessary duplicate diagnostic imaging and laboratory testing? CMS welcomes submission of this information and other data to better understand the potential magnitude of the problem.
- Whether MA organizations and their contracted providers would benefit from expanded conformance testing tools, certification approaches, or CMS-provided best practice

implementation guidance to support consistent adoption of laboratory and imaging exchange standards?

● How MA organizations leverage existing interoperability infrastructure (for example, Patient Access APIs) to improve MA enrollee access to their own diagnostic imaging and laboratory results, and what barriers currently prevent enrollees from accessing this information?

● How provider and MA organizations' policies and interoperable health IT tools should distinguish between clinically necessary repeat testing and potentially avoidable duplication given that repeat imaging or laboratory testing may be clinically appropriate in certain circumstances (for example, trauma, evolving emergencies, or monitoring of chronic conditions), and are there any strategies CMS could implement to facilitate policy alignment?

● How interoperability health IT tools and standards enabling interoperability can be used to improve providers' access to previously performed testing and imaging results, and support MA organization initiatives to reduce clinically inappropriate duplicate diagnostic imaging and laboratory testing?

Finally, although significant progress has been made in advancing the electronic exchange of health care data, CMS recognizes that meaningful opportunities remain to broaden the health technology ecosystem beyond the exchange of clinical data to focus on patient health outcomes. Through the Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model, the CMS Innovation Center is testing an outcome-aligned payment approach in Original Medicare to expand access to new technology-supported care options to help people improve their health and prevent and manage chronic disease. Major health plans have signed a pledge to adopt an outcome-based payment structure aligned to the ACCESS Model.[58] Expanding interoperability to encompass administrative and operational functions such as enrollment and eligibility verification, quality measure data submission, and claims processing could reduce

[58] ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model. CMS Innovation Center. https://www.cms.gov/priorities/innovation/innovation-models/access

burden, increase program efficiency, and improve patient health outcomes. CMS solicits comments on the following:

● What strategies could CMS employ to promote greater adoption and use of interoperable health IT tools and standards to exchange information beyond clinical data between MA organizations and providers to facilitate more outcome-based technology-supported care?

● What opportunities exist to leverage existing interoperability infrastructure to improve and streamline administrative functions, for example, to facilitate more outcome-based payment models and/or support quality measure data exchange between providers and MA organizations?

● What non-technical barriers impede the advancement of interoperability?

● Given the technical and operational costs associated with implementing interoperable health IT tools, are there any financial incentives, shared infrastructure, or other support mechanisms CMS should consider to assist providers and/or MA organizations in adopting additional data exchange capabilities to improve the efficiency of administration and operational functions and improve patients' health outcomes through technology-supported care?

CMS encourages stakeholders to submit comments on any additional issues or opportunities that could advance interoperability in the MA program in both the near- and long-term.

I. Strengthening Maximum Fair Price Effectuation Policies for Medicare Advantage (§§ 422.2, 422.100, and 422.504)

1. Medicare Transaction Facilitator Requirements for Network Providers

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), as proposed to be defined at § 422.2 and discussed in section II.I.8 of this proposed rule, 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: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026, 2027 and 2028 on September 30, 2025 (hereinafter "final guidance for initial price applicability year 2028"). Among other things, the final guidance for initial price applicability year 2028 established the policies for manufacturer effectuation of the MFPs for selected drugs, as proposed to be defined at § 422.2, covered under Part D for 2026, 2027, and 2028.

On July 16, 2026, CMS issued the Draft Guidance, Manufacturer Effectuation of the Maximum Fair Price in 2028[59] under the Medicare Drug Price Negotiation Program (hereinafter "draft guidance"). When finalized, such guidance will be the applicable guidance for

[59] The Draft Guidance, Manufacturer Effectuation of the Maximum Fair Price in 2028 is available at https://www.cms.gov/files/document/ipay-2028-effectuation-draft-guidance.pdf. CMS expects to issue the Final Guidance, Manufacturer Effectuation of the Maximum Fair Price in 2028 in Fall 2026. When issued, this final guidance will supersede for 2028 only the sections of the final guidance for initial price applicability year 2028 with respect to manufacturer MFP effectuation for selected drugs covered under Part D that are included and updated in the final guidance.

manufacturer effectuation of MFPs for 2028 with respect to selected drugs covered under Part D and/or payable under Part B, as applicable. In the draft guidance, we noted that we also planned to engage in rulemaking to propose certain policies under Medicare Parts B and C that relate to or have implications for the Negotiation Program but involve exercising authorities under the Social Security Act ("the Act") that are not subject to the IRA's program instruction requirement as described in the preceding paragraph. Accordingly, as discussed in more detail below, in this proposed rule, we are proposing to amend § 422.504 to require that any contract between the Medicare Advantage (MA) organization (hereinafter, "MA organization") and a provider (as defined in § 422.2), or between a first tier, downstream, or related entity and a provider on the MA organization's behalf, for participation in one or more of the MA organizations' networks, include a provision requiring that if the provider furnishes or administers selected drugs payable under Part B during the period when such drugs are subject to an MFP, the provider must be enrolled in the Negotiation Program's Medicare Transaction Facilitator (MTF) Data Module (DM) (hereinafter "MTF DM") (or any successor to the MTF DM) in a form and manner determined by CMS.

2. Background on the Medicare Transaction Facilitator and Manufacturer Effectuation of MFPs with respect to MA

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) with respect to 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 for initial price applicability year 2028) 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 (as defined in section 1191(c)(2) of the Act) and to pharmacies, mail

order services, and other dispensing entities dispensing selected drugs covered under Part D (hereinafter "dispensing entities") with respect to such MFP-eligible individuals. As discussed in the final guidance for initial price applicability year 2028 and the draft guidance, starting with drugs selected for initial price applicability year 2028 or with a renegotiated MFP for initial price applicability year 2028, Primary Manufacturers are also required to provide access to the MFP of a selected drug to hospitals, physicians and other providers of services or suppliers that furnish or administer selected drugs payable under Medicare Part B (hereinafter "Part B provider(s)") with respect to such MFP-eligible individuals.[60] In sections 40.4 of the final guidance for initial price applicability year 2028 and the draft guidance, we stated that a Primary Manufacturer must provide access to the MFP to dispensing entities and Part B providers, as applicable, in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity or Part B provider when acquiring the drug is no greater than the MFP, or (2) retrospectively providing reimbursement for the difference between the dispensing entity or Part B provider's acquisition cost and the MFP. The MTF, as currently operationalized for selected drugs covered under Part D in 2026 and 2027, has two distinct modules, the MTF DM and the MTF Payment Module (hereinafter "MTF PM"), where the latter is a voluntary option to pass payment for MFP refunds (that is, the amount the Primary Manufacturer has determined is equal to the difference between the dispensing entity and/or Part B provider's acquisition cost and the MFP) from Primary Manufacturers to dispensing entities. As discussed in the draft guidance, CMS intends to expand MTF DM and MTF PM functionality to allow pass through of MFP refunds from Primary Manufacturers to Part B providers, in addition to dispensing entities, in 2028. The combined data and payment facilitation functionalities present in the MTF DM and the MTF PM, respectively, attempt to address the interest expressed by dispensing entities, Part B providers and

[60] Hereinafter, consistent with and in reference to the draft guidance, CMS uses "Part B providers" to refer to hospitals, physicians, and other providers of services or suppliers that furnish or administer selected drugs payable under Part B. In reference to the proposed revisions herein to Part 422, CMS uses the regulatory term "provider" as defined at § 422.2 and specifies when such proposed requirements apply to the subset of such providers that furnish or administer selected drugs payable under Part B.

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.

a. Enrollment in the MTF DM

As discussed in section 40.4.2 of the draft guidance, consistent with section 1193(a)(5) of the Act, CMS believes mandatory participation for Primary Manufacturers in the MTF's data exchange functionality is necessary to administer the Negotiation Program, as well as to promote compliance and oversight. For Primary Manufacturers that reach an agreed-upon MFP for initial price applicability year 2028, we intend to require all such Primary Manufacturers to register with the MTF DM by May 1 of the calendar year before the MFP would go into effect (that is, May 1, 2027) 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 user agreements to participate in the MTF DM; all Primary Manufacturers will be required to sign an MTF DM User Agreement[61] with CMS during the MTF DM enrollment process. Primary Manufacturers who elect to participate in the voluntary MTF PM will also be required to sign the Medicare Transaction Facilitator Payment Module Contractor Agreement (hereinafter the "MTF PM User Agreement") with the MTF PM Contractor. These MTF agreements establish the rights and responsibilities of all parties involved in the MTF. The MTF agreements contain provisions requiring the Primary Manufacturer to comply with data use, privacy, and security requirements to protect the data elements received from and transmitted to the MTF.

In addition to requirements for Primary Manufacturers to participate in the MTF DM, § 423.505(q) states that for contract year 2026 and all subsequent years, Part D plan sponsors are required to include in their pharmacy agreements for participation in one or more of the Part D

[61] See: Medicare Transaction Facilitator for 2028 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) available at https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10912.

sponsor's networks a provision requiring pharmacies to be enrolled in the MTF DM (or any successor to the MTF DM) in a form and manner determined by CMS, as discussed in the "Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" (90 FR 15792) (hereinafter "contract year 2026 final rule").

As stated in section 40.4.2.2 of the draft guidance, dispensing entity enrollment in the MTF DM is necessary for operations related to administration of the Negotiation Program and the Part D program, including creating and making available remittances or Electronic Remittance Advice (hereinafter "ERAs") that use the X12 835 standard adopted under HIPAA (except when MFP refund payments are made outside of the MTF PM), maintaining dispensing entity access to the complaints and disputes submission portal, facilitating continued access to selected drugs that are covered under Part D, and ensuring accurate Part D claims. We refer readers to the contract year 2026 final rule for detailed discussion on the contractual requirement for dispensing entity enrollment (90 FR 15835 through 15837). As discussed in section 40.4.2.2 of the draft guidance and in more detail later in this section, Part B provider enrollment in the MTF DM similarly provides for several key functionalities that benefit Part B providers and support timely and transparent financial and compliance activities related to manufacturer MFP effectuation. These functionalities include collecting and sharing of banking information from Part B providers to Primary Manufacturers; creating and sending of ERAs (for electronic transfer of funds) or remittances (for paper checks) to Part B providers; a streamlined ability to submit complaints and disputes regarding MFP availability with respect to selected drugs furnished or administered to MFP-eligible individuals; and the ability for Part B providers 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.

b. MTF DM Verification of MFP Eligibility

Consistent with the processes for selected drugs covered under Part D, CMS has discussed in the draft guidance that for selected drugs payable under Part B, the MTF DM would support verification that a selected drug was furnished or administered to an MFP-eligible individual, as described in section 40.4.2.1.2 of the draft guidance. With respect to selected drugs payable under Part B that are furnished or administered to Part C enrollees, CMS does not receive actual Part C claims from MA organizations; rather, we receive MA encounter data records that MA organizations submit for risk adjustment. MA encounter data records are not claims; they are records of healthcare services provided to Part C enrollees, including furnished or administered drugs payable under Part B, containing information about patient-provider encounters. Under the Negotiation Program, as discussed in section 40.4.2.1.2 of the draft guidance, CMS intends to use MA encounter data records as the source of information to provide claim-level data elements to Primary Manufacturers for selected drugs payable under Part B that are furnished or administered to an individual enrolled in an MA plan for 2028. For MA encounter data records for Part B items and services, the MTF DM would provide Primary Manufacturers with data that were submitted by the MA organization to the Medicare Advantage Encounter Data System (EDS).[62] That is, under this approach, once an MA organization submits an MA encounter data record to the EDS, no further action is required by the MA organization to review or verify the claim-level data elements extracted from the MA encounter record before the data elements are transmitted from the MTF DM to the Primary Manufacturer.

CMS, using EDS, will also perform verification steps to validate that the individual was enrolled in an MA plan under Part C on the date of service reported on the encounter data record. Encounter data records that have been verified as related to services rendered to individuals enrolled in an MA plan under Part C on the date of service reported are then transmitted to the

[62] At § 422.504(l) MA organizations submit an attestation that the data submitted for risk adjustment purposes is "accurate, complete, and truthful." As discussed in this proposed rule, CMS is proposing to apply a new certification requirement under § 422.504(q)(2) to the data submitted under § 422.504(q)(1).

Integrated Data Repository (IDR). Data in the IDR from the encounter data record that is associated only with a selected drug payable under Part B would be transmitted to the MTF DM, which would prepare the file of claim-level data elements for MFP-eligible claims for transmittal to the applicable Primary Manufacturer. Prior to transmission to the Primary Manufacturer, the MTF DM would confirm that the data reflect furnishing or administration of a selected drug payable under Part B and subject to an MFP by confirming the Healthcare Common Procedure Code Set (HCPCS) code on the MA encounter record received from the IDR contains a selected drug that is subject to an MFP on the claim-from date based on presence of the Selected Drug List and MFP File and, that a modifier indicating furnishing or administration of a selected drug or 11-digit National Drug Code (NDC-11) for a selected drug, as applicable, appears on such record. Therefore, considering that the Part C enrollment status of the individual will have been twice verified, by the MA organization and EDS, and that furnishing or administration of the selected drug will have been verified by the MTF DM 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 payable under Part B that was furnished or administered to an MFP-eligible individual.

c. MFP Payment Window

For operational consistency with manufacturer prompt payment requirements for selected drugs covered under Part D and to ensure Part B providers receive MFP refunds promptly, as discussed in section 40.4.2.1.3 of the draft guidance, we intend to require the same 14-day prompt MFP payment window for selected drugs payable under Part B as for selected drugs covered under Part D. In the draft guidance, we stated that unless the Part B provider'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 draft guidance, the Primary Manufacturer establishes that section 1193(d)(1) of the Act (related to 340B discounts) applies, CMS would require 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 furnished or administered to an MFP-eligible individual to the Primary Manufacturer ("14-day prompt MFP payment window"). For Part D claims, Original Medicare ("OM") claims, and MA encounters, the MTF DM's transmission of the claim-level data elements to the Primary Manufacturer starts the 14-day prompt MFP payment window, within which the Primary Manufacturer must transmit the claim-level payment elements (described further in sections 40.4.3 and 40.4.4 of the draft guidance) for each claim or encounter, as applicable, identified in the claim-level data elements that the MTF DM transmits to the Primary Manufacturer and, if applicable, would be required to transmit payment of an amount that provides access to the MFP when an MFP refund is appropriate. A Primary Manufacturer electing to provide access to the MFP via a retrospective refund would meet its obligation to make the MFP available by transmitting payment of an amount that provides access to the MFP within 14 calendar days of when the claim-level data elements are sent to the Primary Manufacturer by the MTF DM.

d. MTF PM Processes

If a Primary Manufacturer elects to use the MTF PM, then the MTF PM would facilitate the transmission of MFP refund payments from participating Primary Manufacturers to dispensing entities and/or Part B providers on MFP-eligible claims of selected drugs. Participation in the MTF PM would be voluntary for Primary Manufacturers, which would have the option of passing MFP refund payments to Part B providers through the MTF PM or using their own processes outside of the MTF PM to effectuate the MFP. See section 40.4.3.4 of the draft guidance for additional details describing the pass through of Primary Manufacturers' MFP refund payments to Part B providers through the MTF PM for selected drugs payable under Part B.

3. Requirement for MA Organizations' Contracts with Network Providers to Require Enrollment in the MTF DM

CMS has broad contracting authority with respect to MA organizations under section 1857(e) 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 C statute. Under this authority, we propose to modify the regulation at § 422.504 (regarding Contract provisions) to establish that any contract between the MA organization and a provider (as defined in § 422.2), or between a first tier, downstream, or related entity and a provider on the MA organization's behalf, for participation in one or more of the MA organization's networks, must include a provision requiring that if the provider furnishes or administers selected drugs payable under Part B during the period when such drugs are subject to an MFP (as defined in proposed § 422.2), the provider must be enrolled in the MTF DM (or any successor to the MTF DM) in a form and manner to be determined by CMS. We emphasize that under the proposed regulation, such provision must require the provider "to be enrolled" in the MTF DM, as opposed to merely requiring the provider "to enroll" in the MTF DM, to establish an ongoing obligation that the provider maintain its enrollment in the MTF DM. We also propose that such provision must require such provider to maintain and certify to CMS that the enrollment information provided in the MTF DM is accurate, complete, and up to date, in accordance with applicable terms and conditions of participation with the MTF DM, in a form and manner to be determined by CMS. We propose amending § 422.504 by adding paragraph (p) to codify this requirement.

Consistent with section 1857(e)(1) of the Act, such a requirement would be necessary and appropriate and not inconsistent with the Part C statute. As previously mentioned, the MTF DM would contain several key functionalities that are necessary and appropriate for operations related to administration of the Negotiation Program and the Part C program. Through each of the functionalities outlined below, enrollment in the MTF DM of providers that furnish or administer selected drugs payable under Part B would help ensure continued beneficiary access to selected drugs that are payable under Part B by MA organizations.

First, the MTF DM would provide providers enrolled in the MTF DM with ERAs[63] to reconcile MFP refund payments when a Primary Manufacturer chooses to pass payment to the provider through the MTF PM. To meet industry standards in the creation of an accurate ERA, up-to-date banking information for a provider is needed. As part of a provider's enrollment in the MTF DM, the provider would affirm the payment account information, and the corresponding payment information would be used to deposit the MFP refund payment issued by the Primary Manufacturer for MFP-eligible claims in the form of an electronic funds transfer deposit. For Primary Manufacturers that make payments outside of the MTF PM, we intend to make information available to the Primary Manufacturer through the MTF DM, such as the provider's banking information and designated destination for ERAs.

These ERAs would assist providers that furnish or administer selected drugs payable under Part B in closing out their open accounts receivable, thereby minimizing cashflow interruptions. Specifically, the information contained in the ERA will connect the MFP refund amount paid by the Primary Manufacturer with how the payment was made, including the associated electronic funds transfer information, if applicable. We expect this would enable providers to review their accounts receivables (consistent with each provider's own standard business practices) for each claim and determine whether a Primary Manufacturer has paid all the claims the provider believes are MFP-eligible claims, in the amounts the provider believes are sufficient to effectuate the MFP. Moreover, we have consistently heard from interested parties that without an ERA, providers would not have means to determine which claim they were paid an MFP refund on, and which claim they were not.

Second, there would be streamlined access for providers enrolled in the MTF DM to submit complaints and disputes within the MTF DM to help identify issues with timely MFP refund payment, supporting providers in continuing efficient operations and preventing undue

[63] As discussed in the draft guidance, the MTF DM will provide remittances in lieu of ERAs for paper check payments. However, paper check payments will be limited to extenuating circumstances as discussed in the draft guidance.

financial hardship, while maintaining accuracy of MA encounter data records and payment. Allowing providers streamlined access to this system will support the administration of the Negotiation Program and the Part C program. Through the MTF Helpdesk Portal webpage,[64] a provider can submit a complaint related to MFP availability, which CMS will review. While providers are encouraged to remediate with the manufacturer directly if they believe that they have not received a retrospective refund payment necessary to effectuate the MFP, providers may use the complaint and dispute system referenced above to alert CMS if the provider believes Negotiation Program requirements are not being met.

Third, the MTF DM would serve as a central repository for information about providers 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. Consider a scenario in which a provider purchases a selected drug at the average sales price (ASP). Providers may experience a temporary cashflow gap while waiting for payment from the MA organization and a retrospective MFP refund payment from the Primary Manufacturer. However, upon receiving the MFP refund payment, the provider's temporary cashflow gap is reduced, the extent of which is determined by the MA organization's payment terms for selected drugs payable under Part B. 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 a more stable cashflow and lower likelihood of a long-term cash deficit over time. During MTF DM enrollment, we will ask providers to self-identify whether they are a provider that anticipates having material cashflow concerns at the start of the initial price applicability year in connection with Primary Manufacturers' effectuation of MFP. The types of entities we anticipate may self-report through this process include independent physician clinics, providers that furnish or administer a high volume of drugs payable under Part B, providers who predominantly rely on drug administration revenue to maintain business

[64] The MTF Helpdesk is available at https://mtf.helpdesk.cms.gov/home.

operations, rural providers, and sole community hospitals. The information self-reported by providers will be provided to Primary Manufacturers to assist in the development of their MFP effectuation plans, which must include a process for mitigating material cashflow concerns for providers. The MTF DM will also be available to providers enrolled in the MTF that need to update their self-identification with respect to material cashflow concerns, as we anticipate that indication could change over time.

Fourth, we intend that providers enrolled in the MTF DM would be able to view the status of available credits and MFP refunds from Primary Manufacturers through the MTF DM. The ability to track credits and MFP refunds could also help providers better manage their cashflow or aid their financial planning by providing insight into credits incurred based on adjustments to prior claims that may be applied to future MFP refund payments.

Fifth, the MTF DM would collect and share financial information, including banking information, belonging to providers enrolled in the MTF DM with Primary Manufacturers that pay MFP refunds to providers outside the MTF PM. As such, during MTF DM enrollment, providers will have the ability to approve MTF DM use of the provider's financial information as reported in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS), including the banking information that will inform where MFP refunds (as applicable) will be routed; providers opting not to use the PECOS data will have the ability to manually complete the MTF DM enrollment process, including provision of banking information. We believe that collecting and sharing of providers' 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 providers to continue efficient operations.

In sum, we believe that enrollment in the MTF DM by providers that furnish or administer selected drugs payable under Part B would facilitate continued beneficiary and provider access under the MA program to selected drugs that are payable under Part B. Manufacturers and providers have asked the agency to undertake a role in assuring that MFP

refund payments to providers can be made efficiently, and the MTF DM has an important role in that process. With less financial uncertainty, providers are better positioned to continue furnishing or administering selected drugs payable under Part B to MA enrollees. Of the approximately 16,000 providers that furnished or administered drugs selected for initial price applicability year 2028 that are payable under Part B to OM or MA enrollees in CY 2025, approximately 88 percent of National Provider Identifiers associated with those approximately 16,000 providers were included on an MA encounter record for such a drug in CY 2025. Therefore, given the large number of providers that furnish or administer drugs payable under Part B to MA enrollees, we believe this proposed requirement would help reach a substantial number of providers that serve MA enrollees. Requiring MA organizations' network contracts to require enrollment in the MTF DM by providers that furnish or administer selected drugs payable under Part B will help promote successful MFP effectuation by Primary Manufacturers under the Negotiation Program and facilitate continued access to selected drugs payable under Part B for MA enrollees and providers.

For the reasons stated previously, we propose to require at § 422.504(p) that any contract between an MA organization and a provider (as defined in proposed § 422.2), or between a first tier, downstream, or related entity and a provider on the MA organization's behalf, for participation in one or more of the MA organization's networks include a provision that if the provider furnishes or administers selected drugs payable under Part B during the period when such drugs are subject to an MFP (as defined in proposed § 422.2), the provider must be enrolled in the MTF DM (or any successor to the MTF DM), which would entail an ongoing obligation that the provider maintain its enrollment in the MTF DM, in a form and manner to be determined by CMS. We also propose at § 422.504(p) that such provision must require such provider 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, in a form and manner determined by CMS.

4. Requirement – Submission of Encounter Data Records for Selected Drugs Payable under Part B

To facilitate MFP effectuation by Primary Manufacturers and to help ensure prompt payments by Primary Manufacturers to Part B providers to provide access to the MFP with respect to selected drugs payable under Part B furnished or administered to individuals enrolled in MA plans, encounter data records for selected drugs payable under Part B warrant a submission deadline that is different from the risk adjustment encounter data submission deadline requirements at § 422.310(g). For the purposes of risk adjustment, MA organizations typically have 13 months following the service year of which payment is based (that is, the year before the payment year) to submit encounters to CMS for inclusion in final reconciliation. If CMS relied on such encounter data records to identify claims for selected drugs payable under Part B furnished or administered to enrollees of Part C plans for transmission to Primary Manufacturers for the manufacturer's MFP effectuation purposes, Part B providers could wait up to approximately 14 to 26 months to receive access to the MFP (for example, 13 to 25 months for the MA organization to submit encounter data records to the EDS, plus approximately 1 to 3 days for the encounter data records to move from EDS to the MTF DM, 2 days for the MTF DM to transmit claim-level data elements to the Primary Manufacturer, plus up to an additional 14 days for the Primary Manufacturer to transmit an MFP refund payment, and up to 5 banking days for payment transactions to process). If the Primary Manufacturer does not prospectively make the MFP available to the Part B provider, then the lag between when the Part B provider receives payment from the MA organization and when the Part B provider receives the MFP refund payment from the Primary Manufacturer could impose a financial strain on Part B providers given that anticipated MFP refunds could be a material percent of the Part B provider's purchase price. To mitigate potential financial hardship on Part B providers, which could impact Part C enrollee access to selected drugs payable under Part B, and to more closely align the timeline for MFP refund payments to providers that furnish or administer selected drugs payable under Part B

to MA enrollees with the timeline for MFP refund payments to dispensing entities that dispense selected drugs covered under Part D, CMS believes it is appropriate to create a separate new requirement for submission of MA encounter data records, as described at § 422.310(d)(5), for selected drugs payable under Part B for which an MFP (as defined in proposed § 422.2) is in effect on the claim-from date, that is earlier than the risk adjustment data submission deadline specified at § 422.310(g). This proposed new requirement would not affect or supersede existing risk adjustment submission deadlines specified at § 422.310(g) for Part B drugs or for any other items or services provided to MA enrollees. As stated at proposed § 422.504(q)(1), CMS will use this data for risk adjustment purposes unless the MA organization submits risk adjustment data required under § 422.310 by the final risk adjustment submission deadline under § 422.310(g).

In section 40.4.2.1.2 of the draft guidance, we stated that we are evaluating whether to propose a new requirement that MA organizations submit encounter data records for encounters for selected drugs payable under Part B on a timeline that is shorter than the MA risk adjustment submission timeline under § 422.310 to ensure Part B providers receive timely payment of MFP refunds by Primary Manufacturers who elect a retrospective reimbursement model. CMS received and reviewed comments from interested parties on the draft guidance related to the consideration of an earlier submission deadline requirement for encounters for selected drugs payable under Part B and used these comments to inform policy development for this rulemaking. After considering such comments and for the reasons discussed below, CMS proposes to require encounter data submission for selected drugs payable under Part B for which an MFP (as defined in proposed § 422.2) is in effect on the claim-from date, within 30 days of the claim-from date to reduce the maximum amount of time a provider that furnishes or administers a selected drug payable under Part B to an MA enrollee could wait to receive access to the MFP.

We do not receive Part C claims for drugs payable under Part B directly from MA organizations; we receive MA encounter data records that MA organizations submit for the

purpose of risk adjustment. This encounter data record contains claims information for items and services provided to individuals enrolled in an MA plan. While CMS uses MA encounter data records primarily in the development and application of a risk adjustment payment model, we may also use and release these data for other purposes not inconsistent with § 422.310(f). As discussed in the draft guidance, we intend to use MA encounter data records to facilitate manufacturer effectuation of the MFP for selected drugs payable under Part B and furnished or administered to individuals enrolled in an MA plan under Part C as the data includes many fields from the underlying claim that are necessary to facilitate the Primary Manufacturer's obligation to make the MFP available. Therefore, at this time, we believe that use of certain data elements from MA encounter data records in lieu of the actual claim provides the minimum necessary information needed to facilitate Primary Manufacturer effectuation of the MFP for selected drugs payable under Part B and furnished or administered to individuals enrolled in an MA plan under Part C. To minimize the reporting burden imposed on MA organizations, rather than requiring MA organizations to send data elements directly to Primary Manufacturers or directly to the MTF DM, we intend to leverage MA encounter data records submitted by MA organizations to CMS to obtain data elements associated with Part C claims for selected drugs. These data elements will subsequently be transmitted to Primary Manufacturers via the established MTF DM data exchange. Data in the IDR would be transmitted to the MTF DM, which would prepare the file of claim-level data elements for MFP-eligible claims for transmittal to the applicable Primary Manufacturer.

As codified in § 422.310(g), the final risk adjustment data submission deadline is no earlier than January 31 of the year following the payment year. Therefore, the risk adjustment data submission timeline typically allows MA organizations 13 months following the service year of which payment is based (that is, the year prior to the payment year) to submit encounters to CMS for inclusion in final reconciliation. We are concerned that the typical 13- to 25-month timeline for encounter data submission could result in material cashflow concerns for Part B

providers furnishing or administering selected drugs payable under Part B to MA enrollees during a price applicability period, were we to rely on risk adjustment encounter data records submitted pursuant to § 422.310(g) for facilitating Primary Manufacturer MFP effectuation. Part B providers experiencing such cashflow concerns may opt not to purchase selected drugs payable under Part B. This decision could affect the care provided to MA enrollees' by limiting access to these drugs. Therefore, unless CMS establishes a separate deadline for submission of encounter data records for encounters associated with selected drugs payable under Part B, compared to the anticipated MFP refund payment timelines for OM and Part D, the MFP refund payment timeline for MA encounters would be significantly longer. For reference, for selected drugs payable under Part B, OM claims would be typically processed by Medicare Administrative Contractors within 7 to 14 days, up to 2 days for the MTF DM to transmit claims-level data elements to the Primary Manufacturer, up to 14 days for the Primary Manufacturer to transmit an MFP refund payment, and up to 5 banking days for payment transactions to process, resulting in an approximate 21- to 28-day timeline for the Part B provider to receive the MFP refund with respect to an OM claim. For selected drugs covered under Part D, the Part D plan sponsor has 7 days to submit Prescription Drug Event records to CMS through the Drug Data Processing System (DDPS), from which the MTF DM receives data on selected drug claims. Then the MTF DM transmits the claims-level data elements to the Primary Manufacturer within two days, the Primary Manufacturer transmits an MFP refund payment within 14 days, and the MTF PM processes payment transactions within 5 banking days, resulting in an approximate 21- to 28-day timeline for the dispensing entity to receive the MFP refund.

Section 1857(e)(1) of the Act authorizes the Secretary to adopt contract terms and conditions, including requirements to provide information, as the Secretary may find necessary and appropriate and that are not inconsistent with the Part C statute. In accordance with section 1857(e)(1) of the Act, we are proposing to amend § 422.504 by adding paragraph (q) to require MA organizations to submit MA encounter data (as described at § 422.310(d)(5)) records

involving the furnishing or administration of selected drugs payable under Part B for which an MFP (as defined in proposed § 422.2) is in effect on the claim-from date, within 30 days of the claim-from date for the purpose of facilitating manufacturer effectuation of the MFP with respect to MFP-eligible individuals enrolled in an MA plan. Further, as discussed more below, we are proposing to require MA organizations to collect and submit NDC-11 codes on each MA encounter data record for a selected drug payable under Part B for which an MFP is in effect on the claim-from date. We specify that these requirements will equally apply to MA organizations participating in capitated payment arrangements with their contracted providers. Specifically, at § 422.504 (q)(1)(i), we are proposing to require MA organizations to submit encounter data records involving the furnishing or administration of selected drugs payable under Part B for which an MFP (as defined in proposed § 422.2) is in effect on the claim-from date, within 30 days of the claim-from date. We believe that requiring encounter submissions within 30 days of the claim-from date for selected drugs payable under Part B is an appropriate and operationally practical deadline in light of public comments received on the draft guidance and CMS internal analysis. CMS intends to address all public comments received in response to the draft guidance, including comments regarding an earlier submission deadline for encounters for selected drugs payable under Part B in the final guidance that is anticipated for release in Fall 2026. In recent internal analysis, we observed that 55 percent of MA encounter data records are currently submitted by MA organizations within 30 days, and 85 percent are currently submitted within 60 days of the claim from date. We are proposing to require MA organizations to submit encounter data records involving selected drugs payable under Part B for which an MFP is in effect on the claim-from date and furnished or administered to an MFP-eligible individual within 30 days of the claim-from date rather than within 60 days of the claim-from date, to ensure that providers are paid MFP refunds in a reasonable time frame from the date of furnishing or administration of the selected drug. Our concern is that an extended timeline for the MFP refund to be paid to a provider could result in cashflow issues for the provider. If providers experience continual

cashflow issues, the provider may be disincentivized from furnishing or administering a selected drug payable under Part B and subject to an MFP, jeopardizing access to these drugs for beneficiaries enrolled in an MA plan under Part C.

Under CMS' proposed requirement for submission of MA encounter data records for selected drugs payable under Part B, if finalized, payment of MFP refunds would likely be made to the Part B provider within 46 to 51 days (30 days for the MA organization to submit the MA encounter data records to the EDS, 1 to 3 days for the encounter data records to move from EDS to the MTF DM, 2 days for the MTF DM to transmit claims-level data elements to the Primary Manufacturer, 14 days for the Primary Manufacturer to transmit an MFP refund payment, and up to 5 banking days for payment transactions to process). Although this proposal to submit MA encounter data records for selected drugs payable under Part B and subject to an MFP would result in a longer MFP refund timeline for MA encounters as compared to Part D or OM claims, we believe this proposal appropriately balances giving MA organizations sufficient time to process claims and submit associated encounters while minimizing the time lag as much as possible for the MFP refund (as applicable) to be paid to Part B providers.

This proposal would not affect the existing deadline or processes for submission of MA encounter data records for the purpose of risk adjustment under § 422.310. MA encounter data records for selected drugs payable under Part B and subject to an MFP that are submitted to CMS under our proposed requirement would be used for risk adjustment except in the circumstance in which an MA organization submits a subsequent MA encounter data record for the same encounter by the final risk adjustment submission deadline under § 422.310(g). In these circumstances, the data would be processed in the same manner as all other encounter data submissions for MA payment purposes in accordance with § 422.310.[65] Therefore, MA organizations would maintain their existing MA encounter submission processes for risk

[65] See sections 40.4.2.1.2, 40.4.3.2, and 40.4.4.4 of the draft guidance for details regarding the MTF DM's processes for updated claim-level data elements, as well as regarding the credit/debit ledger system that the MTF will maintain for Primary Manufacturers participating in the MTF PM.

adjustment; and using the existing EDS submission processes for both distinct purposes would minimize additional burden for MA organizations.

5. Requirement – Collection and Submission of NDC-11s for Selected Drugs Payable under Part B

Section 1857(e)(1) of the Act authorizes the Secretary to adopt contract terms and conditions, including requirements to provide information, as the Secretary may find necessary and appropriate and that are not inconsistent with the Part C statute. CMS has used this authority to implement contract provisions that require MA organizations to report specific information to CMS for a variety of purposes, with the overall goal of improving the Part C program. For example, we relied on this authority in the Contract Year 2016 Part C and Part D final rule (80 FR 7912) to implement provisions at § 422.504(o) that require that every MA organization develop, maintain, and implement a business continuity plan that meets certain minimum standards. One of the purposes of this requirement is to ensure consistency across plan sponsors that allow beneficiaries to access health care services.

With the implementation of the Negotiation Program, we believe additional requirements for MA organizations are necessary and appropriate for consistency across MA organization operation that ultimately protect beneficiaries from coverage disruptions and facilitate access to the MFP (as defined in proposed § 422.2) for providers in accordance with section 1193(a)(3)(B) of the Act. As discussed in section I.2 of this proposed rule and consistent with the claims-level data elements discussed in section 40.4.2.1 of the draft guidance and listed in Table 6 of the draft guidance, the MTF DM would transmit to the Primary Manufacturer additional information about each claim that may be necessary in calculating the retrospective MFP refund, if applicable, including, but not limited to, the claim line NDC. Primary Manufacturers are required to provide access to the MFP to providers that furnish or administer selected drugs payable under Part B to MFP-eligible individuals. Ensuring timely access to retrospective MFP refund payments for providers is an important policy goal for CMS in administering the Negotiation

Program, and helps to ensure providers furnishing or administering selected drugs payable under Part B subject to an MFP are not disincentivized from furnishing or administering such drugs to beneficiaries enrolled in MA plans under Part C, which in turn protects continued access to such selected drugs for MA enrollees. Accordingly, we have concluded that it is necessary and appropriate to use our authority under section 1857(e)(1) of the Act to propose specific data collection requirements for MA organizations to collect and submit certain data on encounter data record submissions for selected drugs payable under Part B for which an MFP (as defined in proposed § 422.2) is in effect to ensure that Primary Manufacturers have the minimum necessary information needed to effectuate the MFP for selected drugs payable under Part B furnished or administered to individuals enrolled in Part C.

As discussed in detail below and as discussed in the draft guidance, we believe it is necessary and appropriate to require MA organizations to collect NDC-11 data on each MA encounter data record for selected drugs payable under Part B for which an MFP (as defined in proposed § 422.2) is in effect and submit such data to CMS. The proposed requirement to collect and submit NDC-11 codes at § 422.504(q)(1)(ii) is intended to facilitate MFP effectuation and protect access to selected drugs for MA enrollees by collecting information to allow identification of claims for selected drugs payable under Part B. Collecting this information supports accurate and timely MFP refund payments to Part B providers that bill MA organizations, which helps ensure providers are not disincentivized from furnishing or administering selected drugs to individuals enrolled in MA plans. We believe this data collection is necessary to protect continued access to selected drugs for MA enrollees, consistent with the goals described earlier in this section.

In section 40.4.1.2 of the draft guidance, we detailed a challenge regarding the use of HCPCS codes for selected drugs payable under Part B, whereby a Primary Manufacturer may not be able to identify whether a claim billed with a HCPCS code is MFP-eligible. Because a single HCPCS code could include or correspond with multiple NDCs, including NDCs for both

selected and non-selected drugs, it may not always be possible to determine from the HCPCS code alone whether the specific drug furnished or administered to a beneficiary is a selected drug with an applicable MFP. For example, a generic drug that relies on a selected drug that is approved under a New Drug Application (NDA) as its listed drug in the Orange Book and is approved after the selected drug is selected (and before such selected drug is deselected from the Negotiation Program) may be assigned to the same HCPCS code as the selected drug.

As described in section 40.4.1.2 of the draft guidance, this challenge is illustrated by the following scenario: drug X is a selected drug for initial price applicability year 2028, has one NDC-11 assigned to HCPCS code J1234, and is marketed under one approved NDA. Drug Y, a generic drug that has drug X as its listed drug, is determined to be approved and marketed on a date between November 2, 2026, and March 31, 2028. In this scenario, selected drug X would remain a selected drug for calendar year 2028, meaning the MFP would apply for 2028, and drug X would not cease to be a selected drug until January 1, 2029, as described in section 70 of the final guidance for initial price applicability year 2028. If drug X and drug Y share the same HCPCS code, for the period of time for which drug X and drug Y are both approved and marketed and before drug X is deselected from the Negotiation Program, the Primary Manufacturer of drug X cannot readily determine, based on the HCPCS code alone, whether a given claim for J1234 represents the furnishing or administration of drug X's NDC-11, and therefore whether the MFP for drug X should apply.

To address this scenario, we are considering different approaches, outlined in section 40.4.1.2 of the draft guidance, to identify MFP-eligible claims where an MFP-eligible NDC-11 for a selected drug has been administered or furnished to an MFP-eligible individual. One option to address the scenario described above is to require reporting of the NDC-11 for each claim for a selected drug payable under Part B. For that purpose, we are proposing to require MA organizations to collect and submit NDC-11s on each encounter data record for selected drugs payable under Part B for which an MFP (as defined in proposed § 422.2) is in effect on the

claim-from date. This requirement only applies to HCPCS codes that include a selected drug payable under Part B for which an MFP is in effect on the claim-from date, including HCPCS codes that only include the selected drug. We believe it is necessary to require NDC-11 reporting even in instances where the HCPCS code alone would demonstrate that a selected drug payable under Part B was furnished or administered, to facilitate operational simplicity and support automation, as well as to allow for greater precision in the calculation of whether refunds are necessary to make the MFP available, and in what amount.

An alternative option considered and discussed in section 40.4.1.2 of the draft guidance, is requiring the use of a claims modifier to indicate whether an MFP-eligible NDC for a selected drug was furnished or administered. As an alternative to the collection of NDC-11s, we are considering requiring the collection and submission of modifiers by MA organizations on all claims for drugs payable under Part B submitted for a HCPCS code that includes a selected drug subject to an MFP. Specifically, we could establish two modifiers that would be reported on MA encounters submitted for a HCPCS code that includes a selected drug: one modifier to indicate an MFP-eligible NDC for a selected drug was furnished or administered and a second modifier to indicate an NDC for a non-selected drug was furnished or administered. For example, when a HCPCS code that includes a selected drug is used, the illustrative "JM" modifier would be used to report that an MFP-eligible NDC for a selected drug was furnished or administered and the illustrative "JN" modifier would be used to report that an NDC for a non-selected drug was furnished or administered. CMS solicits comment on whether the collection and submission of HCPCS modifiers is preferable over the proposed collection and submission of NDC-11s and for what reasons. We anticipate that collection and submission of NDC-11s or these modifiers would support the verification that a selected drug payable under Part B for which an MFP is in effect on the claim-from date was furnished or administered to an MFP-eligible individual as discussed in section 40.4.2.1.2 of the draft guidance and would support timely MFP refund payments.

6. Requirement – Certification of Accuracy of Encounter Data Records Submitted for Selected Drugs Payable under Part B

Section 422.504(l) requires MA organizations submitting encounter data records under § 422.310 to certify that these data are accurate, complete, and truthful. The certification must be made by a Chief Executive Officer (CEO), Chief Financial Officer (CFO), or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer. As discussed previously, section 1857(e)(1) of the Act authorizes the Secretary to adopt contract terms and conditions, including requirements to provide information, as the Secretary may find necessary and appropriate and that are not inconsistent with the Part C statute. CMS has used this authority to implement contract provisions that require MA organizations to report specific information to CMS for a variety of purposes, with the overall goal of improving the Part C program.

To maintain parity with the existing certification requirements as discussed in § 422.504(l), we believe it necessary and appropriate to require a separate certification requirement under proposed new paragraph § 422.504(q)(2) regarding the data submitted under proposed §§ 422.504(q)(1). We would rely on the completeness and accuracy of the encounter data records submitted by MA organizations for purposes of risk adjustment (if the MA organization does not submit other encounter data records before the risk adjustment deadline), as well as for identifying MFP-eligible claims to be transmitted to the Primary Manufacturer. That is, CMS would rely on the completeness and accuracy of the submitted, certified data to verify MFP eligibility. CMS is concerned that absent a certification requirement, there would be insufficient safeguards for verification of MFP eligibility, resulting in inadequate information for a Primary Manufacturer to determine whether a MFP payment is owed to the provider. This proposed new requirement would require the CEO, CFO, or individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, to certify (based on best

knowledge, information, and belief), in a form and manner as specified by CMS, that the data submitted under proposed §§ 422.504(q)(1) are accurate, complete and truthful.

We believe that the provision at proposed § 422.504(q) would not have an impact on the Medicare Trust Fund. There is no collection of information related to this change and, therefore, no change to paperwork burden to MA plans or individuals.

7. Medicare Advantage Out-of-Network Cost Sharing for Selected Drugs Payable Under Part B

As discussed in section 80 of the draft guidance, pursuant to the requirement in section 11001(c) of the IRA that CMS use program instruction or other forms of program guidance to implement section 11001 of the IRA, including amendments made by such section, for 2028, CMS intends to establish through guidance for 2028 that when an MA plan uses coinsurance, the dollar amount of in-network coinsurance for selected drugs payable under Part B for individuals enrolled in MA plans must be calculated based on a price that is no more than the MFP. In the draft guidance, CMS solicited comments on whether, consistent with this intended policy for in-network coinsurance, a potential requirement to establish that MA plans must calculate the 50 percent out-of-network coinsurance cap for selected drugs payable under Part B based on the MFP would implement necessary and sufficient safeguards to ensure MA enrollees are not subject to benefit design that discriminates on the basis of health status-related factors or is likely to substantially discourage enrollment by certain MA-eligible individuals, as prohibited by section 1852(b)(1) of the Act. CMS used the comments submitted in response to the comment solicitation to inform policy development for this rulemaking.

CMS has broad contracting authority with respect to MA organizations under section 1857(e) 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 C statute. Furthermore, under section 1852(b)(1) of the Act, CMS shall not approve an MA plan if its design and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals with the organization. Under these authorities, we propose to modify the regulation at

§ 422.100(f)(6)(i) to establish that for selected drugs payable under Part B that are subject to an MFP (as defined in proposed § 422.2) and furnished or administered by an out-of-network provider, 50 percent coinsurance or an actuarially equivalent copayment value under 42 CFR 422.100(f)(6)(i) must be calculated based on a price that is equal to or less than the MFP for out-of-network cost sharing. CMS believes the proposed modification to the regulation, if finalized, would be necessary and appropriate and would implement safeguards to ensure MA enrollees are not subject to discriminatory benefits or discriminatory costs for basic benefits.

Consistent with section 1852(b)(1) of the Act, such a requirement would be necessary to ensure that MA plans (including Employer Group Waiver Plans) are not designed to substantially discourage enrollment by MA-eligible individuals who are furnished or administered selected drugs payable under Part B. Under section 80 of the draft guidance, the maximum dollar amount of in-network coinsurance an MA enrollee may be charged for a selected drug payable under Part B is based on the MFP of such selected drug in the same manner as it would have been if the individual had been enrolled under OM. This proposal would similarly ensure that MA enrollees who obtain a selected drug out of network receive the benefit of the MFP for coinsurance purposes and would ensure MA plans are not designed to substantially discourage MA-eligible individuals who are furnished or administered selected drugs payable under Part B from enrolling in MA.

To illustrate the impact on beneficiary out-of-pocket costs, take an example selected drug with an ASP of $125 and an MFP of $100. In a situation under which the MA organization's total financial liability for an out-of-network provider furnishing or administering a selected drug payable under Part B is ASP + 6 percent, the total cost for the drug would be $132.50. Beneficiary coinsurance calculated at the maximum for out-of-network services of 50 percent would be $66.25. At MFP + 6 percent, the total cost for the drug would be $106. Under our proposed change to the regulation, beneficiary coinsurance calculated at the maximum for out-of-network services would be no greater than $53, savings of $13.25.

We believe that the proposed changes to the regulatory text would not have an impact on the Medicare Trust Fund. There is no collection of information related to this change and, therefore, no change to paperwork burden to MA plans or individuals.

8. Definitions for Key Terms Related to the Negotiation Program

As discussed above, we are proposing to define two terms from the Negotiation Program statute that are used in our proposed revisions to §§ 422.100 and 422.504. Specifically, we propose to add definitions at § 422.2 for the following terms: "Maximum fair price (MFP)" and "Selected drug".

- "Maximum fair price (MFP)"

We propose to define "maximum fair price (MFP)" as having the meaning specified in section 1191(c)(3) of the Act.

- "Selected drug"

We propose to define "selected drug" as having the meaning given such term in section 1192(c) of the Act and any applicable regulations and guidance. Such definition aligns with the definition used in the Part D regulations at § 423.100.

J. Low Performer Icon (LPI) Notice (§§ 422.2267 and 423.2267)

Sections 1851(d)(1) and 1860D-1(c) of the Act require CMS to take the necessary actions to provide Medicare beneficiaries with information regarding coverage options to promote active and informed enrollment decisions. As part of this responsibility, CMS has established the Medicare Star Ratings system to provide beneficiaries with information regarding the quality and performance of MA and Part D plans.

As described in 42 CFR 422.162 and 423.186, CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA-PD contract, and a Part C summary rating for each MA-only contract using a 5-star rating system, with 1 being the lowest rating and 5 being the highest. Contracts that receive one or two stars are designated as "low performing" and receive an icon designating such status. Since 2012, CMS has mailed a low performing icon (LPI) notice to beneficiaries enrolled in MA, MA-PD, or standalone Part D plans that have received an overall Star Rating of less than 3 stars (that is, ratings of 1, 1.5, 2, or 2.5 stars) for 3 or more consecutive contract years in order to inform beneficiaries that their plan has demonstrated consistently low performance and encourage them to review other plan options available in their area. The notice also informs beneficiaries of their ability to use a special enrollment period (SEP) to enroll in a plan that is not identified as a low-performing plan. CMS currently produces and mails this notice as CMS Product No. 11627.

We are proposing to codify a requirement at §§ 422.2267(e)(31) and 423.2267(e)(33) that plans meeting the LPI notice threshold furnish the CMS-approved LPI notice directly to their enrollees rather than CMS mailing the notice on the plans' behalf. Under this proposal, plans that have received an overall Star Rating of less than three stars for three or more consecutive contract years would be responsible for providing a standardized notice to affected beneficiaries. We are proposing that plans must furnish the notice no later than November 15 of each contract year to beneficiaries enrolled during the current plan year. We believe this deadline is appropriate because it falls after CMS releases updated Star Ratings on Medicare Plan Finder,

ensuring the notice reflects the most current Star Ratings information available, and ensures beneficiaries receive the notice during the annual election period (AEP), which runs from October 15 through December 7, providing them with sufficient time to review their plan options and exercise their SEP rights. If finalized, this requirement would apply beginning with Star Ratings issued for contract year 2028, which means that plans that are designated with the LPI for 2028 would have to mail notices no later than November 15, 2027.

CMS would continue to develop and approve the notice content and would require plans to use the CMS-approved LPI notice with only minimal alterations, consistent with the standardized materials requirements under §§ 422.2267(b) and 423.2267(b). We believe this approach would improve transparency and accountability by clearly establishing plan responsibility for furnishing the notice while ensuring that beneficiaries continue to receive consistent and accurate information regarding plan performance and available enrollment options, and applicable SEP rights that are currently provided through the notice.

Current regulations do not expressly require low-performing plans to furnish the notice directly to their enrollees. We believe codifying this requirement would establish a clear and durable regulatory framework to promote consistent administration of the notice requirement and align communication responsibilities. We recognize that affected plans would incur costs associated with furnishing the notice to enrollees. However, because plans routinely communicate with their members and maintain enrollee mailing information, we believe plans are operationally positioned to implement this requirement.

K. LI NET Program: Definition of Pharmacies "In Good Standing" and Other Changes (§§ 423.2504 and 423.2508)

Division CC, title I, subtitle B, section 118 of the Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116-260) amended section 1860D-14 of the Social Security Act (the Act) by redesignating subsection (e) of section 1860D-14 of the Act as subsection (f) and by establishing a new subsection (e) Limited Income Newly Eligible Transition (LI NET) Program. Subsection (e)(1) directs the Secretary to carry out a program to provide transitional coverage for covered Part D drugs for LI NET eligible individuals no later than January 1, 2024. We published the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule (88 FR 22342) in April 2023 establishing the LI NET program as a permanent part of Medicare Part D at 42 CFR part 423 subpart Y, beginning at § 423.2500.

Section 1860D-14(e)(4)(B)(ii) of the Act requires the LI NET program to permit all pharmacies that are determined by the Secretary to be in good standing to process claims under the program. Section 423.2508(b) requires the LI NET sponsor to allow pharmacies in good standing, whether considered participating in its network or not, to process claims under the LI NET program. Additionally, § 423.2512(c)(6) requires the LI NET sponsor to adjudicate claims from out-of-network (OON) pharmacies that are in good standing according to the LI NET sponsor's standard reimbursement for their network pharmacies. Based on experience implementing the program to date, we understand that the LI NET sponsor faces challenges with respect to auditing and collecting overpayments for LI NET claims from OON pharmacies. An OON pharmacy does not have a contract with the LI NET sponsor and is not a first tier, downstream, or related entity (FDR) of the LI NET sponsor, as such terms are defined at §§ 423.501 and 423.4. As such, the obligations on the LI NET sponsor to require its FDRs to allow CMS to audit and inspect records related to Part D contracts by agreeing to the audit and

records retention requirements in § 423.505(i) are not applicable with respect to OON pharmacies. Similar FDR audit and records provisions in, for example, § 423.505(b)(10) and (e)(2) are not applicable because OON pharmacies are not FDRs. As OON pharmacies are not contractually obligated to provide information to the LI NET sponsor in response to an audit request, OON LI NET claims have historically been challenging to audit. Because the LI NET sponsor contracts with CMS, it must meet the necessary conditions as a Part D plan sponsor at § 423.504(b)(4)(vi) and requirements listed in § 423.505 (that are not waived under § 423.2536). This includes the adoption and implementation of an effective compliance program, including measures that prevent, detect, and correct noncompliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. To help the LI NET plan sponsor meet this obligation, CMS proposes adding agreement to and compliance with the LI NET sponsor's audit and record retention requirements as a reasonable and necessary criterion for determining whether a pharmacy is in good standing for purposes of section 1860D-14(e)(4)(B)(ii) of the Act.

Under our authority under sections 1860D-14(e)(4)(B)(ii) and (iv) of the Act, we propose to amend the current definition of a licensed pharmacy in good standing at § 423.2508(b) to include agreeing to and complying with the LI NET sponsor's audit and record retention standards when submitting a claim. These audit and record retention standards would be the same for OON pharmacies as they are for the LI NET sponsor's in-network pharmacies. We propose that the LI NET sponsor has the right to audit, evaluate, collect, and inspect any books, contracts, computer or other electronic systems, including prescription drug claims. OON pharmacies would be considered to have agreed to comply with such standards by virtue of submitting a claim to the LI NET sponsor. If an OON pharmacy fails to comply with the audit and record retention standards, the LI NET sponsor may determine that the pharmacy is no longer in good standing in accordance with its contract noncompliance process. Requiring pharmacies to agree to and comply with the LI NET sponsor's audit and record retention

standards to be considered in good standing would grant the LI NET sponsor authority to audit LI NET claims from OON pharmacies, which would improve program oversight, ensure the accuracy of claims, and protect federal funds.

Next, we propose clarifying the circumstances in which LI NET enrollment may be shorter than two months. Current regulations at § 423.2504(c)(1) state that enrollment in the LI NET program ends after two months, with the exception for those with retroactive coverage per paragraph (c)(2) of such section. This regulatory text does not expressly account for the fact that LI NET enrollment may be shorter than two months in certain circumstances, such as when an individual elects to disenroll from LI NET or enrolls in a Part D plan and that coverage starts before the start of the second month. We propose to amend § 423.2504(c)(1) to reflect that enrollment ends after 2 months, with the exception for those with retroactive coverage per paragraph (c)(2) of this section, unless the individual's enrollment ends under § 423.2504(d) prior to the end of two months.

We also propose to specify the frequency at which an individual can be granted enrollment into the LI NET program on the basis of immediate need. Section 423.2504(a) establishes that an individual is eligible for LI NET coverage if they satisfy the criteria at (a)(1) of this section related to low-income subsidy (LIS) eligibility or (a)(2) of this section related to immediate need. Specifically, § 423.2504(a)(2) provides for "immediate need LI NET coverage" to an individual who states their eligibility for LIS and immediate need for their prescription, but whose LIS eligibility as defined at § 423.773 cannot be confirmed at the point-of-sale. Current regulation text would not prevent individuals whose LIS status cannot be determined at the point-of-sale from repeatedly stating their immediate need for their prescription. To guard against individuals who are not LIS eligible from being able to repeatedly fill their prescriptions by citing their immediate need, we propose to limit an individual's use of immediate need to once per year. This approach is consistent with and would codify the LI NET sponsor's past and current process of limiting the frequency of enrollment on the basis of

immediate need to no more than once every twelve months. We propose to amend § 423.2504(a)(2) to specify that an individual who states their eligibility for LIS and immediate need for their prescription, but whose eligibility as defined at § 423.773 cannot be confirmed at the point-of-sale, will be granted immediate need LI NET coverage no more than once every twelve months.

CMS believes these proposals would have a negligible burden impact on the LI NET sponsor's operations. The proposed changes would help the LI NET sponsors receive the information from their OON pharmacies more easily, saving some administrative burden. Specifying the circumstances in which a beneficiary is enrolled in LI NET for fewer than two months and the frequency with which individuals can cite immediate need would have no impact as they both codify existing practices. All information collection impacts have already been accounted for under OMB control number 0938-1441 (CMS-10831).

L. PACE Retroactive Effective Dates (§ 460.158)

Sections 1894(f)(2) and 1934(f)(2) of the Act direct CMS to incorporate into regulation the requirements applied to Programs of All-inclusive Care for the Elderly (PACE) demonstration programs under the PACE protocol as published by On Lok, Inc., the parent company of On Lok Senior Health Services, to the extent consistent with the provisions of sections 1894 and 1934 of the Act. The Act also authorizes CMS to modify or waive certain provisions of the PACE protocol in the development of the regulation, if the modification or waiver were not inconsistent with and would not impair the essential elements, objectives, and requirements of sections 1894 and 1934 of the Act.

The CMS-1201-F rule (71 FR 71244) published in the **Federal Register** on December 8, 2006, finalized HCFA-1903-IFC, the interim final rule with comment period published in the **Federal Register** on November 24, 1999 (64 FR 66234). CMS-1201-F established requirements for PACE under the Medicare and Medicaid programs, including regulations at § 460.158 related to the effective dates of enrollment into a PACE program. Section 460.158 specifies that the participant's enrollment in the program is effective on the first day of the calendar month following the date the PACE organization receives the signed enrollment agreement. We defined a participant as an individual enrolled in a PACE program and also identified a Medicare beneficiary who is enrolled in a PACE program as a Medicare participant and a Medicaid recipient who is enrolled in a PACE program as a Medicaid participant. As eligibility to enroll in a PACE program is not restricted to an individual who is either a Medicare beneficiary or Medicaid recipient, we acknowledge that the start or end date of an individual's enrollment in PACE is not directly linked to Medicare or Medicaid entitlement. While Medicare or Medicaid entitlement may impact a PACE participant's premium or cost sharing obligations, the lack of such entitlement cannot be used as a basis for denying PACE enrollment or involuntarily disenrolling a PACE participant, as neither Medicare nor Medicaid entitlement is required. An individual's enrollment in the PACE program is effective the first day of the calendar month

following the date the PACE organization receives the signed enrollment agreement, regardless of the individual's Medicare or Medicaid status at that time.

CMS issued an HPMS memo titled "Medicare Enrollment for PACE Participants with Prospective or Retroactive Medicare Entitlement" on October 19, 2012 stating that PACE enrollment effective dates when an individual obtains retroactive Medicare entitlement could be up to one year prior to the month the request is received by the CMS Account Manager. However, this policy is not codified in regulation. The HPMS memo further explained that requests for retroactivity are limited to cases where the individual receives a retroactive Medicare entitlement award from SSA or becomes entitled to Medicare for a reason other than age (for example, disability, ESRD) that was not immediately identified and addressed by the PACE organization in a timely manner. PACE organizations with participants who later become entitled to Medicare, for example, as in cases in which an individual receives a retroactive Medicare entitlement determination from SSA or becomes entitled to Medicare for a reason other than aging into Medicare (for example, disability, ESRD), should use the retroactive process to effectuate the change in the participant's status to reflect Medicare entitlement.

Subregulatory guidance in Chapter 4 of the PACE manual specifies that CMS expects PACE programs to follow the procedures described in the Medicare Advantage & Prescription Drug Plan Communications User Guide (PCUG) to successfully submit accurate transactions to CMS within the current operating month cycle. As we reiterated in the HPMS memo entitled "Clarification of Enrollment of PACE Participants for Medicare Payment" on August 28, 2025, plans are expected to submit MARx transactions within a five-month period that begins one month before the participant becomes eligible for Medicare. However, following the guidance in the earlier 2012 HPMS memo, PACE organizations had been able to submit enrollments for PACE participants who obtain retroactive Medicare entitlement to the CMS Account Manager and request an effective date of up to a year retroactive from the month the retroactive request was submitted to CMS. This guidance potentially allows PACE organizations to delay the

submission of timely Medicare status transactions after they are informed of the PACE participants' new entitlement to Medicare. When there is a delay in submitting the appropriate transaction that reflects the PACE participant's Medicare status, it may result in PACE coverage conflicting with other program enrollments, such as MA, Part D, and LI NET, and incorrect capitation payments made to the PACE organization based on conflicting Medicare entitlement statuses reflected in MARx. For example, an individual who should be enrolled in PACE with dually-eligible status is enrolled in PACE with Medicaid-only status, or an individual who should be enrolled in PACE with Medicare-only status is still considered private pay for PACE.

When a current PACE participant gains Medicare entitlement and the retroactive request overlaps with prior MA, Part D, or LI NET coverage, the CMS Account Manager must contact the MA organization, Part D sponsor, or LI NET sponsor to determine if the prior coverage period can be cancelled and the PACE Medicare status effectuated for a retroactive date, in order to ensure that the other plan has not been used and that services have not been provided to the individual before moving forward with the retroactive request. If appropriate, then CMS's Retroactive Processing Contractor (RPC) makes the update, and the Medicare capitation payment is given to the correct plan of record for the retroactive period to avoid double payment. The majority of retroactive enrollments submitted by PACE organizations have effective dates that are fewer than 90-calendar days from the month the CMS Account Manager receives the request from the PACE organization. A small percentage of PACE enrollments have retroactive effective dates that are more than one year from the month the CMS Account Manager receives the request from the PACE organization, and even fewer go back more than two years. In 2023, 12 percent of retroactive enrollment requests had effective dates dating back more than one year from the month the CMS Account Manager received the request from the PACE organization. In 2024, this increased to 16 percent and, in 2025, it slightly decreased to 14 percent. Despite the relatively low percentage of enrollments with effective dates that go back more than one year from the month the CMS Account Manager receives the request from the PACE organization,

each retroactive enrollment request places additional burden on PACE organizations to submit documentation to CMS and on CMS Account Managers to review and make a determination. When retroactive requests date back for an extended period of time, the complexity of the review increases significantly. CMS Account Managers must assess potential overlaps with prior plan coverage, coordinate with the RPC and, in some cases, contact other plan sponsors to confirm whether coverage was provided during the retroactive period. Timely and accurate Medicare entitlement status is critical to ensuring PACE participants receive the correct level of benefits and that capitation payments accurately reflect the Medicare and/or Medicaid entitlement status of PACE participants. Delays in updating Medicare entitlement status can result in beneficiaries being incorrectly classified – for example, as Medicaid-only or private pay – potentially affecting the scope of services they receive, and the financial obligations placed upon them.

We propose to codify at § 460.158(b)(1) a retroactive timeframe of up to 3 months prior to the month the retroactive request is received when a PACE participant becomes entitled to Medicare retroactively. Codifying this timeframe provides PACE organizations with clarity and stability regarding this policy that was previously outlined in sub-regulatory guidance. By codifying a 3-month retroactive window, CMS aims to protect PACE participants from the adverse consequences that may result from conflicting information regarding enrollment status, plan premium, cost sharing and coverage for past periods, while continuing to provide PACE organizations with a reasonable timeframe to identify and submit retroactive Medicare status requests. Limiting the retroactive window to 3 months would reduce the frequency of these complex, resource-intensive reviews and allow CMS Account Managers to monitor timely and accurate enrollment processing.

CMS acknowledges that there may be cases that necessitate retroactive effective dates that extend beyond the 3-month retroactive timeframe, although we expect these to be rare. CMS recognizes that there may be instances in which strict application of this timeframe may not be appropriate for PACE participants and organizations alike. Accordingly, we propose that

CMS may approve a retroactive effective date beyond the 3-month time period from the month the CMS Account Manager receives the retroactive effective date request when CMS makes a determination that neither the PACE organization nor the participant bears responsibility for the circumstances that gave rise to the need for a retroactive effective date request. This proposal seeks to improve the timeliness of retroactive PACE submissions, reduce the potential for retroactive Medicare status change requests that overlap with other coverage, and reduce the overall number of retroactive submissions that exceed the codified timeframe of 3 months.

In addition, we propose to codify at § 460.158(b)(2) the limited reasons for when a retroactive request may be approved, which include when an individual receives retroactive Medicare entitlement from SSA or becomes entitled to Medicare for a reason other than aging into Medicare (for example, disability, ESRD). We also propose redesignating the current regulation text at § 460.158 as § 460.158(a) and adding a new heading.

CMS believes that codifying a 3-month retroactive limit will incentivize PACE organizations to act promptly to submit PACE participant status updates to CMS upon learning of a participant's retroactive Medicare entitlement and therefore minimize adverse impacts on PACE participants. Under the current subregulatory guidance, the availability of up to a 12-month retroactive window may have inadvertently reduced the urgency for PACE organizations to submit timely Medicare status transactions. By establishing a timeframe in regulation, CMS expects PACE organizations to develop internal processes to identify and act on retroactive entitlement determinations in a timely manner to reduce the overall volume of delayed submissions and associated payment reconciliation issues.

We request comments on whether the proposed 3-month retroactive timeframe is appropriate, or whether a shorter or longer timeframe would better serve the needs of PACE participants and PACE organizations.

M. Specialty Tier Eligibility with Respect to Selected Drugs and Technical Correction (§ 423.104)

1. Background

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

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" (86 FR 5864, hereinafter "Contract Year 2022 Final Rule") which appeared in the **Federal Register** on January 19, 2021, we codified at § 423.104(d)(2)(iv)(A) our methodology for setting and annually adjusting the specialty-tier cost threshold. This threshold is set to maintain approximately one percent of Part D drugs as specialty-tier eligible, consistent with § 423.104(d)(2)(iv)(A)(*3*).

Under § 423.104(d)(2)(iv)(A)(*5*), CMS approves placement of a Part D drug on a specialty tier when that Part D sponsor's claims data from the time period specified in paragraph (d)(2)(iv)(C) of this section demonstrates that greater than 50 percent of the Part D sponsor's prescription drug events (PDEs) for a given Part D drug, when adjusted for 30-day equivalent supplies, have ingredient costs for 30-day equivalent supplies, as described in paragraph (d)(2)(iv)(A)(*2*) of this section, that exceed the specialty-tier cost threshold. In accordance with § 423.104(d)(2)(iv)(A)(*6*), for newly FDA-approved Part D drugs only recently available on the

market for which Part D sponsors would have little or no claims data, CMS approves placement of a Part D drug on a specialty tier when that Part D sponsor estimates that the ingredient cost portion of their negotiated prices for a 30-day equivalent supply, as defined in subparagraph (d)(2)(iv)(A)(*2*), is anticipated to exceed the specialty-tier cost threshold more than 50 percent of the time, subject to the requirements at §§ 423.120(b), (e), and (f).

Section 11001 of the Inflation Reduction Act of 2022 (Pub. L. 117-169) created Part E under Title XI of the Act (sections 1191 through 1198) and established the Medicare Drug Price Negotiation Program which permits the Secretary to negotiate MFPs for certain high expenditure, single source drugs and biological products with participating manufacturers. The MFPs for the first 10 selected drugs took effect on January 1, 2026. Additional drugs will be selected for negotiation each subsequent year or selected for renegotiation beginning with initial price applicability year 2028, and new MFPs will take effect each year subject to agreement between CMS and participating manufacturers.

Section 11001 of the IRA also amended section 1860D-2(d)(1) of the Act by adding subparagraph (D), which requires that, in the case of a covered Part D drug that is a selected drug (as referred to in section 1192(c) of the Act) with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), the negotiated price used for payment shall be no greater than the MFP (as defined in section 1191(c)(3) of the Act) for such drug and for each year during such period plus any dispensing fees. Because the ingredient cost for a 30-day equivalent supply of a Part D drug is the negotiated price net of dispensing fees, administration fees, and sales tax, and because section 1860D-2(d)(1)(D) of the Act caps the negotiated price for a selected drug at the MFP plus dispensing fees, the ingredient cost for a 30-day equivalent supply of a selected drug cannot exceed the MFP. Further, because the MFP for a selected drug is published in advance of the applicable contract year, the maximum ingredient cost for a selected drug is prospectively known for that year.

This stands in contrast to other covered Part D drugs for which the ingredient cost is not prospectively known. CMS established the methodologies at § 423.104(d)(2)(iv)(A)(5) and (6) to determine whether the ingredient cost exceeds the specialty-tier cost threshold. The claims-history methodology described at paragraph (A)(5) uses a Part D drug's claims history as indicative of whether the drug's ingredient costs exceed the specialty-tier cost threshold. This approach reflects that, for most Part D drugs, the most recent complete data available at the time of annual bid and formulary submissions is the claims history from the plan year ending 12 months prior, and that drug prices historically have not decreased year over year. Similarly, for newly FDA-approved drugs that have little or no claims history, paragraph (A)(6) relies on the Part D sponsor's estimate of the ingredient cost portion of its negotiated prices because the ingredient cost for such drugs is not known in advance. These methodologies are not applicable to selected drugs with an MFP in effect because the selected drug's maximum ingredient cost – and therefore its eligibility for placement on a specialty tier under § 423.104(d)(2)(iv) – can be prospectively known by using the MFP. CMS has therefore applied the MFP, consistent with § 423.104(d)(2)(iv), as the basis for specialty-tier eligibility determinations for selected drugs for contract years 2026 and 2027. Applying the claims-history methodology to determine whether a selected drug is eligible for the specialty tier based on ingredient costs from a period before the MFP took effect would be inconsistent with the purpose of the specialty tier and the text of § 423.104(d)(2)(iv), which reserve the specialty tier for drugs whose ingredient costs exceed the specialty-tier threshold.

On April 23, 2026, CMS issued an HPMS memorandum titled "CY 2027 Part D Formulary Submission Information"[66] which clarified that with respect to selected drugs that have an MFP in effect for the upcoming contract year, we will not use claims history reported on PDEs to determine if the selected drug is eligible for placement on the specialty tier because,

[66] CY 2027 Part D Formulary Submission Information. April 23, 2026. https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-april-20-24

under section 1860D-2(d)(1)(D) of the Act, the ingredient cost for a 30-day equivalent supply cannot exceed the MFP for the price applicability period. Because the MFP for a selected drug is a published, known maximum ingredient cost, CMS can prospectively determine specialty-tier eligibility for selected drugs based on the published MFP for the applicable contract year. As a result, CMS will only approve placement on the specialty tier for those selected drugs for which the MFP in effect for the upcoming contract year exceeds the specialty-tier cost threshold.

In this rule, consistent with existing policy, we propose to revise our specialty-tier regulations to expressly state that, for selected drugs with an MFP in effect for the applicable contract year, CMS will use the MFP rather than PDE claims history to determine specialty-tier placement eligibility. We also propose to make a technical correction to our specialty-tier regulations at § 423.104(d)(2)(iv).

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

Section 423.104(d)(2)(iv)(A) states that CMS sets the specialty-tier cost threshold for a plan year in accordance with this paragraph (d)(2)(iv)(A), using the following steps. Paragraphs (*1*) through (*4*) of this section describe the methodology for calculating the threshold. However, paragraphs (*5*) and (*6*), do not address the methodology for setting the specialty-tier cost threshold, but rather set forth the standards CMS applies when approving a Part D drug for placement on the specialty tier. Placing the specialty-tier approval standards under paragraph (A) instead of under their own paragraph was an inadvertent structural error made when these policies were originally codified in the Contract Year 2022 Final Rule.

This current structure of § 423.104(d)(2)(iv)(A) creates a potential source of confusion since the specialty-tier approval standards at paragraphs (A)(*5*) and (A)(*6*) are not part of the specialty-tier cost threshold-setting methodology; they are distinct concepts. We are therefore proposing a clarifying technical correction to restructure § 423.104(d)(2)(iv)(A) to separate the four paragraphs addressing the specialty-tier cost threshold methodology from the two

paragraphs addressing the specialty-tier placement approval. Specifically, we propose to add new paragraph (E) at § 423.104(d)(2)(iv)(E), titled "Specialty-tier placement," to consolidate the specialty-tier placement criteria. We first propose to redesignate current § 423.104(d)(2)(iv)(A)(*5*), which addresses placement approval based on claims history, as § 423.104(d)(2)(iv)(E)(*1*). Additionally, we propose to redesignate current § 423.104(d)(2)(iv)(A)(*6*), which addresses placement approval for newly FDA-approved drugs with little or no claims history, as § 423.104(d)(2)(iv)(E)(*2*). Finally, we propose to codify the new criterion for selected drugs, discussed in detail below, at new § 423.104(d)(2)(iv)(E)(*3*).

We note that the proposed redesignations at § 423.104(d)(2)(iv)(E)(*1*) and (*2*) make no substantive change to the criteria CMS currently applies when approving specialty-tier placement based on claims history and for newly FDA-approved drugs.

3. Specialty-Tier Eligibility for Selected Drugs (§ 423.104(d)(2)(iv))

Under § 423.104(d)(2)(iv)(A)(*1*), the ingredient cost reflected on the PDE is used to determine the ingredient cost for a 30-day equivalent supply of a Part D drug for purposes of the specialty-tier cost threshold determination. As stated in the Contract Year 2022 Final Rule, negotiated prices in the PDE record are composed of ingredient cost, administration fee (when applicable), dispensing fee, and sales tax (when applicable). Because the ingredient cost generally accounts for most of the negotiated price, and has fewer variables than the negotiated price overall, the ingredient cost represents the most transparent, least complex, and most predictable of all the components of negotiated price upon which to base the determination of the specialty-tier cost threshold. The ingredient cost reflected on the PDE is therefore the negotiated price for the drug net of any dispensing fees, administration fees, and sales tax.

Section 1860D-2(d)(1)(D) of the Act, as added by section 11001 of the IRA, requires that, for a selected drug with an MFP in effect for a price applicability period, the negotiated price used for payment shall be no greater than the MFP for such drug plus any dispensing fees. Because the ingredient cost reflected on the PDE represents the negotiated price net of

dispensing fees, administration fees, and sales tax, and because the statute caps the negotiated price for a selected drug at the MFP plus dispensing fees, the ingredient cost for a 30-day equivalent supply of a selected drug cannot exceed the MFP.

Section 423.104(d)(2)(iv) requires that a drug's ingredient cost for a 30-day equivalent supply exceed the specialty-tier cost threshold for the drug to be eligible for specialty-tier placement. For most Part D drugs, CMS has had to establish methodologies, based on claims history under paragraph (A)(5) or sponsor estimates for newly FDA-approved drugs under paragraph (A)(6), to determine whether that ingredient cost exceeds the specialty-tier cost threshold because the ingredient cost is not known in advance. Those methodologies are not applicable to selected drugs with an MFP in effect because, under section 1860D-2(d)(1)(D) of the Act, the negotiated price for a selected drug shall be no greater than the MFP plus any dispensing fees, meaning that the ingredient cost, which is a component of that negotiated price, cannot exceed the MFP during the price applicability period. Because the MFP is published in advance, CMS and Part D sponsors will prospectively know whether a selected drug's maximum ingredient cost exceeds the specialty-tier cost threshold for the applicable contract year and whether the drug is eligible for specialty-tier placement, without CMS needing to apply the methodologies set forth at paragraphs (A)(5) and (A)(6). In other words, the methodologies set forth at paragraphs (A)(5) and (A)(6) for determining specialty-tier eligibility are not applicable to selected drugs during their price applicability period because the MFP for a selected drug is published and CMS can prospectively determine specialty-tier eligibility for the selected drug based on the published MFP for the applicable contract year.

Historical PDE claims data from prior contract years likely will no longer be reflective of the drug’s ingredient costs when a drug becomes a selected drug and its MFP goes into effect. As a result, using historical PDE claims data to determine specialty-tier eligibility for selected drugs would produce misleading results for selected drugs during their price applicability period as that data reflects ingredient costs from prior contract years, before the MFP for a selected drug took

effect. Because the specialty tier is reserved for drugs whose ingredient costs exceed the specialty-tier cost threshold, it would be inconsistent with both the statute and the regulatory definition of the specialty tier at § 423.104(d)(2)(iv) to base approval of specialty-tier placement for a selected drug on the drug's historical cost when the MFP in effect for the applicable contract year no longer exceeds the threshold and is prospectively known.

We are therefore proposing, consistent with the April 23, 2026 HPMS memorandum, to make explicit in our regulations that for selected drugs as defined at § 423.100, CMS will only approve placement on the specialty tier for those selected drugs that have an MFP in effect, as adjusted for inflation, if applicable, for the upcoming contract year that exceeds the specialty-tier cost threshold. If the MFP for a selected drug does not exceed the specialty-tier cost threshold, then, consistent with section 1860D-2(d)(1)(D) of the Act, the ingredient cost for a 30-day equivalent supply of that drug cannot exceed the threshold, and the selected drug would not be eligible for specialty-tier placement. In other words, we are proposing that we would not use claims data reported on previous years' PDEs to determine if a selected drug is eligible for placement on the specialty tier. Instead, we are proposing to use the MFP, which is a published, known maximum price, to prospectively determine specialty-tier eligibility for the applicable contract year.

We note that, while the MFP represents the statutory maximum amount for the negotiated price (net of dispensing fees) for a selected drug, a Part D sponsor's actual negotiated price for that drug may be lower than the MFP. However, for purposes of determining eligibility for specialty-tier placement, CMS is proposing to use the MFP, as adjusted for inflation, if applicable, not the sponsor's negotiated price, as the basis for the specialty-tier eligibility determination. This approach ensures a consistent, prospective standard across all Part D plan sponsors, and reflects that the MFP is the published, known maximum price against which eligibility can be objectively assessed.

When a Part D sponsor's negotiated price is lower than the MFP, but the MFP exceeds the specialty-tier cost threshold, we are proposing that the drug would be eligible for specialty-tier placement. This approach is consistent with how CMS currently applies the existing PDE-based methodology, under which claims data are used as a standardized benchmark to determine whether a Part D drug's costs exceed the specialty-tier cost threshold. The MFP-based placement standard that we are proposing in this proposed rule would operate similarly by using the MFP as a standardized benchmark for determining whether a selected drug is eligible for specialty-tier placement.

This proposal is consistent with the intent of the specialty tier, which is intended to encompass high-cost drugs whose ingredient costs exceed the specialty-tier cost threshold. Because the MFP represents the statutory maximum amount for the ingredient cost for a selected drug during the price applicability period, the MFP is the appropriate measure for prospectively determining specialty-tier eligibility for such drugs.

We are therefore proposing to add new § 423.104(d)(2)(iv)(E)(*3*) to specify that, for a selected drug, as defined at § 423.100, with an MFP, as defined at section 1191(c)(3) of the Act, in effect for the applicable contract year, CMS would approve placement of that drug on the specialty tier only if the MFP in effect for the contract year exceeds the specialty-tier cost threshold set in accordance with § 423.104(d)(2)(iv)(A) for that contract year. We also propose to revise newly redesignated § 423.104(d)(2)(iv)(E)(*1*) to add an exception for selected drugs.

N. Request for Information (RFI) on an Interim Medicare Part D Payment Reconciliation

1. Background

CMS makes prospective payments to Part D plan sponsors for various subsidies, including the low-income cost-sharing (LICS) subsidy, selected drug subsidy, and reinsurance. Pursuant to our authority under sections 1860D-14(c)(1)(C) and (c)(2), 1860D-14D, and 1860D-15(d)(1) of the Act, and in accordance with §§ 423.315, 423.329, and 423.343, these subsidies are paid prospectively based on information in the approved basic bid and other data provided by CMS, such as enrollment data, which updates payments throughout the year. Following the end of the coverage year, CMS performs a final Part D payment reconciliation to compare the finalized prospective payments and the corresponding actual costs reported on prescription drug event (PDE) records and, in the case of reinsurance, direct and indirect remuneration (DIR) data. CMS then makes payment adjustments according to the rules for each payment methodology. Payment adjustments can be positive or negative.

During the Part D payment reconciliation, CMS also performs the risk corridor calculation pursuant to section 1860D-15(e) of the Act and in accordance with § 423.336. This calculation utilizes the total DIR amount. The purpose of the risk corridor calculation is to limit a plan's exposure to unexpected expenses not already included in the reinsurance subsidy or considered through health status risk adjustment. The federal government and the plan share the profits or losses resulting from expenses for the basic benefit within defined symmetrical risk corridors around a target amount. The payment can be positive, negative, or zero.

Under current regulations at §§ 423.336(c) and 423.343(c), (d), and (e), sponsors are required to submit the necessary data for reconciliation, including PDE and DIR data, within 6 months following the end of the coverage year. This final data is certified by Part D sponsors in accordance with § 423.505(k)(3) and (5) and is used to calculate the final subsidy amounts as well as the final risk corridor payment. This process ensures payment accuracy for both CMS and Part D sponsors.

CMS is seeking feedback on implementation of an additional, earlier reconciliation process, known as "Interim Reconciliation" (IR), as a mechanism to address uncertainty in bidding that could result from various market factors and lead to actual costs significantly exceeding bid estimates. The plan's bid reflects the revenue needed to provide beneficiaries with the Medicare prescription drug benefit, which CMS pays through prospective subsidy payments.

When the bid closely aligns with actual costs, the Part D payment reconciliation results in smaller payment adjustments. However, these reconciliation payments can be volatile, influenced by shifts in drug utilization, drug pricing, plan bidding behavior, and statutory changes to the Part D benefit year to year. If a plan underestimates utilization, drug mix, or liability in its bid, CMS pays more during the Part D payment reconciliation. Conversely, if a plan overestimates these costs, CMS recoups payments as determined by the reconciliation calculations. For instance, the introduction of new hepatitis C prescription drug treatments significantly increased drug spending and consequently increased reconciliation amounts for coverage years 2013 through 2015. By 2016 and 2017, reconciliation amounts had stabilized as historical experience began to reflect these new drug treatments, resulting in improving bid accuracy and formulary management. Similarly, there was also a sharp increase in reconciliation amounts for coverage year 2024, likely driven by uncertainty with the Inflation Reduction Act Part D redesign. As plan sponsors gain more experience with the redesigned Part D benefit there will be less uncertainty with bidding assumptions, which is anticipated to stabilize the reconciliation payment amounts.

2. The Interim Reconciliation (IR) Concept

The IR would serve as a reconciliation process that would begin in January immediately following the coverage year, prior to the final data (PDE and DIR) submission deadline. Payment adjustments to remit or recover the estimated IR amounts would most likely occur with the March payment following the coverage year.

CMS would include the LICS, selected drug subsidy, and reinsurance calculations in the IR. The risk corridor payment would not be included in the IR because the information necessary to calculate such payment – specifically, the final Direct Subsidy Amount determined during the Final Risk Adjustment reconciliation – would not yet be available.

The estimated IR amount would be calculated based on PDE data with dates of service through December 31st as of mid-January following the coverage year (referred to here as the PDE data cut-off). CMS will need an estimate of the total DIR amount for the IR. We could require that each plan provide an estimated total DIR amount based on their actual claims experience through December 31st. The plan would submit this estimate to CMS in January following the coverage year. Alternatively, we could estimate the total DIR amount based on the sponsor's approved bid for the coverage year. To estimate the total DIR amount for IR, we would apply a ratio as follows: the projected total DIR amount in the bid divided by the projected drug costs in the bid, then multiplied by the actual drug costs as reflected in the PDE data as of the PDE data cut-off. We have concerns regarding the alternative approach, particularly if the projected total DIR amount included in the bid significantly differs from the actual experience (which as we state above is the issue we would be attempting to address with an IR process), and we request comments on this approach below.

Using this preliminary data, CMS would determine interim amounts for the LICS, reinsurance, and selected drug subsidy. This process would lead to an IR payment adjustment, with some sponsors receiving payments from CMS while others would be required to remit payments to CMS at the time of the IR payment adjustment. Our IR simulation using coverage year 2024 data show that a number of plans would have been required to remit payment to CMS at the time of the IR payment adjustment had the IR process been in place for coverage year 2024.

Based on our analysis, we could consider an IR process that would allow plans to voluntarily opt in. Under this voluntary process, we anticipate that plans would estimate their

potential IR reconciliation amount and make an informed decision regarding participation. However, if a plan's estimate is inaccurate and results in an amount owed to CMS through IR, CMS will recoup the calculated IR amount. Due to the timing between the IR and the final Part D payment reconciliation, we anticipate that an IR would not be eligible for reopening under § 423.346 or for appeal under § 423.350.

IR payment adjustments would be fully reconciled during the final Part D payment reconciliation, which takes place after the June data submission deadline and uses final, certified PDE and DIR data. The risk corridor calculation will also be completed at this time as part of the standard final Part D payment reconciliation process.

3. Request for Public Comment

CMS is soliciting comments on this IR concept to assess its necessity and feasibility, evaluate potential impacts on Part D sponsors, and determine whether such a policy would be beneficial for the Part D program. We are interested in feedback from all Part D sponsors, with a particular interest in understanding the potential effects on smaller, regional health plans. Specifically, we are requesting comments, data, and examples regarding the following:

- Potential Benefits and Risks:

++ Considering the pattern that CMS has observed, where using more representative historical data leads to improved bids and greater reconciliation stability, is it necessary to introduce a new and complex IR process?

++ What do you see as the primary benefits of an IR, if any? Conversely, what are the most significant risks or potential unintended consequences for sponsors and beneficiaries?

- Operational and Administrative Impact:

++ What would be the administrative burden and operational challenges for your organization to participate in an IR? Please comment on any required system modifications, resource allocation, and the processes involved in tracking and validating IR calculations.

++ During which month of the coverage year would your organization have sufficient information to determine whether to opt in to a voluntary IR? Given the information provided in this RFI, what is the likelihood that your organization would choose to opt in to an IR?

- Financial Impact: What effect would an interim payment or recoupment in March following the coverage year have on your organization's cash flow and overall financial stability? If possible, please provide quantitative examples to illustrate the potential impact.

- Accuracy and Data Reliability:

++ Provide feedback regarding the two possible methods for estimating the total DIR amount. Discuss the feasibility of providing an estimated total DIR amount in January following the coverage year, utilizing actual claims experience through the coverage year. Comment on the alternative approach and the accuracy of an IR that depends on an estimated total DIR amount from your bid. What is the usual difference between your bid-projected DIR and your final, actual DIR?

++ Comment on the completeness of PDE data available mid-January following the coverage year for dates of service through December 31st. What percentage of your total PDE data for a coverage year is typically submitted after mid-January following the coverage year? What percentage of your accepted PDE data for a coverage year is typically adjusted or deleted after mid-January following the coverage year? Provide examples of how PDE data evolves between January and the final June submission. How might this affect the accuracy of the IR calculations?

++ Provide comments on potential incentives that may lead to the submission of inaccurate DIR estimates. Additionally, offer insights regarding PDE data submissions, specifically addressing whether an IR could incentivize non-compliance with PDE timeliness requirements by delaying the submission of adjustment or deletion PDE records beyond the 90 calendar days allowed after discovering or receiving notification of an issue necessitating changes to previously submitted and accepted PDE records, as outlined in § 423.325(a)(2).

- Bidding and Market Effects: In what ways could an IR influence your organization's approach to bid development for upcoming plan years?

Please be advised that this is a request for information only. This RFI is issued exclusively for informational and planning purposes; it does not constitute a solicitation, a promise to issue a solicitation in the future, or a commitment to implement the policy described.

O. Request for Information on Strategies Employed by Medicare Advantage Organizations to Serve Individuals with Serious Mental Illness and Dementia

Individuals with serious mental illness face numerous health challenges and typically incur higher healthcare costs.[67] Definitions for serious mental illness vary but generally focus on chronic or ongoing conditions that have moderate-to-severe impacts on functional impairment to daily activities.[68] For example, the Substance Abuse and Mental Health Services Administration defined serious mental illness as an individual over 18 having (within the past year) a diagnosable mental, behavioral, or emotional disorder that substantially interferes with a person's life and ability to function. Conditions often associated with serious mental illness include moderate-to-severe major depressive disorder, bipolar disorder, and schizophrenia and schizoaffective disorders.[69] Furthermore, individuals diagnosed with mental disorders may develop substance use disorders and vice versa, adding to the complexity of care for these individuals.[70] In 2023, 28.6 percent of individuals enrolled in Medicare Advantage were diagnosed with depression (this includes a range of severities) at some point in their life and of those currently experiencing depression symptoms, 40.6 percent reported that it made life somewhat, very, or extremely difficult. Of respondents, 8.9 percent of individuals enrolled in Medicare Advantage were diagnosed with a mental condition other than depression at some point in their life.[71] Among individuals who are dually eligible for Medicare and Medicaid, there are a significant number of enrollees with serious mental illness: one study estimated that more

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[67] Chukrun T, Tran O, Hobbs K, Taylor JB. An innovative model of behavioral healthcare for older adults with serious mental illness, substance use disorders, and dementia. J Am Geriatr Soc. 2025;73(4):1237–1249. doi:10.1111/jgs.19313.

[68] Gonzales L, Kois LE, Chen C, López-Aybar L, McCullough B, McLaughlin KJ. Reliability of the Term "Serious Mental Illness": A Systematic Review. Psychiatr Serv. 2022 Nov 1;73(11):1255-1262. doi: 10.1176/appi.ps.202100661. Epub 2022 Jul 27. PMID: 35895839.

[69] Substance Abuse and Mental Health Services Administration. "Serious Mental Illness and Serious Emotional Disturbances." Available at: https://www.samhsa.gov/mental-health/serious-mental-illness/about. Accessed June 26, 2026.

[70] Common Comorbidities with Substance Use Disorders Research Report. Bethesda (MD): National Institutes on Drug Abuse (US); 2020 Apr. Available from: https://www.ncbi.nlm.nih.gov/books/NBK571451/.

[71] CMS. "2023 Mental Health Among Medicare Beneficiaries PUF." 2026. Available at: https://www.cms.gov/data-research/research/medicare-current-beneficiary-survey/data-tables/2023-mental-health-among-medicare-beneficiaries-puf. Accessed June 26, 2026.

than four million dually eligible enrollees had a serious mental illness in 2022.[72] Individuals with serious mental illnesses, such as schizophrenia and bipolar disorder, are more likely to die prematurely, have increased rates of other chronic diseases, and incur significant health care costs.[73,74,75]

To identify promising practices and policy opportunities, CMS included a request for information (RFI) in the "Medicare Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program" final rule (90 FR 54984) that invited comments on how to support improved access to treatment and care coordination for individuals with mental health conditions or substance use disorders, with a focus on opportunities within special needs plans (SNPs). CMS received several comments describing various challenges that impact the ability of MA organizations to offer chronic condition special needs plans (C-SNPs) focused on serving individuals with serious mental illness and substance use disorders.

In this proposed rule, CMS has pursued several policy changes based on comments received from last year's RFI and on other related proposals. For example, CMS is proposing that all SNPs must include a behavioral health provider as part of the interdisciplinary team where such a provider is actively treating or coordinating care for the enrollee, based on comments received in response to last year's rule. CMS is also proposing additional care coordination requirements for C-SNPs and institutional equivalent special needs plans (IE-SNPs) regarding Medicaid services, which should also benefit dually eligible individuals in accessing

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[72] McGinty EE, Daumit GL, Zhang M, Zhang Y. Enrollment in Integrated Special Needs Plans Among Dually Eligible Beneficiaries With Serious Mental Illness. *JAMA Netw Open.* 2026;9(6):e2616124. doi:10.1001/jamanetworkopen.2026.16124.

[73] Olfson M, Gerhard T, Huang C, Crystal S, Stroup TS. Premature Mortality Among Adults With Schizophrenia in the United States. JAMA Psychiatry. 2015 Dec;72(12):1172-81. doi: 10.1001/jamapsychiatry.2015.1737.

[74] Davenport S, Gray T, Melek S. "How do individuals with behavioral health conditions contribute to physical and total healthcare spending?" Milliman Research Report. August 2020. Available at: https://media.milliman.com/v1/media/edge/images/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/Articles/Milliman-High-Cost-Patient-Study-2020.pdf.

[75] Cook JA, Jonikas JA, Steigman PJ, et al. Registry-Managed Care Coordination and Education for Patients With Co-occurring Diabetes and Serious Mental Illness. *Psychiatric Services*. 2021;72(8):912-919. doi:10.1176/appi.ps.202000096.

and using their full range of covered services to address any mental health needs. However, sustained efforts and additional policy changes are needed to address this multifaceted issue.

CMS recognizes that individuals with serious mental illness face a complex set of challenges that extend well beyond any single policy lever. Through this RFI, CMS is focused specifically on understanding how MA plans, including SNPs, are currently serving, or could better serve, beneficiaries with serious mental illness, with particular emphasis on care coordination models, plan benefit design, community partnerships, and strategies for identifying and engaging this population.

CMS notes that prior comment processes have generated substantial feedback on topics such as risk adjustment, utilization management practices, cost-sharing requirements, and Mental Health Parity and Addiction Equity Act applicability. While CMS appreciates the importance of these broader issues, this RFI is not intended to solicit feedback on those topics, and comments focused primarily on risk adjustment, utilization management, cost-sharing, or other payment and coverage policy matters outside the scope of MA plan operations and care delivery for individuals with serious mental illness will not be the focus of CMS's review of responses to this RFI.

Instead, CMS encourages commenters to focus their responses on operational strategies, care coordination approaches, benefit design innovations, workforce solutions, and community-based partnerships that have demonstrated, or show promise for, improving access to care and health outcomes for MA enrollees with serious mental illness. CMS is particularly interested in hearing from MA organizations, SNPs, behavioral health providers, beneficiary advocates, and other stakeholders with direct experience serving this population about what is working, what is not, and what targeted changes CMS could make to support greater plan participation and improved care for individuals with serious mental illness.

To continue this progress, CMS invites comments on the following questions:

- What strategies are SNPs and non-SNP MA plans employing to address serious mental illness, substance use, and other mental health conditions among their enrollees?
- What factors are preventing SNPs from designing and offering tailored plans to address serious mental illness and how should CMS consider policies to address these hurdles?
- What are related strategies that MA plans are leveraging that would benefit this population?
- What supplemental benefits or other services have MA plans identified as beneficial for addressing the needs of individuals with serious mental illness?
- How are MA plans leveraging strategic partnerships with community-based organizations or supplemental benefit vendors to serve this population?
- Some studies have noted differences in utilization of services by individuals with serious mental illness between those enrolled in Original Medicare and those in Medicare Advantage or following disenrollment from MA.[76,77] What factors contribute to these differences? What conclusions can be drawn regarding access to care and care management?
- How are MA plans balancing the delivery of appropriate inpatient services with maintaining access to home and community-based services for individuals with serious mental illness?
- What lessons learned or best practices from state-based initiatives and Medicaid managed care organizations regarding care coordination and management for individuals with serious mental illness could be applicable for MA plans?
- How are MA plans currently identifying enrollees with serious mental illness within their populations, and what processes are in place to ensure these individuals are connected to appropriate behavioral health services and care coordination supports? What challenges do MA

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[76] Park S. Effect of Medicare Advantage on health care use and care dissatisfaction in mental illness. *Health Serv Res*. 2022;57(4):820-829. doi: 10.1111/1475-6773.13945.

[77] Liu A, Ayers B, Meiselbach MK. Mental Healthcare Use After Leaving Medicare Advantage for traditional Medicare: Mental Healthcare Use for Switchers. The American journal of managed care. 2025 Dec;31(12):765. Available at: https://www.ajmc.com/view/mental-health-care-use-after-leaving-medicare-advantage-for-traditional-medicare.

plans face in identifying and engaging this population, and what strategies have proven most effective in overcoming those challenges? Do MA plans have unique processes in place or challenges they face in identifying enrollees with serious mental illness residing in rural areas and connecting them to appropriate services?

- What care coordination models or approaches have MA plans found most effective in serving enrollees with serious mental illness? For example, have MA plans successfully integrated evidence-based models such as Assertive Community Treatment (ACT), Coordinated Specialty Care (CSC), or partnerships with Certified Community Behavioral Health Clinics (CCBHCs) into their care delivery? What operational or regulatory conditions enabled or hindered the adoption of these practices?
- Where do current MA plan benefit offerings fall short in meeting the needs of beneficiaries with serious mental illness? What types of plans, benefit designs, or care coordination structures are most needed but currently unavailable or insufficiently available in the market? What barriers (financial, operational, regulatory, or workforce-related) prevent MA plans from developing more robust benefit offerings for this population?
- For the significant share of individuals with serious mental illness who are dually eligible for Medicare and Medicaid, what approaches have been most effective in coordinating benefits across both programs to address their behavioral health needs? What gaps in coordination persist, and what plan structures or policy changes would best support more seamless integration of Medicare and Medicaid services for this population?
- What outcome-based measures or performance metrics have MA plans found most meaningful and feasible for evaluating the quality of care and care coordination provided to enrollees with serious mental illness? Are there existing measures (from HEDIS, state Medicaid programs, or other sources) that CMS should consider incorporating or adapting to better assess MA plan performance for this population?

- What regulatory flexibilities or policy changes would most meaningfully improve the ability of MA plans to design and deliver high-quality, coordinated care for beneficiaries with serious mental illness? Are there existing requirements that create unintended barriers to serving this population effectively?

Individuals with dementia, Alzheimer's disease, and other brain disorders resulting in memory loss, cognitive decline, and behavioral changes experience fragmented care and poor health outcomes, with significant burdens placed on their family caregivers. These disorders are common in the Medicare population, with researchers estimating that 42 percent of Americans over the age of 55 will eventually develop dementia and the number of new dementia cases per year expected to double by 2060.[78,79] While distinct from serious mental illness, CMS is interested in public comments on similar questions to better understand promising strategies and challenges experienced by MA plans. Further, dementia and conditions associated with cognitive impairment, which include Alzheimer's disease, intellectual and developmental disabilities, traumatic brain injuries, disabling mental illness associated with cognitive impairment, and mild cognitive impairment are included in the list of severe and disabling chronic conditions that can be used as the focus for C-SNPs, see 42 CFR 422.2 "Severe or disabling chronic condition." There are a limited number of C-SNPs that focus on these conditions, as with serious mental illness, which indicates that there may be barriers or challenges in offering these types of C-SNPs. Therefore, CMS seeks public comment on the following questions:

- What strategies are SNPs and non-SNP MA plans employing to address dementia and related disorders among their enrollees?

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[78] Lopez-Mendez, M., Meyers, D.J., Shier, V. *et al.* National trends in the prevalence of dementia in Medicare Advantage and Traditional Medicare. *BMC Health Serv Res* **26**, 519 (2026). https://doi.org/10.1186/s12913-025-13404-2.

[79] National Institutes of Health. "Risk and future burden of dementia in the United States." Published February 18, 2025. Available at: https://www.nih.gov/news-events/nih-research-matters/risk-future-burden-dementia-united-states.

- What factors are preventing SNPs from designing and offering tailored plans to address dementia and related disorders and how should CMS consider policies to address these hurdles?

- What are related strategies that MA plans are leveraging that would benefit this population?
- What supplemental benefits or other services have MA plans identified as beneficial for addressing the needs of individuals with dementia and related disorders?
- How are MA plans leveraging strategic partnerships with community-based organizations or supplemental benefit providers to serve this population?
- How are MA plans currently identifying enrollees with dementia within their populations, and what processes are in place to ensure these individuals are connected to appropriate healthcare services and care coordination? What challenges do MA plans face in identifying and engaging this population, and what strategies have proven most effective in overcoming those challenges? Do MA plans have unique processes in place or challenges they face in identifying enrollees with dementia residing in rural areas and connecting them to appropriate services?

Finally, CMS welcomes commenters to share any other considerations or regulatory changes they believe may be necessary to support individuals with serious mental illness and dementia. Please note, this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for

self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

IV. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.166 and 423.186)

A. Introduction

CMS develops and publicly posts a 5-star rating system for Part C,[80] more commonly referred to as Medicare Advantage (MA), and Part D plans as part of its responsibility to disseminate comparative information, including information about quality, to beneficiaries under sections 1851(d) and 1860D-1(c) of the Act. The Part C and D Star Ratings system is used to determine quality bonus payment (QBP) ratings for MA plans under section 1853(o) of the Act and the amount of MA beneficiary rebates under section 1854(b) of the Act. We use multiple data sources based on the collection of different types of quality data under section 1852(e) of the Act to measure the quality and performance of contracts, such as CMS administrative data, surveys of enrollees, and information provided directly from health and drug plans. CMS regulations, including §§ 417.472(j) and (k), 422.152(b), 423.153(c), and 423.156, require plans to report on quality improvement and quality assurance and to provide data that help beneficiaries 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 changes proposed here would 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[81] as it evolves over time to increase the health and wellbeing of enrollees. In this proposed rule, we propose removing additional measures to

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[80] We generally use "Part C" to refer to the quality measures and ratings system that apply to MA plans and cost plans.

[81] https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.

continue to simplify and refocus the areas included in the Star Ratings, building on the changes to the measure set finalized in the Contract Year 2027 final rule. The proposed measure set of 15 measures reflects our ongoing effort to sharpen the Star Ratings program's focus on clinical outcomes while continuing to encourage high performance on patient experience and would also include a small number of process measures in areas of high clinical importance where better performance would improve quality of care for beneficiaries. The proposed revised measure set would continue to motivate high performance on patient experience while reducing the emphasis on process-oriented measures that assess whether a specific action was completed, rather than whether that action meaningfully improved an enrollee's health or experience. We believe this greater emphasis on outcome measures better reflects the actual effects of care on enrollees' health and wellbeing, and more directly captures whether contracts are delivering the care enrollees need.

In the Contract Year 2027 final rule we also solicited comments on ways to simplify and modify the Star Ratings methodology to further improve quality of care. Consistent with that policy goal and some of the comments we received on the Star Ratings proposals in the rule, we propose removing the reward factor. We are also proposing modifying the improvement measure hold harmless to apply only to contracts receiving 4.5 or higher stars for their highest rating. These changes to the measure set and methodology would streamline and simplify the Star Ratings. They would also raise the bar for achieving high Star Ratings and associated Quality Bonus Payments (QBPs), incentivizing plans to improve performance and deliver the highest quality of care for their enrollees. We believe these proposed changes will create a Star Ratings program directly aligned with the outcomes and patient experiences that matter most to Medicare enrollees. We also propose a change to the methodologies for setting cut points to account for the potential impact of the ADVaNCE MA model proposed in section VIII. of this proposed rule. We also propose a substantive update to the Controlling Blood Pressure measure, a clarification related to displaying Star Ratings domains on the Medicare Plan Finder (MPF) website, language

related to disclosing preliminary data shared with plans during the plan preview periods, and a clarification related to the extreme and uncontrollable circumstances policy.

B. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184)

The regulations at §§ 422.164 and 423.184 specify the criteria and procedures for adding, updating, and removing measures for the Part C and Part D Star Ratings program. 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 D Star Ratings system and anticipated that over time measures would be added, updated, and removed. We also specified at §§ 422.164(d) and 423.184(d) rules for measure updates based on whether they are substantive or non-substantive. The regulations, at paragraph (d)(1), list examples of non-substantive updates. See also 83 FR 16534 through 16537. Due to the regular updates and revisions made to measures, CMS does not codify a list of the measures (and their specifications) adopted for the Part C and D Star Ratings program. CMS adds or substantively updates measures through rulemaking, as set forth in §§ 422.164 and 423.184, and lists the measures used for the Star Ratings each year in the Medicare Part C & D Star Ratings Technical Notes or similar guidance issued with publication of the Star Ratings.

1. Updating Measure -- Controlling Blood Pressure (Part C)

Consistent with § 422.164(c)(1), we continue to review measures that are nationally endorsed and in alignment with private sector organizations, such as the National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA). As discussed in the Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment, NCQA, the measure steward, was exploring updates to the Controlling High Blood Pressure (CBP) measure. NCQA has decided to move forward with updates to this measure. CMS is proposing to replace the current

version of the CBP measure with the updated version, referred to as the Blood Pressure Control for Patients with Hypertension (BPC-E) measure, starting with the 2029 measurement year and 2031 Star Ratings. Both the current (CBP) and the updated (BPC-E) measures assess the percentage of members 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mm Hg) during the measurement year. Both measures use the same blood pressure threshold, numerator, age range, and exclusions. For CBP, beneficiaries are captured in the denominator when they have two or more outpatient, telephone, or virtual visits on different dates of service with a diagnosis of hypertension. BPC-E expands the denominator by including beneficiaries if they have two or more outpatient, telephone, or virtual visits on different dates of service with a diagnosis of hypertension, or they have one or more outpatient, telephone, or virtual visits with a diagnosis of hypertension and one or more dispensed antihypertensive medications. Since the updated measure expands the denominator, it is a substantive change as defined at § 422.164(d)(2). NCQA is also transitioning the measure to electronic clinical data systems (ECDS) reporting (a non-substantive change). The only two changes from CBP to BPC-E are the change in denominator to allow beneficiaries to be included if they have at least one outpatient, telephone, or virtual visit with a diagnosis of hypertension and at least one dispensed antihypertensive medication, and the transition to ECDS reporting. Both the legacy measure (CBP) and the new measure (BPC-E) will be collected for the 2027 and 2028 measurement years. The existing CBP measure will continue to be in Star Ratings through the 2028 measurement year and 2030 Star Ratings. We are proposing to replace the existing CBP measure with the updated BPC-E measure for the 2029 measurement year and the 2031 Star Ratings. The updated BPC-E would continue to be referred to as the "CBP" measure in the Star Ratings, although the current version would be replaced with BPC-E as of the 2031 Star Ratings. The updated measure would be on the display page for the 2029 and 2030 Star Ratings and would be included in the 2031 Star Ratings if finalized through rulemaking. If the updated

measure is added to the Star Ratings, it would have a weight of 1 for the first year and then return to a weight of three for future years.

2. Summary of Measures with Substantive Specification Changes for the Part C and D Star Ratings

Table IV.B-1 summarizes information about the addition of the BPC-E measure addressed in this proposed rule, beginning with the 2031 Star Ratings. The measure description listed in this table is a high-level description. The annual Star Ratings measure specifications supporting document, the *Medicare Part C & D Star Ratings Technical Notes,* provides detailed specifications for each measure. Detailed specifications include, where appropriate, more specific identification of a measure's: (1) numerator; (2) denominator; (3) calculation; (4) timeframe; (5) case-mix adjustment; and (6) exclusions. The Technical Notes document is updated annually. The annual Star Ratings are produced in the fall of the prior year. For example, Star Ratings for the year 2030 are produced in the fall of 2029. If a measurement period is listed as "the calendar year 2 years prior to the Star Ratings year" and the Star Ratings year is 2030, the measurement period is referencing the January 1, 2028 to December 31, 2028 period. As noted earlier in section IV.B. of this proposed rule, CMS does not codify the specific measures for the Part C and Part D Quality Rating System; doing so would be unnecessarily lengthy and cumbersome due to the relative regularity with which measure specifications are updated.

TABLE IV.B-1. SUMMARY OF NEW INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2029

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								
Controlling Blood Pressure	The percentage of MA members 18–85 years of age who had a diagnosis of hypertension (HTN) (denominator) and whose blood pressure (BP) was adequately controlled (less than 140/90 mm Hg) (numerator).	Managing Chronic (Long Term) Conditions	Intermediate Outcomes Measure Weight of 3	HEDIS*	The calendar year 2 years prior to the Star Ratings year	00167-02-C-PARTC	Percentile distribution	MA-PD and MA-only

3. Removing Measures

In the Contract Year 2027 final rule, CMS removed 11 measures from the Part C and D Star Ratings program, and we noted that we would consider removing additional measures in the future to further simplify and refocus the program (91 FR 17498). Consistent with that direction, we propose transitioning the Star Ratings to a smaller measure set focused mainly on the areas of the highest importance – outcomes and patients' experience of care measures. We also propose keeping a small number of process measures in areas of high clinical importance and where significant opportunity for quality improvement exists. Further reducing the number of measures is consistent with recommendations from MedPAC[82] that CMS consider having fewer measures in the Part C and D Star Ratings program. If this proposal is finalized, we would remove the measures proposed for removal in this proposed rule beginning with the 2028 measurement year and the 2030 Star Ratings, whereas the 11 measures finalized for removal in the Contract Year 2027 final rule are being removed beginning with the 2026 and 2027 measurement years. This phased approach to removing measures would allow plans the opportunity to adjust to a reduced measure set over several years while CMS continues streamlining, simplifying, and refocusing the Part C and D Star Ratings on the areas of highest importance for quality of care.

Table IV.B-2 shows the measures we propose removing beginning with the 2030 Star Ratings (measurement year 2028). Table IV.B-3 shows the 2030 Star Ratings measure set under this proposal including outcome, intermediate outcome, and patients' experience of care measures along with two process measures. The Health Plan Quality Improvement and Drug Plan Quality Improvement measures would continue to be included in the Star Ratings. The detailed measure specifications for the measures in Tables IV.B-2 and IV.B-3 are included in the

[82] Replacing the Medicare Advantage quality bonus program—MedPAC. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch3_reporttocongress_sec.pdf

Medicare 2027 Part C & D Star Ratings Technical Notes located at

https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data.

TABLE IV.B-2. STAR RATINGS MEASURES PROPOSED FOR REMOVAL BEGINNING WITH THE 2030 STAR RATINGS

Part	Measure	Type	Primary Data Source
C	Breast Cancer Screening	Process	HEDIS
C	Colorectal Cancer Screening	Process	HEDIS
C	Annual Flu Vaccine	Process	CAHPS
C	Monitoring Physical Activity	Process	HEDIS-HOS
C	Care for Older Adults – Medication Review	Process	HEDIS
C	Care for Older Adults – Functional Status Assessment	Process	HEDIS
C	Osteoporosis Management in Women who had a Fracture	Process	HEDIS
C	Diabetes Care – Eye Exam	Process	HEDIS
C	Kidney Health Evaluation for Patients with Diabetes	Process	HEDIS
C	Reducing the Risk of Falling	Process	HEDIS-HOS
C	Improving Bladder Control	Process	HEDIS-HOS
C	Transitions of Care	Process	HEDIS
C	Depression Screening and Follow-up	Process	HEDIS
C	Getting Appointments and Care Quickly	Patients' Experience of Care	CAHPS
C	Rating of Health Plan	Patients' Experience of Care	CAHPS
D	Rating of Drug Plan	Patients' Experience of Care	CAHPS
D	Statin Use in Persons with Diabetes	Process	HEDIS
D	Concurrent Use of Opioids and Benzodiazepines	Process	Prescription Drug Event (PDE) data
D	Polypharmacy: Use of Multiple Anticholinergic Medications in Older Adults	Process	Prescription Drug Event (PDE) data

TABLE IV.B-3. PROPOSED MEASURE SET FOR 2030 STAR RATINGS

Part	Measure	Type	Primary Data Source
C	Improving or Maintaining Physical Health	Outcome	HOS
C	Improving or Maintaining Mental Health	Outcome	HOS
C	Diabetes Care – Blood Sugar Controlled	Intermediate Outcome	HEDIS
C	Controlling Blood Pressure	Intermediate Outcome	HEDIS
C	Plan All-Cause Readmissions	Outcome	HEDIS
C	Follow-up after Emergency Department Visit for People with Multiple High-Risk Chronic Conditions	Process	HEDIS
C	Getting Needed Care	Patients' Experience of Care	CAHPS
C	Care Coordination	Patients' Experience of Care	CAHPS
C	Health Plan Quality Improvement	Improvement	Star Ratings
D	Getting Needed Prescription Drugs	Patients' Experience of Care	CAHPS
D	Drug Plan Quality Improvement	Improvement	Star Ratings
D	Medication Adherence for Diabetes Medications	Intermediate Outcome	Prescription Drug Event (PDE) data
D	Medication Adherence for Hypertension (RAS antagonists)	Intermediate Outcome	Prescription Drug Event (PDE) data
D	Medication Adherence for Cholesterol (Statins)	Intermediate Outcome	Prescription Drug Event (PDE) data
D	Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR)	Process	Part D Plan Reporting

We propose removing 16 process measures listed in Table IV.B-2 to streamline the Star Ratings measure set and increase the emphasis on outcomes and the remaining patients'

experience of care measures. Under this proposal, we would retain two process measures as shown in Table IV.B-3. We would continue including the Follow-up after Emergency Department Visit for People with Multiple High-Risk Chronic Conditions measure because it addresses potential gaps in care coordination for a vulnerable beneficiary population in particularly acute episodes of care, and current scores indicate room for MA contract improvement with an average contract score of 64 percent for the 2027 Star Ratings. We would also continue including Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) because medication safety and beneficiary engagement in managing their medications and health are of high importance to CMS. MTM plays a critical role in addressing polypharmacy and high-risk medication use in beneficiaries with complex regimens. Additionally, CMRs can identify medication issues tied to other Part D patient safety measures that are being proposed for removal from the Star Ratings. There is also room for improvement on this measure. Currently, among MA-PD and PDP contracts, the average contract score for the calendar year 2025 measurement period is 44 percent and 35 percent, respectively, with significant variation across contracts.

In the Calendar Year 2027 Part C and D final rule, CMS did not finalize the proposed removal of the Diabetes Care - Eye Exam measure, stating that we would retain the measure because "routine retinal screening is a critical component of comprehensive diabetes care and can identify broader health concerns," and that the measure "focuses on a clinically distinct and preventive aspect of diabetes care that is not fully addressed by other measures" (91 FR 17507). CMS has since reconsidered this position. The agency now proposes to remove the Diabetes Care - Eye Exam measure from the Star Ratings program because it is a process measure rather than an outcome measure, and it is therefore less reflective of the quality improvements the program is intended to drive. This shift is consistent with CMS's broader effort to streamline the Star Ratings measure set by prioritizing outcome-based measures over process-based measures that do not directly capture improvements in patient health. Although this measure would no

longer be part of Star Ratings if this proposal is finalized, diabetic eye exams remain an important part of patient care. CMS expects plans and providers to continue ensuring that beneficiaries with diabetes receive this needed testing, regardless of whether the measure is removed from the Star Ratings.

While we finalized the addition of the Depression Screening and Follow-up measure to the Star Ratings measure set beginning with the 2029 Star Ratings in the Contract Year 2027 final rule (91 FR 17510 through 17514), we are revisiting the inclusion of this measure as part of the broader measure set redesign to refocus the Star Ratings mainly on outcome measures. The Depression Screening and Follow-up measure assesses whether a screening for depression was conducted and whether a specified follow-up step occurred within a defined timeframe, but it does not assess whether the enrollee's depressive symptoms changed, improved, or resolved as a result. It is, in other words, a process measure rather than an outcome measure. The proposed 2030 Star Ratings measure set would continue to include the Improving or Maintaining Mental Health measure, which captures enrollees' self-reported mental health outcomes, including depressive symptoms, over time. Because this outcome measure already provides a mechanism for assessing contracts' performance in this area, we do not believe retaining the Depression Screening and Follow-up measure as one of the limited process measures is necessary to avoid a gap in measurement. We are therefore proposing to remove it beginning with the 2030 Star Ratings.

CMS will continue to monitor and publicly report removed measures on the display page at https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data to maintain continued public transparency and support program compliance activities. A measure's absence from Star Ratings does not lower its importance. Plans remain responsible for beneficiary care regardless of whether a given topic area is included as a Star Ratings measure. For example, contracts are responsible for ensuring that their Medicare enrollees receive critical cancer screenings. Similarly, diabetes-related eye exams remain a critical component of high-quality

care for diabetics even if this measure is removed from Star Ratings. Removal of these measures from Star Ratings does not diminish the measures' clinical importance, and CMS expects plans to support appropriate screening, outreach, and provider engagement in support of furnishing enrollees with the highest-quality care.

In the "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" final rule, which appeared in the **Federal Register** on April 12, 2023 (88 FR 22120) ("Contract Year 2024 final rule"), we reduced the weight of the patients' experience of care measures to balance this category's weight with that of clinical outcomes measures. Our proposed changes to the measure set in this proposed rule place further emphasis on clinical outcomes measures while still recognizing the importance of patients' experience of care. This is consistent with recommendations from MedPAC and other stakeholders that quality programs focus on outcomes measures.[83] Of the six current patients' experience of care measures, we propose removing the three measures listed in Table IV.B-2 (Getting Appointments and Care Quickly, Rating of Health Plan, and Rating of Drug Plan) while retaining the other three listed in Table IV.B-3 (Getting Needed Care, Care Coordination, and Getting Needed Prescription Drugs) to incentivize continued focus and improvement in patients' experience of care. As a result, the proposed measure set for the 2030 Star Ratings would consist of eight outcomes or intermediate outcomes measures, three patients' experience of care measures, two process measures, and the two Part C and D improvement measures. We believe this proposed mix of measures will further increase the focus on clinical outcome measures, while continuing to encourage high performance on patient experience.

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[83] Replacing the Medicare Advantage quality bonus program—MedPAC. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch3_reporttocongress_sec.pdf
Dzau, VJ, McClellan, MB, & McGinnis, MJ (2017). Vital Directions for Health and Health Care Priorities From a National Academy of Medicine Initiative. JAMA 317(14),1461-1470. https://jamanetwork.com/journals/jama/fullarticle/2612013
Ta, T, Erickson, SC, Qui, W, & Patel, BV (2016). Is There a Relationship Between Part D Medication Adherence and Part C Intermediate Outcomes Star Ratings Measures? J Manag Care Spec Pharm 22(7). https://www.jmcp.org/doi/10.18553/jmcp.2016.22.7.787

We are also proposing removal of the reward factor as discussed in section V.G. of this proposed rule, increasing the level of quality necessary to achieve high ratings. The reward factor was included in the Part C and D Star Ratings program beginning with the 2009 Star Ratings with the purpose of creating additional incentives for high and stable relative performance across measures by discouraging contracts from having a lot of variation in performance across measures (that is, a mix of low and high performance across measures). Together with the greater emphasis on improvement measures resulting from this proposal, given that the relative weight of improvement measures increases as the total number of measures in the Star Ratings decreases, this would strengthen incentives for contracts to improve performance across critical outcome and patient experience Star Ratings measures. To identify the impact of the proposals to modify the Star Ratings measure set and methodology (that is, removing reward factor and modifying the improvement measure hold harmless as discussed in sections V.G. and V.H.) in this proposed rule on the Star Rating distribution, we need to consider them together. The impact of the proposed changes on the Star Ratings distribution, including the removal of measures, removal of the reward factor, and change to the improvement measure hold harmless methodology is discussed in section V.I. of this proposed rule.

We solicit comment on our proposal to remove the 19 measures in Table IV-2 to further streamline and refocus the measure set on outcomes measures. We are interested in feedback on the removal of each of these measures individually, including any measure-specific considerations commenters believe are relevant to retaining a particular measure. We note that we may finalize removal of all, some, or none of the 19 measures proposed for removal in Table IV.B-2, after consideration of public comments.

C. Cut Point Methodology Changes to Account for Potential Impact of ADVaNCE MA Model (§§ 422.166(a)(2) and (3) and 423.186(a)(2) and (3))

In section VIII. of this proposed rule, CMS proposes to implement the Aligning Data and Value to Nurture Competition and Efficiency in Medicare Advantage (ADVaNCE MA) model.

Because this model would test different quality and payment incentives for MA contracts in selected states, the ADVaNCE MA model may impact how model contracts perform on the quality measures included in the Part C and D Star Ratings. While Star Ratings would not be calculated for model contracts, removing the model contracts from the calculation of the Star Ratings measure cut points for non-model contracts could result in shifting of the cut points that is unrelated to the performance of non-model contracts. Therefore, CMS proposes to calculate the Star Ratings measure cut points for MA contracts using adjusted measure scores for model contracts to avoid biasing the cut points for non-model contracts and to avoid impacting non-model contracts' Star Ratings. The adjusted measure scores for model contracts would account for the estimated average impact of the ADVaNCE MA model on measure scores and would only be calculated for measures that are the same across model and non-model contracts. These adjusted model contract scores would only be used for the purpose of calculating Star Ratings cut points for star assignments of non-model contracts. The adjusted scores for model contracts would not be publicly available and would be available to all Part C and D plan sponsors only for measures included in the de-identified sample measure data provided in the Health Plan Management System (HPMS) during the second plan preview period.

At §§ 422.166(a)(2)(iv) and (v), 422.166(a)(3)(vi), 423.186(a)(2)(iv) and (v), and 423.186(a)(3)(vi), we propose to calculate the average impact of the ADVaNCE MA model on Star Ratings measure scores for model contracts, which receive scores on Star Ratings measures but are not assigned measure-level Star Ratings, in each year of the model using a contract-level regression model. The regression would include all contracts' scores (model and non-model) as outcomes and a primary explanatory variable that is an indicator of model participation, while also adjusting for baseline measure quality, defined as measure performance in the year prior to ADVaNCE MA model implementation. This baseline quality adjustment is included because states and contracts included in the ADVaNCE MA model may differ in quality from non-

Mandatory States and contracts prior to ADVaNCE MA model implementation. The regression model would be run separately for each year and Star Ratings measure as follows:

$$Y_{ik} = \beta_{0i} + \beta_{1i}S_{ik} + \beta_{2i}C_{ik} + \beta_{3i}P_{ik} + \varepsilon_{ik},$$

where i indexes the Star Ratings measure, k indexes the contract, Y_{ik} is the contract-level measure score, S_{ik} is state-level baseline quality for the states covered by contract *k*, C_{ik} is contract-specific baseline quality,[84] and P_{ik} is the model participation indicator (equal to 1 for model contracts and 0 for non-model contracts).

We propose at §§ 422.166(a)(2)(iv)(A)(1) and (2), 422.166(a)(3)(vi), 423.186(a)(2)(iv)(A)(1) and (2), and 423.186(a)(3)(vi) to apply case-mix adjustment at the level results are aggregated, such as state, contract, or parent organization for measures that are case-mix adjusted. For all other measures, we propose to calculate the state-level baseline quality measure, S_{ik}, as weighted averages of state-level average measure scores, where the weights represent the proportion of total enrollees from contract k that reside in each state as of July of the measurement year for the applicable Star Ratings year. For single-state contracts (this would include all model contracts which must be in a single state, as well as non-model contracts with enrollees solely within one state), the state-level pre-model quality adjustor would be the state-level average measure score. For non-model contracts and new contracts with service areas spanning multiple states, S_{ik} is an enrollment-weighted average of the state-level average measure scores using states the given contract has enrollees in. The state-level average measure scores would be calculated as average scores within each state using patient-level data across enrollees residing within the state as of July of the measurement year prior to ADVaNCE MA model implementation. These state-level average measure scores would remain fixed for the duration of the model.

[84] This measure is the contract-level quality for contracts that existed at baseline, the average parent organization quality for new contracts that are part of parent organizations that existed at baseline, and the national average for new contracts in new parent organizations.

We propose at §§ 422.166(a)(2)(iv)(A)(1), 422.166(a)(3)(vi), 423.186(a)(2)(iv)(A), and 423.186(a)(3)(vi) to calculate the contract-specific baseline quality, C_{ik}, as the contract-level or parent organization-level average measure scores (the level depends on data availability) from the measurement year prior to ADVaNCE MA model implementation. We propose to assign model contracts with single-state service areas at baseline and all non-model contracts regardless of service area their baseline contract-level measure score, when available. For all new contracts, including model contracts that had service areas spanning multiple states at baseline and were required to reconfigure to single-state contracts, we propose at §§ 422.166(a)(2)(iv)(A)(1) and (2), 422.166(a)(3)(vi), 423.186(a)(2)(iv)(A)(1) and (2), and 423.186(a)(3)(vi) to calculate C_{ik} as their parent organization-level measure score at baseline or the national-level measure score at baseline if the parent organization did not exist prior to model implementation. The parent organization-level measure score at baseline for case-mix adjusted measures would be calculated following the measure specifications for case-mix adjusted measures, but with case-mix adjustment applied at the level of the parent organization. For measures that are not case-mix adjusted, the parent organization-level measure score at baseline would be calculated as the weighted average measure score across contracts in the same parent organization that had measure scores in the measurement year prior to implementation of the ADVaNCE MA model, where the weights are contract enrollment as of July of the measurement year prior to implementation of the ADVaNCE MA model. This approach is designed to adjust for baseline quality at the two points of model impact (that is, state and contract) using the best information available for each contract at baseline and thus to obtain the best estimate of the model effect. If CMS identifies that a contract-level measure score at baseline is inaccurate, incomplete, or biased as described at §§ 422.164(g) and 423.184(g), CMS would use the national-level measure score as the measure of contract-specific baseline quality.

For new measures or measures returning after a substantive specification change in the applicable Star Ratings year, we considered using data from the year prior to inclusion in Star

Ratings to calculate baseline quality adjustors. However, as the model impacts the availability of certain supplemental benefits or may otherwise impact the quality of care in the state, using data after model implementation for new or substantially revised measures may not fully separate out model impacts from state or contract quality differences. Therefore, we propose at §§ 422.166(a)(2)(iv)(B), 422.166(a)(3)(vi), 423.186(a)(2)(iv)(B), and 423.186(a)(3)(vi) for new measures or measures returning after a substantive specification change to utilize the state-level averages, and the contract-level averages (or parent organization-level or national-level averages, as applicable) of all Star Ratings measures in the applicable Star Ratings year using data from the measurement year prior to model implementation. These averages would represent the overall quality in the state and contract prior to the start of the model.

The baseline quality adjustors for any unit measured (that is, contract, state, parent organization) would remain fixed for the duration of the ADVaNCE MA model. CMS would update the enrollment-weighted state average quality adjustors annually for each non-model contract that operates across multiple states to account for changes in enrollment and assign appropriate baseline quality adjustment for all new contracts.

Before we calculate measure-level cut points each year, we would run the regression model described earlier in this section for each measure and adjust all model contract scores by subtracting the estimated average effect of participation. For example, if we found that participating model contracts have, on average, higher scores than non-model contracts by 2 percentage points for Breast Cancer Screening after controlling for differences in baseline quality, we would adjust the Breast Cancer Screening contract scores for each model contract down by 2 percentage points prior to calculating the measure cut points used to determine Star Ratings for the non-model contracts. We would also adjust the contract measure scores for model contracts upward if the model effect was negative, meaning model participation resulted in lower performance on a measure where higher scores mean better performance for a particular year. These adjustments would only be used for the purpose of calculating Star Ratings measure-level

cut points for non-model contracts. The proposed adjustments would control for model impacts prior to calculating measure-level Star Ratings cut points for non-model contracts, but they would not directly impact the scores for either model or non-model contracts.

We also propose at §§ 422.166(a)(2)(v) and 423.186(a)(2)(v) to exclude model contracts from score and cut point calculations of the Star Ratings for Health Plan and Drug Plan Quality Improvement measures for non-model contracts. We propose to treat the improvement measures differently from the other Star Ratings measures because the improvement measures assess year-over-year change in performance rather than the level of performance in a given year. We assume that model contracts, in the absence of the ADVaNCE MA model, would have experienced year-over-year performance changes similar to those of non-model contracts. Therefore, excluding model contracts from the improvement measures would not substantially shift cut points. However, we anticipate that year-over-year changes in performance for model contracts may differ from non-model contracts because of their participation in the model. Model contracts may also differ in the year-to-year correlations of the measure scores that are included in the improvement measures, relative to the non-model contracts. Both factors would affect improvement measure stars. Excluding model contracts from the improvement measure score and cut point calculations would avoid model contracts impacting the improvement measure stars for non-model contracts.

The reward factor ranges from 0.0 to 0.4 and is added to the overall and summary ratings to incentivize consistently high performance. We propose adding language at §§ 422.166(f)(1)(i) and 423.186(f)(1)(i) to exclude model contracts from the calculation of the weighted variance and weighted mean thresholds used to determine the reward factor for the duration of the ADVaNCE MA model, and removing language that references the reward factor calculations for the 2022 Star Ratings only. During the model, ADVaNCE MA model contracts will not receive Star Ratings and could cause some shifting of the thresholds; thus, we propose to exclude ADVaNCE MA model contracts from these calculations. We note, however, that if CMS

finalizes the removal of the reward factor starting with the 2030 Star Ratings as proposed in section V.G. of this proposed rule, there would be no need to adjust the reward factor during the ADVaNCE MA model or to finalize the proposed additional language at §§ 422.166(f)(1)(i) and 423.186(f)(1)(i).

The categorical adjustment index (CAI) is a factor that is added to or subtracted from an overall or summary Star Rating (or both) to adjust for the average within-contract (or within-plan as applicable) disparity in performance associated with the percentages of beneficiaries who are dually eligible for Medicare and enrolled in Medicaid, beneficiaries who receive a Low Income Subsidy or have disability status in that contract (or plan as applicable). We propose adding language at §§ 422.166(f)(2) and 423.186(f)(2) to exclude model contracts from the calculation of the CAI for the duration of the ADVaNCE MA model. During the model, ADVaNCE MA model contracts will not receive Star Ratings; thus, we propose to exclude ADVaNCE MA model contracts from these calculations.

We solicit comment on these proposed changes to the Star Ratings methodology to account for the potential impact of the ADVaNCE MA model. We propose implementing these changes beginning with the 2031 Star Ratings for the duration of the proposed ADVaNCE MA model.

D. Star Ratings Domains (§§ 422.166(b)(1)(iii) and 423.186(b)(1)(iii))

As described at §§ 422.166(b) and 423.186(b), CMS groups Star Ratings measures by domains solely for the purpose of publicly reporting the data on MPF. We propose to clarify at §§ 422.166(b)(1)(iii) and 423.186(b)(1)(iii) that only domains with measures included in the Star Ratings for the applicable year will be displayed on MPF. As we remove measures from the Star Ratings, some domains may not have any remaining measures; thus, those domains would not be displayed. We are planning to re-visit the existing domains; thus, we may propose changes to these domains in future rulemaking. We welcome any suggestions on alternative domains.

We solicit comment on the proposed clarification to the display of domains when a domain does not have any Star Ratings measures for the applicable year.

E. Plan Preview of Star Ratings (§§ 422.166(h)(2) and 423.186(h)(2))

During the first plan preview, CMS expects MA organizations and Part D sponsors to closely review the methodology and their posted numerical data for each measure in HPMS prior to display on MPF. The second plan preview includes data revisions made as a result of the first plan preview and provides preliminary Star Ratings for each measure, domain rating, summary rating, and overall rating. During the second plan preview, MA organizations and Part D sponsors should again review their data closely. Following the second plan preview, CMS makes any necessary corrections identified by contracts or CMS during the preview periods and then finalizes the Star Ratings.

Our goal is for Medicare beneficiaries to make informed plan decisions that take into consideration the cost, benefits, and quality of the plans in their geographic area. To that end, based on our authority under sections 1856(b)(1), 1857(e)(1), and 1860D-12(b)(3)(D) of the Act, which grant the Secretary authority to establish by regulation standards that are consistent with and to carry out the statute and to include additional contract terms and conditions that are not inconsistent with the statute and that the Secretary finds necessary and appropriate, we are proposing language at §§ 422.166(h)(2) and 423.186(h)(2) to codify that MA organizations, PDPs, and first tier, downstream, and related entities may not publicly disclose any preliminary data displayed in HPMS until the Star Ratings have been finalized and released on MPF. Data displayed in HPMS during the plan preview periods are preliminary and subject to change. Public release of these preliminary data creates a risk that Medicare beneficiaries will rely on inaccurate quality information to make a plan selection since Medicare beneficiaries may hear about the preliminary ratings through the media or other communication channels. CMS develops and publicly posts the Star Ratings as part of its responsibility to disseminate comparative information to beneficiaries in order to promote an active, informed selection

among available coverage options, as required by sections 1851(d) and 1860D-1(c) of the Act. Medicare beneficiaries exposed to preliminary Star Ratings data may not have sufficient information to understand that these ratings are preliminary and subject to change, and they may rely on these data to make plan selections without confirming the final ratings once they are released on MPF. Thus, to minimize the risk that Medicare beneficiaries will rely on preliminary and potentially inaccurate information and to promote the active, informed selection of coverage options, we are proposing that no preliminary Part C and D Star Ratings data can be disclosed to the public until CMS releases the final Star Ratings data on MPF in mid-October.[85]

F. Extreme and Uncontrollable Circumstance Policy Clarification (§§ 422.166(i)(5) and 423.186(i)(3))

Under the extreme and uncontrollable circumstances policy codified at §§ 422.166(i)(5) and 423.186(i)(3) CMS holds affected contracts harmless from the addition of applicable new measures in the Star Ratings year by using the higher of the contract's summary or overall rating or both calculated with and without including all of the applicable new measures as described at §§ 422.166(i)(5) and 423.186(i)(3). We propose to clarify at §§ 422.166(i)(5) and 423.186(i)(3) that contracts that do not have enough measures to have the summary or overall rating or both calculated under one of the two scenarios (that is, either with or without including all applicable new measures) will receive the rating from the summary or overall rating that had enough measures to be calculated.

G. Reward Factor (§§ 422.166(f)(1) and 423.186(f)(1))

The reward factor described at §§ 422.166(f)(1) and 423.186(f)(1) was included in the Part C and D Star Ratings program beginning with the 2009 Star Ratings with the purpose of creating additional incentives for high and stable relative performance across measures by discouraging contracts from having a lot of variation in performance across measures (that is, a

[85] When the final Star Ratings are released publicly by CMS in mid-October, Part C and D contracts that terminate or are withdrawn for the ratings year, and are not shown on MPF, can also publicly disclose their ratings.

mix of low and high performance across measures). In the Contract Year 2024 final rule, we finalized the removal of the reward factor along with the addition of the health equity index (HEI) reward. Subsequently, in the Contract Year 2027 final rule, we finalized a policy that retained the reward factor in lieu of implementing the HEI reward for two reasons: (1) to incentivize improvement efforts on clinical care, outcomes, and patient experience, rather than on improvement among certain populations, and (2) to keep the Star Ratings methodology consistent while we explored ways to simplify and modify the methodology to further drive quality improvement.

While we believe it was important to retain the reward factor methodology for consistency while we explored ways to simplify and streamline the Star Ratings methodology, we also stated in the Contract Year 2027 final rule that CMS would consider whether the historical reward factor should continue to be part of the Star Ratings in the future. As we explained in the Contract Year 2024 final rule, the reward factor is less effective in serving its intended purpose in the Star Ratings as overall contract performance has continued to increase. At the beginning of the Star Ratings program, the distribution of ratings across contracts looked very different, with overall performance much lower than it is today. Over time, we have established additional methodological enhancements to foster performance improvement across measures, such as the addition of the Health Plan Quality Improvement and the Drug Plan Quality Improvement measures as described at §§ 422.164(f) and 423.184(f). The improvement measures are weighted 5 and reward contracts for improving performance from the prior year across measures. The linkage between Star Ratings and QBP ratings has further motivated MA organizations to perform well across measures. As a result, contract performance has improved and become more consistent across Star Ratings measures over time.

These considerations suggest that the reward factor may no longer be necessary; thus, we are proposing in this rule the removal of the reward factor. If CMS finalizes the removal of the reward factor from the Star Ratings methodology, contracts would still have incentives to

perform well and improve because high performance on individual Star Ratings measures, including the Health Plan Quality Improvement and the Drug Plan Quality Improvement measures, translates into better overall and summary ratings.

Removing the reward factor would place downward pressure on Star Ratings and would create additional incentives for contracts to improve performance. This is consistent with our objectives to simplify the Star Ratings methodology and further drive quality improvement on the refocused set of Star Ratings measures finalized in the Contract Year 2027 final rule and proposed in this rule.

We solicit comment on our proposal to remove the reward factor from the Star Ratings beginning with the 2030 Star Ratings.

H. Improvement Hold Harmless (§§ 422.166(g)(1) and 423.186(g)(1))

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, we discussed that one of the goals of the Part C and D Star Ratings program is to drive quality improvement for plans and providers (83 FR 16521). In that final rule, CMS adopted, at §§ 422.166(g)(1) and 423.186(g)(1), a hold harmless provision for the inclusion of the Part C or Part D or both improvement measures for contracts with 4 or more stars for their highest rating (that is, the overall rating for MA-PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs). Under this provision, the highest rating is calculated both with and without the improvement measures; contracts with 4 or more stars without including the improvement measures are held harmless from having the highest rating reduced by the addition of the improvement measures. The original intent of this hold harmless provision was to recognize that higher performing contracts have less room to improve (83 FR 16578).

Upon further reflection, the hold harmless provision for the highest rating may suppress improvement incentives for 4 star contracts, because these contracts still have the potential to

increase scores across measures and thus their Star Ratings. This is particularly important as we propose to further refocus the measure set and to remove the reward factor. We want to ensure that all contracts are motivated to reach the highest levels of performance across the refocused set of Star Ratings measures. In order to encourage continued improvement across measures for contracts with 4 stars for their highest rating, we propose to modify § 422.166 at paragraphs (g)(1)(i) and (ii) and § 423.186 at paragraphs (g)(1)(i) and (ii) to apply the improvement measure hold harmless provision to only contracts with 4.5 and 5 stars for their highest rating beginning with the 2030 Star Ratings.

We welcome feedback on this proposal.

I. Impact of Proposed Changes

Simulations of the impact of removing 19 measures, removing the reward factor, and modifying the improvement measure hold harmless, as proposed in sections V.B., V.G., and V.H. of this proposed rule, using data from the 2027 Star Ratings (2025 measurement year) but updating the measure set to also remove the 11 measures finalized for removal in the Contract Year 2027 final rule, show approximately 36 percent of MA-PD contracts would have no change in their overall rating compared to the 2027 Star Ratings. The overall rating for MA-PD contracts would increase for approximately 6 percent of contracts and would decrease for approximately 58 percent of contracts. Approximately 2 percent of MA contracts would gain QBPs, and approximately 20 percent of contracts would lose QBPs. For PDP contracts, the Part D rating would stay the same for approximately 43 percent of contracts, increase for 10 percent and decrease for 47 percent.

V. Strengthening Current Medicare Advantage Special Needs Plans Program Policies

A. Reducing Model of Care (MOC) Burden, Improving Special Needs Plans (SNP) Care Coordination Requirements, and Updating HRA Outreach Requirements (§ 422.101)

Congress permanently authorized special needs plans (SNPs) through section 50311(a) of the Bipartisan Budget Act (BBA) of 2018. Under section 1859(f)(2) through (4) of the Act, SNPs are required to restrict enrollment to Medicare beneficiaries who are: institutionalized individuals, who are currently defined in § 422.2 as those residing or expecting to reside for 90 days or longer in a long-term care facility, and institutionalized equivalent individuals who reside in the community but need an institutional level of care when certain conditions are met (Institutionalized Special Needs Plan or I-SNP); individuals entitled to medical assistance under a State plan under Title XIX (Dual eligible SNP or D-SNP); or other individuals with certain severe or disabling chronic conditions who would benefit from enrollment in a SNP (Chronic condition SNP or C-SNP).

Section 1859(f)(5)(A) of the Act imposes specific care management requirements for all SNPs effective January 1, 2010. As a result, all SNPs are required to implement care management requirements that have two core components: an evidence-based model of care (MOC) and care management services for each enrollee.

CMS is proposing to amend and add new regulations at § 422.101(f) in order to, first, adequately address gaps in care management by SNPs based on findings from the CMS SNP audit process, second, reduce unnecessary plan and provider burden associated with SNP MOC training requirements, and third, amend current health risk assessment (HRA) requirements to take into account technological advancements employed by MA organizations when communicating with enrollees. Specifically, CMS proposes to: amend § 422.101(f)(1)(vii) to require that person-centered goals and objectives in individualized care plans (ICPs) be specific to all active needs and diagnoses based on available data and input from the enrollee, address supplemental benefits available to the enrollee under the plan, and ensure that the ICP is shared

among a designated group; amend interdisciplinary care team (ICT) regulations at § 422.101(f)(1)(ix) to better suit the unique populations served by SNPs; remove MOC training requirements at § 422.101(f)(2)(ii) to alleviate SNP and provider burden; and amend § 422.101(f)(1)(iv) to remove the prohibition on automated phone calls when conducting outreach to enrollees for the purpose of completing an HRA. Collectively, these proposals are intended to reduce care coordination gaps identified through CMS program audits, improve the person-centeredness of SNP care planning, and reduce regulatory burden associated with current SNP care coordination requirements.

1. Improving SNP Care Coordination and Communication

Section 164 of the Medicare Improvements for Patients and Providers Act added care management provisions for all SNPs as set forth in section 1859(f)(5) of the Act (42 U.S.C. 1395w-28(f)(5)). The mandate requires SNPs to implement a care management model with two core components. The first core component is an evidence-based MOC with an appropriate network of providers and specialists to meet the specialized needs of the SNP target population. The second core component is a set of care management services that includes: a comprehensive initial HRA and annual reassessments; an ICP with goals and measurable outcomes; and an ICT to manage care. Section 1859(f)(5) is the foundation for much of CMS's MOC regulatory standards. Section 422.101(f)(1) requires MA organizations offering SNPs to implement a MOC with care management as the centerpiece, designed to meet the specialized needs of the plan's targeted enrollees.

During the review of SNP care coordination findings in the CMS Medicare Parts C and D program audits, CMS routinely sees plans struggle to complete HRAs and/or annual assessments in a timely manner, create and develop ICPs that comply with all requirements, and facilitate ICT meetings between their enrollees' key providers and care managers. Audits have also demonstrated that some SNPs are more adept at employing HRAs, ICPs, and ICTs as care management tools. The use of these care management tools is meant to improve the care of

special needs individuals enrolled in SNPs, and the proposed care management amendments to § 422.101(f) are intended to improve SNP performance in carrying out statutorily required care coordination practices.

CMS is proposing to amend the SNP ICP requirements at § 422.101(f)(1)(vii), which require MA organizations offering SNPs to develop a comprehensive ICP within 90 days of conducting a comprehensive initial HRA, or within 90 days after the effective date of enrollment, whichever is later, that meets additional requirements at paragraphs (f)(1)(vii)(A)–(D). CMS has identified opportunities to improve the content of ICPs. For example, CMS reviewed ICPs that did not reflect needs and conditions that often have significant impacts on beneficiary health outcomes and experiences, were only loosely related to the needs and preferences of enrollees, or that did not contain measurable outcomes. To address some of these findings, CMS is proposing several amendments to § 422.101(f)(1)(vii).

First, CMS proposes to insert new language at § 422.101(f)(1)(vii)(C) that ICPs should document all active needs and diagnoses for the enrollee based on available data. In addition to the requirement at paragraph (vi) of this section, the SNP must utilize available enrollee-specific data, including but not limited to current diagnoses, health status information, and other clinical data where available. Over the years, CMS has found that some plans will produce ICPs that do not address aspects of the enrollee's current healthcare needs. Although CMS recognizes that information collected during an HRA—along with involvement of the enrollee and/or enrollee's personal representative, as applicable—is valuable in developing an ICP, SNPs are expected to formulate an ICP based on all information gathered and should draw from enrollee-specific data, including but not limited to, current diagnoses and health status information and other clinical data where available, claims and prescription history, prior authorization records, discharge summaries, or other information from the enrollee's providers when HRA material is not available. Therefore, the proposed new language at § 422.101(f)(1)(vii)(C) requires SNPs to use enrollee-specific data, including but not limited to current diagnoses, health status information,

and other clinical data where available. Note that section 1859(f)(5)(B)(iii) of the Act and § 422.101(f)(1)(vi) require that SNPs ensure the results from the comprehensive initial and annual HRA conducted for each enrollee are addressed in the enrollee's ICP. This amendment would assist SNPs in meeting and completing ICP requirements when enrollees are unable to participate or when limited information is gathered from the HRA process.

CMS also proposes to amend the existing requirement at § 422.101(f)(1)(vii)(C), which requires that SNPs identify, as part of the ICP process, person-centered goals and objectives (as prioritized by the enrollee), including measurable outcomes as well as specific services and benefits to be provided. CMS proposes to redesignate § 422.101(f)(1)(vii)(C) as § 422.101(f)(1)(vii)(D) with revisions and reorder the current language at § 422.101(f)(1)(vii)(D) as § 422.101(f)(1)(vii)(F). CMS proposes revising this section to require that, when enrollee input is obtainable from the HRA or other consultations with the enrollee, the ICP documents discussions between the enrollee and the ICT regarding all active needs, diagnoses, and available resources for those needs. Documentation must include when the enrollee has chosen not to focus on an active need or diagnosis. The ICP must reflect the enrollee's chosen person-centered goals and objectives (as prioritized by the enrollee), including measurable outcomes, as well as specific services and benefits to be provided. This would help ensure SNPs create ICPs that appropriately reflect a discussion of all active needs and available resources for the enrollee as well as the enrollee's chosen goals, resulting in more comprehensive care planning, improved care coordination, and better health outcomes.

Consistent with a person-centered approach, the ICP should reflect the enrollee's identified goals, preferences, and priorities, even when additional health conditions or needs are identified through the HRA or available data. For example, if an enrollee uses tobacco but does not wish to pursue smoking cessation, the ICP should document that tobacco use was identified and discussed, and that cessation resources were offered, as well as the enrollee's decision not to prioritize smoking cessation at that time. The ICP should then reflect the enrollee's chosen goals

and priorities rather than include interventions the enrollee has declined. Another example is where an enrollee needs support for one or more Activities of Daily Living (ADLs), but through discussion as part of the ICP development, the SNP has identified that the enrollee has sufficient caregiver support within the home and does not want to receive other supports. In this scenario, the plan would document the discussion and relevant facts of the circumstance, with the conclusion that the enrollee does not wish to prioritize this need and then specify the enrollee's chosen goals and priorities as identified through the discussion.

In addition, CMS proposes adding a new paragraph at § 422.101(f)(1)(vii)(E) regarding situations in which an enrollee does not participate in the ICP process or does not participate in the HRA process. Specifically, if the enrollee declines to participate or cannot be reached, the SNP must identify person-centered goals and objectives for the enrollee based on available data so that they are addressed in the ICP, including measurable outcomes as well as specific services and benefits to be provided. If an enrollee does not participate meaningfully in these processes, the SNP must identify person-centered goals and objectives for the enrollee based on all available data to ensure a comprehensive ICP. CMS has noted in the past that the ICP is an essential tool for managing care for all SNP beneficiaries, regardless of whether they complete or participate in an HRA. Additionally, MA regulations at § 422.152(g)(2)(v) require that, as part of a SNP's quality improvement program, it must implement an ICP for each beneficiary. However, observations from audits and other activities have identified that when enrollee input was not obtained through the HRA for some SNPs, the ICPs lack detail or enrollee-specific information. This proposed change, taken with the proposed new language at § 422.101(f)(1)(vii)(C), will ensure that ICPs are specific to each enrollee by utilizing other information available to the plan.

CMS still maintains that obtaining enrollee input through the HRA is the best way to develop a comprehensive, person-centered ICP. CMS will continue to monitor SNP compliance with HRA and ICP requirements through the SNP audit process and notes that many

organizations continue to have high unable to reach rates. CMS requests comments on methods that organizations can use to lower these unable to be reached rates.

Next, CMS proposes adding a new requirement at § 422.101(f)(1)(vii)(G) to ensure that SNPs take available supplemental benefit offerings included in the enrollee's specific plan benefit package (PBP) into account when creating an ICP to address the enrollee's needs or to make enrollees aware of supplemental benefits under their plan. Specifically, as proposed, SNPs would identify in the enrollee's care plan the available and relevant supplemental benefits as described in § 422.102 and notify enrollees who have been identified as eligible for such benefits that those benefits are accessible to address their identified care needs. In providing the ICP to the enrollee and/or enrollee's personal representative, SNPs would be required to proactively inform enrollees of both eligibility and availability of supplemental benefits under their plan that address the enrollee's identified care needs as part of the ICP process. As noted above, SNPs are already required to take HRA information into consideration when drafting an ICP and CMS proposes codifying a requirement that SNPs use available enrollee-specific information to complete an ICP when the enrollee is unavailable to complete an HRA and/or ICP. It is likely that some SNPs are already informing enrollees of available supplemental benefits relevant to the enrollee's identified care needs as part of the ICP creation process. CMS acknowledges that supplemental benefit offerings vary significantly across MA plans and contract years and clarifies that SNPs would be expected to consider benefits available under the enrollee's specific PBP, including Special Supplemental Benefits for the Chronically Ill (SSBCI) for which the enrollee is eligible, but not benefits available under other plans or programs. When reviewing and updating the ICP, the ICT should consider any supplemental benefits available to the enrollee under the enrollee's specific PBP, as applicable, and identify those benefits in the ICP when they support the enrollee's care goals and needs. Extending the requirement for the ICP to account for supplemental benefits would further increase the effectiveness of the ICP, enhance existing care coordination requirements under§ 422.101(f), and improve quality outcomes,

particularly given the critical role supplemental benefits can play in providing medical and non-medical items and services not covered by Medicare Parts A and B.

Next, CMS proposes to add a new requirement at § 422.101(f)(1)(vii)(H) that would require SNPs to share and make accessible the ICP with the following parties: the enrollee; the enrollee's personal representative, if applicable and consistent with 45 CFR 164.502(g); the ICT required under § 422.101(f)(1)(ix); and, for facility-based institutional special needs plans (FI-SNPs), the enrollee's long-term care facility. Of note, the sharing of the ICP must be consistent with current statutory and regulatory requirements regarding the sharing of protected health information. SNP audit findings indicate that SNPs are inconsistent in providing a copy of the ICP to the enrollee or making it available through an easily accessible platform, such as a plan portal. This proposal would expand access beyond the enrollee to include their personal representative, in alignment with the HIPAA Privacy Rule at 45 CFR 164.502(g), as well as members of the enrollee's ICT. CMS is not proposing to designate a specific method for communicating the ICP to the parties identified in the proposed rule. MA organizations are best positioned to identify an appropriate method of communication. However, any form of dissemination should permit individuals to readily retrieve, store, and secure the ICP as they see fit, consistent with HIPAA and other applicable privacy and security requirements. This requirement would also apply to enrollees who did not participate in an HRA, as SNPs are required to develop ICPs for all enrollees.

Lastly, CMS proposes to revise § 422.101(f)(1)(ix) to strengthen the current statutory and regulatory framework requiring SNPs to employ an ICT in providing coordination of enrollee care. Section 1859(f)(5)(A)(ii)(III) of the Act requires SNPs to use an ICT in the management of care. In addition, for C-SNPs, section 1859(f)(5)(B)(i) of the Act requires the ICT to include providers with demonstrated expertise, including training in an applicable specialty, in treating individuals similar to the targeted population of the plan. CMS implemented these statutory requirements in regulation at § 422.101(f)(1)(ix) to apply to all SNP types. In addition to

relabeling paragraph (ix) as "Interdisciplinary Care Team (ICT)," CMS proposes to add several new requirements specifying the types of providers that, at a minimum, should be part of an enrollee's ICT.

First, CMS proposes adding at § 422.101(f)(1)(ix)(A) a general ICT requirement applicable to all SNP types—D-SNPs, C-SNPs, and I-SNPs—that would require SNPs to include, at a minimum, the following: a primary care provider or a member of their clinical staff such as nurse practitioners, physician assistants, or registered nurses, acting as the provider's representative, a care manager, any behavioral health care provider actively treating or coordinating care for the enrollee, and at least one other individual with clinical training or expertise who is delivering or coordinating care for the enrollee. If the enrollee is not receiving treatment or care coordination from a behavioral health provider, the SNP is not required to have a behavioral health provider serve on that enrollee's ICT. Second, CMS proposes adding at § 422.101(f)(1)(ix)(B) an additional ICT requirement specific to C-SNPs to ensure that the ICT includes a specialist provider who focuses on the specific chronic disease(s) of focus. For C-SNPs that serve enrollees with multiple chronic conditions, the ICT only needs to include one specialist. Next, CMS proposes adding at § 422.101(f)(1)(ix)(C) an additional ICT requirement specific to I-SNPs serving institutionalized individuals and/or institutionalized-equivalent individuals as defined at § 422.2. For I-SNP enrollees who are institutionalized, the ICT would also be required to include a member of the clinical team providing care from the enrollee's long-term care facility. For I-SNP enrollees who are institutionalized-equivalent but reside in the community, the ICT would also be required to include a home health provider, nurse, or other individual providing care in the home, as applicable based on the enrollee's care needs. Last, CMS proposes adding at § 422.101(f)(1)(ix)(D) an additional ICT requirement specific to D-SNPs. For D-SNP enrollees who are full-benefit dually eligible and residing in the community, the ICT would be required to include a home health provider, nurse, personal care aide, or other individual providing care in the home.

CMS is proposing these requirements to strengthen the value of ICTs by including the providers most critical to the enrollee's care and well-being. CMS believes the participation of these providers will close any gaps that may exist in the enrollee's care by providing a forum for sharing and exchanging information key to maintaining the enrollee's health. However, CMS acknowledges that requiring the inclusion of specific providers on the ICT may not directly increase provider participation in the ICT process, which audits have shown to be a recurring issue for many SNPs. CMS reiterates that the general requirement at paragraph (ix)(A) applies in addition to the type-specific requirements at (ix)(B), (ix)(C), and (ix)(D), not in lieu of them. CMS is seeking public comment on whether there are additional requirements CMS should consider in future rulemaking that would increase provider participation in the ICT process. In addition, CMS did consider whether to further specify ICT requirements based on the needs of enrollees, such as those that have a higher risk of poor health outcomes or greater needs for care coordination, drawing from observations in the Financial Alignment Initiative and other similar efforts. However, given the populations served by SNPs, it is anticipated that all SNP enrollees would benefit from strengthened ICT requirements. CMS requests comment on this approach and whether further specifying ICT requirements based on enrollee risk would be beneficial.

2. MOC Training and Reducing Plan and Provider Burden

CMS is proposing to remove the current requirement at § 422.101(f)(2)(ii) requiring SNPs to have appropriate staff (employed, contracted, or non-contracted) trained on the SNP MOC to coordinate and/or deliver all services and benefits. The original regulation at § 422.101(f)(2) was established to ensure that MA organizations offering SNPs maintained a robust and effective care management infrastructure capable of meeting the complex needs of their targeted enrollee populations. At its core, the requirement that SNPs have appropriate staff—whether employed, contracted, or non-contracted—trained on the SNP's MOC was intended to operationalize the broader statutory mandate that SNPs provide specialized, coordinated care to vulnerable beneficiaries.

Over the years, SNPs and their provider partners have consistently communicated to CMS that the MOC training requirement, as written, imposes a significant and disproportionate administrative burden. Plans report that while they can reasonably ensure that their employed staff receive MOC training, extending that obligation to both in-network and non-contracted providers presents substantial logistical and operational challenges. SNPs note that attempting to track, document, and verify MOC training completion for a broad and ever-changing universe of both in-network and non-contracted providers consumes significant administrative resources without producing a commensurate improvement in care coordination outcomes. Additionally, in-network providers are often torn between clinical obligations and meeting the many administrative requirements associated with contemporary healthcare, for example prior authorization forms and clinical documentation requirements. Moreover, non-contracted providers, by definition, do not have a formal relationship with the plan and therefore have no contractual obligation to participate in plan-sponsored training activities.

Provider organizations and professional associations have similarly raised concerns that the training requirement places an undue burden on individual clinicians and care teams who may serve patients enrolled in multiple SNPs—each with its own distinct MOC and training curriculum. Providers note that complying with MOC training requirements across numerous plans is not only time-consuming but also creates confusion when training content varies significantly from plan to plan.

In light of this sustained stakeholder feedback, CMS's own observations through program oversight, and to align with Executive Order 14192's call to alleviate unnecessary regulatory burden,[86] the proposal to remove § 422.101(f)(2)(ii) reflects a recognition that the regulation, as currently structured, imposes administrative costs that are not proportionate to its demonstrated impact on care quality or enrollee outcomes. CMS continues to expect that SNPs will maintain a well-trained and capable care management workforce. However, this expectation can be more

[86] Executive Order 14192 (90 FR 9065; February 3, 2025).

effectively advanced through other existing regulatory requirements—including the broader MOC framework, care coordination standards, and quality improvement program requirements—without the specific prescriptive training mandate that has proven difficult to implement and enforce consistently across the diverse range of providers involved in SNP care delivery. If finalized, CMS and NCQA will revise the current matrix for MOC evaluation and approval to remove tracking of MOC training. CMS is seeking public comment on the removal of this requirement.

3. Modernizing HRA Outreach Requirements for SNPs

Under the current regulatory framework at § 422.101(f)(1)(iv), SNPs are required to make at least three attempts to reach an enrollee, excluding any automated phone calls, on different days and at different times of day in order to schedule a comprehensive initial or annual HRA. If the enrollee remains unresponsive after three attempts, the SNP must send a follow-up letter. Additionally, SNPs are required to document all outreach attempts and, where applicable, the enrollee's decision not to participate. These requirements were designed to ensure that SNPs make meaningful, good-faith efforts to engage enrollees in the HRA process. However, the lack of clarity around emerging technologies, like Super Intelligence (SI)-enabled platforms that can be used for outreach, and the explicit prohibition on automated phone calls, has increasingly limited the ability of SNPs to leverage modern communication technologies that some enrollees may prefer and that have become standard practice in healthcare outreach.[87]

CMS is proposing to amend § 422.101(f)(1)(iv) to remove the prohibition on automated phone calls subject to applicable Federal and State communications, accessibility, and privacy requirements, and to afford SNPs the flexibility to use a broader range of communication technologies when conducting outreach to enrollees for the purpose of completing an HRA. This proposed change reflects CMS's recognition that the communication landscape has evolved

[87] The terms "Super Intelligence" and "SI" are used herein to refer to what was formerly known as Artificial Intelligence or AI. See Exec. Order No. 14434, Inaugurating the Era of Super Intelligence, 91 FR 63,129 (October 2, 2026).

significantly since the original regulation was promulgated. Enrollees today increasingly interact with healthcare organizations through digital channels, including text messages, secure patient portal communications, and automated interactive voice response systems. Requiring SNPs to rely exclusively on non-automated, live-agent phone calls as the primary mode of HRA outreach is no longer consistent with how many beneficiaries prefer to communicate with their health plans.

Under the proposed amendment, SNPs would be permitted to use automated phone calls, SI-assisted outreach, text message communications, and secure portal messaging methods that comply with applicable privacy and security requirements as part of their HRA outreach efforts to meet the three-attempts requirement under § 422.101(f)(1)(iv)(A). This flexibility is intended to allow SNPs to tailor their outreach strategies to the communication preferences of their enrollee populations, consistent with the person-centered care principles that underpin the MOC framework. For example, a SNP serving a predominantly younger dual-eligible population may find that text message outreach yields significantly higher response rates than live phone calls, while a SNP serving an older institutionalized population may choose to rely on direct staff contact as the most effective approach. The proposed amendment would allow each SNP to determine the most appropriate and effective outreach modality for its specific population, rather than mandating a one-size-fits-all approach. CMS understands that many SNPs already employ some of these outreach tools, but an additional intent of this proposed rule is to eliminate any ambiguity that may exist with the current regulation and potential outreach methods that plans could use to communicate with enrollees.

Importantly, the proposed amendment does not eliminate the requirement that SNPs make meaningful outreach efforts to reach enrollees for HRA completion. SNPs would still be expected to document their outreach attempts and, where applicable, the enrollee's decision not to participate. The core accountability framework — including the requirement to send a follow-up letter when an enrollee has not responded — would be retained to ensure that SNPs continue

to make good-faith efforts to engage all enrollees in the HRA process. The proposed change is narrowly focused on removing the prohibition on automated outreach and expanding the permissible methods of contact, not on reducing the overall standard of care coordination expected of SNPs.

This proposed amendment is consistent with CMS's broader policy goals of reducing administrative burden on plan sponsors while simultaneously improving the quality and effectiveness of care coordination for SNP enrollees. Recent reporting data indicates that across all SNPs, the mean percent of new enrollees that were unreachable for an initial assessment was roughly 20 percent, with 37.52 percent unreachable for the annual assessment in 2024. Notably, there were very small percentages of enrollees refusing to participate in either the initial or annual assessments, which indicates that there are significant opportunities to improve assessment completion rates through enhanced outreach strategies. By permitting the use of modern communication technologies—including SI-assisted outreach tools that can personalize messaging, optimize contact timing, and adapt to enrollee response patterns—CMS aims to increase HRA completion rates, improve the timeliness of care plan development, and ultimately enhance health outcomes for the vulnerable populations served by SNPs. In particular, communications through patient portals that are compliant with the HIPAA Privacy and Security Rules offer a secure and enrollee-friendly channel that protects beneficiary privacy and security while enabling more efficient and responsive outreach than traditional mail or live phone contact alone.

CMS also recognizes that the adoption of SI and automated communication technologies in healthcare is accelerating, and that regulatory frameworks must evolve to keep pace with these developments. Allowing SNPs the flexibility to incorporate these tools into their HRA outreach processes positions the program to benefit from ongoing technological innovation while maintaining the robust enrollee protections and care coordination standards that are central to the SNP program. As with any regulatory change, CMS may reevaluate this position if there are

unintended consequences, impacts on compliance with other regulations, or potential beneficiary harms following implementation.

Lastly, CMS also proposes amending paragraph (f)(1)(iv) to permit CMS to review SNP HRA communication policies and/or procedures upon request. If finalized, CMS intends to review HRA communication and outreach policies through the annual MOC submission process. For instance, NCQA and CMS could potentially ask SNPs to provide an overview of their HRA outreach and communication process, including whether they use SI and automated communication technologies, how plans are operationalizing HRA refusals, and documentation of outreach attempts for enrollees across different communication modalities. CMS anticipates that corresponding changes would be made to the MOC matrix through an update of OMB Control Number 0938-1296 (CMS-10565) titled, "Medicare Advantage Model of Care Submission Requirements." CMS will continue to assess individual enrollee outreach attempts through the regular program audit processes.

CMS estimates that this proposal will reduce SNP burden, which is discussed in section IX.B.5. of the proposed rule. CMS is seeking comments on all foregoing proposals. Specifically, CMS is looking for feedback on whether SNPs should be required to document each enrollee's preferred method of HRA communication at the time of enrollment and use the enrollee's stated preference as the primary outreach modality for HRA scheduling. Lastly, CMS also welcomes comments from the public on the required composition for the SNP ICTs, including additional requirements by SNP type, and whether additional or different providers, staff, or other professionals should be added for the interdisciplinary care team.

B. Improvements for Specials Needs Plans (§§ 422.2, 422.66, and 422.101)

1. Require Certain Chronic Condition Special Needs Plans and Institutional Special Needs Plans to Coordinate with Medicaid for Dually Eligible Individuals (§ 422.101)

In 2025, there were approximately 12.5 million people dually eligible for Medicare and Medicaid. Dually eligible individuals totaled 20 percent of the Medicare population in 2022 but accounted for 36 percent of Medicare spending. Similarly, dually eligible individuals comprised 13 percent of all Medicaid beneficiaries but accounted for 27 percent of Medicaid spending in 2022. Dually eligible individuals frequently encounter fragmentation in the health care system as they navigate the Medicare and Medicaid programs. CMS has been working to improve care and reduce avoidable expenditures 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) create a seamless experience for dually eligible individuals; and (3) mitigate cost-shifting incentives between the two programs.

C–SNPs restrict enrollment to special needs individuals with one or more specific severe or disabling chronic conditions as defined at § 422.2. The Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123) amended section 1859 of the Act to revise the definition of "severe or disabling chronic condition" for purposes of identifying the special needs individuals eligible to enroll in C–SNPs. The Contract Year 2025 Medicare Advantage and Part D final rule, which appeared in the **Federal Register** on April 23, 2024 (hereafter referred to as the April 2024 final rule; 89 FR 30448), codified the definition of severe or disabling chronic conditions at § 422.2, which includes a list of 22 co-morbid and medically complex chronic conditions that are life threatening or significantly limit overall health or function, have a high risk of hospitalization or other significant adverse health outcomes, and require intensive care coordination, and that which is designated by the Secretary under sections 1859(b)(6)(B)(iii)(II) and 1859(f)(9)(A) of the Act. Some examples of these conditions include chronic alcohol use disorder and other

substance use disorders, autoimmune disorders, cancer, cardiovascular disorders, chronic heart failure, dementia, diabetes mellitus, HIV/AIDS, chronic lung disorders, chronic and disabling mental health conditions, and neurological disorders. In addition, the April 2024 final rule codified a list of five combinations of commonly co-existing chronic conditions that may be the focus of a C–SNP at § 422.4(a)(1)(iv)(B). These groupings include diabetes mellitus and chronic heart failure; chronic heart failure and cardiovascular disease; diabetes mellitus and cardiovascular disorders; diabetes mellitus, chronic heart failure, and cardiovascular disorders; stroke and cardiovascular disorders; anxiety associated with chronic obstructive pulmonary disease (COPD); chronic kidney disease (CKD) and post-(renal) organ transplantation; and substance use disorders (SUD) and chronic mental health disorders (89 FR 30661 through 30668).

I-SNPs are SNPs that restrict enrollment to MA eligible individuals who meet the definition of institutionalized or institutionalized-equivalent per § 422.2. The April 2024 final rule codified three I–SNP subtypes: facility-based institutional special needs plan (FI–SNP), hybrid institutional special needs plan (HI–SNP), and institutional-equivalent special needs plan (IE–SNP). (89 FR 30649 through 30653). D–SNPs are specialized MA plans for individuals who are entitled to medical assistance under a State plan under Title XIX, per § 422.2.

As discussed in the preceding proposals, consistent with section 1859(f)(5)(A) of the Act, all SNPs are required to implement care management requirements that have two core components: an evidence-based model of care (MOC) and care management services for each enrollee. All SNPs must submit their MOCs to CMS for NCQA evaluation and approval, and an MA organization sponsoring multiple SNPs must develop a separate MOC to meet the needs of the targeted population for each SNP type it offers as required at §§ 422.4(a)(1)(iv),

422.101(f)(3)(i), and 422.152(g). SNPs must submit the MOCs to CMS the Friday before the first Monday in June.[88]

Section 422.101(f)(1) requires SNPs to conduct an initial and annual health risk assessment (HRA) for each enrollee. They must also ensure that the results of the HRA are addressed in the enrollee's individualized care plan (ICP). SNPs are further required to ensure that the ICP is person-centered and based on the enrollee's preferences, including the delivery of services and benefits, and the needs identified in the HRA. The ICP must also identify person-centered goals and objectives including measurable outcomes as well as specific services and benefits to be provided. In addition, per § 422.101(f)(2)(iii), SNPs must coordinate the delivery of care across healthcare settings, providers, and services to assure continuity of care.

The Contract Years 2020 and 2021 Medicare Advantage and Part D final rule, which appeared in the April 16, 2019 **Federal Register** (hereafter referred to as the April 2019 final rule; 84 FR 15680), codified language at § 422.107(c)(1)(i) requiring contracts between an MA organization seeking to offer a D-SNP and a State Medicaid agency to document the MA organization's responsibility to coordinate the delivery of Medicaid benefits for individuals who are eligible for such services. In addition, the April 2019 final rule included language at § 422.562(a)(5) to require D-SNPs to offer to assist an enrollee in that plan with obtaining Medicaid covered services and resolving grievances, including requesting authorization of Medicaid services, as applicable, and navigating Medicaid appeals and grievances in connection with the enrollee's own Medicaid coverage, regardless of whether such coverage is in Medicaid fee-for-service or a Medicaid managed care plan, such as a Medicaid managed care organization (MCO), prepaid inpatient health plan (PIHP), or prepaid ambulatory health plan (PAHP) as defined in § 438.2. If the enrollee accepts the offer of assistance, the plan must provide the assistance.

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[88] HPMS e-mail from September 3, 2025, "Contract Year 2027 Model of Care Submission Timeline Updates." Available at: https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-1-september-1-5.

As described in the Contract Year 2027 Medicare Advantage and Part D proposed rule, which appeared in the November 28, 2025 **Federal Register** on (hereafter referred to as the November 2025 proposed rule; 90 FR 54894), the number of C-SNPs offered by MA organizations has increased substantially in recent years as well as the number of dually eligible individuals enrolled in C-SNPs. (90 FR 54979 through 54981) We also noted in the November 2025 proposed rule that the number of dually eligible individuals enrolled in C–SNPs grew from 103,877 enrollees in CY 2021 to 210,983 enrollees in CY 2025, an increase of more than 100 percent. The highest level of growth during that timeframe occurred between CY 2024 and CY 2025 with enrollment of dually eligible individuals increasing from 133,706 enrollees in CY 2024 to 210,983 enrollees in CY 2025, an increase of 57.8 percent in one year. In CY 2026, the number of dually eligible individuals enrolled in C-SNPs grew further to 354,790, an increase of 68 percent over CY 2025. Over the same timeframe, the number of C–SNPs with a high proportion of dually eligible enrollees (defined as dually eligible individuals representing 60 percent or more of total enrollment consistent with the definition of D-SNP look-alike at § 422.514(d)) increased from 16 C-SNPs in CY 2021 to 66 in CY 2025 and 108 in CY 2026. MedPAC's analysis in the March 2026 Report to Congress found a similar pattern of growth.[89] Compared to C-SNPs, the number of I-SNPs offered by MA organizations has remained relatively consistent in recent years. Dually eligible individuals represented the vast majority of I-SNP enrollees at approximately 90 percent of total enrollment each year given their needs for long-term care. The higher proportion of dually eligible individuals in other SNP types is not unexpected – dually eligible individuals frequently have higher rates of chronic disease and those enrolled in I-SNPs have significant long-term care needs, which can be costly and impact spenddown to Medicaid eligibility.

[89] MedPAC, March 2026 Report to Congress, Chapter 15. https://www.medpac.gov/wp-content/uploads/2026/03/Mar26_MedPAC_Report_To_Congress_SEC.pdf

Inappropriate marketing may be one of the reasons why there are some C-SNPs with significant proportions of dually eligible enrollees.[90] Additionally, C-SNPs with high proportions of dually eligible individuals frequently have benefit designs that specifically attract dually eligible individuals. In an analysis of the 108 C-SNPs with dually eligible individuals representing 60 percent or more of total enrollment in CY 2026, 90 percent of the C-SNPs have the highest possible Part D deductible ($615). Of these C-SNPs with a high proportion of dually eligible enrollees, 89 percent had the maximum Part A and B out-of-pocket limit ($9,250) and another 7 percent of these plans had Part A and B out-of-pocket limits between $6,500 and $8,850. Most dually eligible individuals do not benefit from lower levels of Part A and B out-of-pocket limits since Medicaid covers their Part A and B cost-sharing. Similarly, C-SNPs that target dually eligible individuals do not have the same incentives as other MA plans to charge lower Part D deductibles and premiums because the Part D low-income subsidy covers the Part D deductible and premiums. While CMS recognizes that dually eligible individuals can enroll in any type of MA plan based on their unique preferences, the data suggests such benefit designs result in higher proportions of dually eligible individuals enrolled in certain C-SNPs because non-dually eligible individuals would have high out-of-pocket costs, which makes the plans unattractive for these individuals. Another factor that could contribute to dually eligible individuals enrolling in C-SNPs is their high prevalence for chronic conditions, which we discuss later in this section. We also recognize that a dually eligible individual may choose a C-SNP over a D-SNP due to their own unique preferences.

We support options that continue to emphasize beneficiary choice of health plans but maintain concern for the quality of care received by dually eligible individuals. Much of the feedback we received from our C-SNP request for information (RFI) in the November 2025 proposed rule supported a system where dually eligible individuals who are enrolled in a C-SNP

[90] HPMS memorandum, Marketing to Individuals Dually Eligible for Medicare and Medicaid, April 16, 2026. Available at: https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-3-april-13-17

or I-SNP can access high-quality integration, including accessing their Medicaid and Medicare benefits without delay and have access to quality person-centered care coordination. The central argument was that dually eligible individuals deserve the same level of coordinated care regardless of which SNP type they are enrolled in. A dominant theme from the commenters was support for extending the D-SNP care coordination requirements to C-SNPs and I-SNPs serving dually eligible individuals, particularly regarding coordination with Medicaid for long-term services and supports (LTSS) and behavioral health. Some plans recommended that CMS standardize care coordination requirements across D-SNPs, C-SNPs, and I-SNPs for full-benefit dually eligible individuals, including integrated health risk assessments and care plans.

A commenter noted that dually eligible individuals experience significantly higher prevalence of severe and disabling chronic conditions than Medicare-only beneficiaries. Thus, overlap between dual eligibility and C-SNP enrollment is clinically expected and reflects appropriate targeting of chronic conditions, not circumvention of program requirements. A commenter also stated that C-SNPs offer supplemental benefits that are targeted for treating the designated chronic condition as well as specialized provider networks specific to treating that chronic condition. A commenter noted that given the high rate at which dually eligible individuals enroll in both C-SNPs and I-SNPs and given that these beneficiaries will ultimately require the same level of care and benefit coordination regardless of the plan type in which they choose to enroll, the commenter suggested that CMS improve the quality of care and patient experience of dually eligible individuals by standardizing care coordination requirements for these members across SNP types. Another commenter noted that C-SNPs can provide more tailored care coordination for complex populations such as persons with end-stage renal disease (ESRD). In C-SNPs, this population may experience more timely access to specialists such as nephrologists compared to other plan types where wait times may be increased or out-of-network

arrangements may be more frequent. Relatedly, a commenter noted that C-SNPs can better help manage disease progression and potentially delay the need for higher levels of care.

Other commenters suggested that CMS leverage data, such as through payer-to-payer application programming interface (API) regulations codified in the 2024 CMS Interoperability and Prior Authorization final rule which appeared in the **Federal Register** on February 8, 2024 (89 FR 8758), to enable flow of clinical data, prior authorization, and claims data between Medicare and Medicaid payers to ensure care coordination without affecting beneficiary choice or market competition. A commenter suggested that CMS allow delegated or partnered LTSS integration models where MA plans could lead overall care coordination while LTS remains with the Medicaid partner.

Some commenters opposed any new care coordination requirements for C-SNPs and I-SNP. These commenters highlighted that SNPs, including C-SNPs and I-SNPs, currently have requirements to coordinate delivery of care across healthcare settings, providers, and services to ensure continuity of care. They believed that any new care coordination requirements would likely be redundant and refocus C-SNPs on enrollees' dually eligible status rather than their chronic conditions.

To ensure full-benefit dually eligible individuals enrolled in C-SNPs and full-benefit dually eligible individuals enrolled in I-SNPs who reside in the community receive the benefits of care coordination with Medicaid similar to those enrolled in D-SNPs, we propose to add a requirement at § 422.101(f)(2)(iii)(B) that C-SNPs and IE-SNPs, where 60 percent or more of the plan's total enrollment is enrollees who are entitled to Medicaid, as determined by CMS using the January enrollment of the current year, coordinate with Medicaid across healthcare settings, providers, and services for full-benefit dually eligible enrollees. We propose to add a similar requirement at new § 422.101(f)(2)(iii)(C) for full-benefit dually eligible HI-SNP enrollees who reside in the community. We explained in the RFI included in the November 2025 proposed rule that the challenges with C-SNPs and I-SNPs enrolling high percentages of dually

eligible individuals are similar to the challenges of D-SNP look-alikes, which are non-SNP MA plans that enroll 60 percent or more dually eligible individuals as a percent of their total enrollment. (90 FR 54981) For purposes of our proposal, we recommend setting the threshold at 60 percent or more dually eligible individuals as a percentage of total enrollment consistent with how CMS defines D-SNP look-alikes at § 422.514(d). As we explained in the April 2024 final rule addressing D-SNP look-alikes, the 60-percent threshold indicates a level of dually eligible enrollment that would not be the result for any plan that simply reflected the concentration of dually eligible enrollees in its service area. (89 FR 30708) This analysis also includes service areas where C-SNPs and I-SNPs are offered so the 60-percent threshold is appropriately applicable to C-SNPs, IE-SNPs, and HI-SNPs as well. Under this proposal, C-SNPs, IE-SNPs, and HI-SNPs would be required to identify full-benefit dually eligible individuals enrolled in their plan, strategies for coordinating Medicaid covered services in response to enrollee needs, and methods for coordination. For HI-SNPs, the proposed requirement would only apply to full-benefit dually eligible individuals who reside in the community. Section 1856(b)(1) of the Act authorizes the Secretary to establish by regulation standards consistent with, and to carry out, Part C. Additionally, section 1857(e)(1) of the Act authorizes the Secretary to establish MA organization contract terms and conditions that are necessary and appropriate and not inconsistent with other Part C statutory requirements. We believe that our proposed contract terms requiring certain C-SNPs, IE-SNPs, and HI-SNPs to assist full-benefit dually eligible individuals in accessing Medicaid benefits is not inconsistent with the Part C statute and is necessary and appropriate to ensure full-benefit dually eligible individuals have access to services that could prevent future acute care events and avoid any duplication of benefits across the two programs.

While we note that § 422.101(f)(2)(iii) already requires MA organizations offering SNPs to coordinate the delivery of care across healthcare settings, providers and services to assure continuity of care, it does not specifically include coordination with Medicaid. Medicaid covers

key services including long-term services and supports (LTSS), behavioral health, durable medical equipment (DME), dental, vision, transportation, and caregiver supports. We believe that it is beneficial for MA plans to coordinate with Medicaid to ensure full-benefit dually eligible individuals have access to the Medicaid services they need to manage chronic conditions and other care needs. Dually eligible individuals have a high prevalence for chronic conditions. Sixty-three percent of dually eligible individuals have three or more chronic conditions. Sixty-four percent of full-benefit dually eligible individuals have a behavioral health diagnosis, such as depression or serious mental illness, and 37 percent of full-benefit dually eligible individuals use LTSS.[91] We have already noted how a large portion of C-SNP and IE-SNP enrollees are dually eligible individuals. The definition of C-SNPs in section 1859(b)(6)(B)(i)(II) of the Act states that enrollees in these plans require intensive care coordination. Dually eligible enrollees often have greater needs for the types of services that are covered under Medicaid. Without coordination for the services that are provided under Medicaid, there can potentially be a larger gap in fulfilling the needs of these enrollees. At a minimum, it can delay care or services which could result in the potential for acute or chronic conditions to worsen or the need for institutional equivalent individuals to receive a higher level of care.

We are also proposing at § 422.101(f)(2)(iii)(A) that D-SNPs coordinate the delivery of Medicaid benefits for individuals who are eligible for such services consistent with § 422.107(c)(1)(i). D-SNPs are already subject to regulatory requirements regarding coordination of Medicaid benefits and beneficiary assistance under §§ 422.107(c)(1) and 422.562(a)(5), so this is not a new substantive requirement for these plans. In addition, these regulatory requirements to coordinate with Medicaid are already reflected in the Model of Care Requirements for Medicare Advantage Special Needs Plans.[92] However, we believe it is

[91] Integrated Care Resource Center. Working with Medicare: Introduction to Dual Eligibility, June 2025 slides. Retrieved from: https://integratedcareresourcecenter.com/sites/default/files/ICRCWWMIntrotoDualEligibility.pdf

[92] The valid OMB control number for this information collection is 0938- 1296 (CMS-10565). The current expiration date is December 31, 2028. Available from: https://snpmoc.ncqa.org/static/media/MOC_Matrix_Requirements.cea14a013041134e2c56.pdf.

important to include D-SNPs under this section along with C-SNPs, IE-SNPs, and HI-SNPs for clarity. This will be a new requirement for C-SNPs, IE-SNPs, and HI-SNPs where dually eligible individuals represent 60 percent or more of total enrollment.

We are not proposing to require C-SNPs, IE-SNPs, and HI-SNPs with high proportions of dually eligible individuals to coordinate with Medicaid for partial-benefit dually eligible individuals because the only Medicaid benefits these individuals receive is coverage of Medicare cost-sharing. However, due to eight-to-nine percent of partial-benefit dually eligible individuals becoming full-benefit dually eligible individuals each year, we believe it is important that these plans are ready to coordinate with Medicaid when a partial-benefit dually eligible individual reaches full-benefit eligibility and thus are proposing to include them in the 60-percent threshold.[93] Consistent with the approach we use to determine D-SNP look-alikes at § 422.514(d)(2), we are proposing to use January enrollment of the current year to determine which C-SNPs, IE-SNPs, and HI-SNPs meet the 60-percent threshold. If this proposal is finalized, the C-SNPs, IE-SNPs, and HI-SNPs that meet this threshold would be required to coordinate with Medicaid across healthcare settings, providers, and services for full-benefit dually eligible enrollees for the upcoming year. This means that CMS would use the enrollment data from January 2027 to determine the C-SNPs, IE-SNPs, and HI-SNPs that meet the 60 percent threshold for CY 2028.

We are limiting the proposal to exclude I-SNP enrollees who meet the definition of institutionalized in § 422.2. We believe that IE-SNP and HI-SNP enrollees who reside in the community could benefit most from the enhanced care coordination, as their care is likely to be more fragmented which results in the need to coordinate with more resources, similar to persons in D-SNPs and C-SNPs. In contrast, I-SNP enrollees who are institutionalized receive more

[93] Lei, L, Wysocki, A. Assessing the Value of D-SNP Enrollment for Partial-Benefit Dually Eligible Individuals: D-SNP Enrollment Among Full and Partial-Benefit Dually Eligible Individuals—Final Report. Mathematica Policy Research. August 2023. Available from: https://www.mathematica.org/publications/assessing-the-value-of-d-snp-enrollment-for-partial-benefit-dually-eligible-individuals.

centralized care coordination with facility-based staff that is likely to be familiar with how to coordinate with Medicaid due to the proportion of people in the facility being eligible for Medicaid. However, we solicit comments regarding whether enhanced care coordination requirements should apply to all I-SNPs and all I-SNP enrollees given the importance of coordinating care and benefits for dually eligible individuals residing in long-term care nursing facilities.

While D-SNPs have access to State Medicaid agency information and Medicaid enrollment information as a result of State Medicaid agency contracts (SMACs), C-SNPs, IE-SNPs, and HI-SNPs do not execute SMACs with States. They have access to data on dual eligibility status through Monthly Membership Report data that CMS shares with MA plans for each beneficiary enrolled in the plan. Through the Monthly Membership Report file, all MA plans, including C-SNPs, IE-SNPs, and HI-SNPs, can ascertain whether enrollees are partial- or full-benefit dually eligible individuals. Also, MA plans receive the MA Medicaid Status Data File, which includes monthly dually eligible statuses and corresponding dually eligible status code report.[94] Partial-benefit Medicaid eligibility categories can include qualified Medicare beneficiaries (QMBs) only; specified low-income Medicare beneficiaries (SLMBs) only; qualifying individuals (QIs); or qualified disabled and working individuals (QDWIs). The full-benefit dual Medicaid eligibility categories can include full Medicaid, QMB plus, or SLMB plus. We note that States may vary in determining their eligibility categories; therefore, there may be State-specific differences in the eligibility levels in comparison to those listed here.

In addition, if this proposal is finalized, C-SNPs, IE-SNPs, and HI-SNPs may need to determine whether an individual is in Medicaid fee-for-service or a Medicaid managed care organization and related points of contact. The Payer-to-Payer API regulations codified in the February 2024 final rule will facilitate obtaining this information. Per § 422.121(b), beginning in

[94] Plan User Communication Guide for Medicare Advantage Prescription Drug Plans, Section 7.7. May 2026. Available from: https://www.cms.gov/files/document/mapd-plan-communications-user-guide-v19-1-may-2026.pdf-1 .

CY 2027, MA plans, including C-SNPs, IE-SNPs, and HI-SNPs must establish and maintain a process to identify an enrollee's previous and current payer(s) to facilitate Payer-to-Payer data exchange. The MA plan must outreach to current enrollees no later than January 1, 2027, and must outreach to new enrollees no later than one week after the coverage start date or no later than one week after receiving acceptance of enrollment from CMS, whichever is later. If an enrollee does not respond or additional information is necessary, the MA organization must make reasonable efforts to engage with the enrollee to collect this information. MA plans must request information from enrollees about their previous and concurrent payers that would allow the plan to identify and request data from those payers, which could include the payer's name and patient ID or similar identifier. (89 FR 8834) For example, if a C-SNP enrollee who is also enrolled in a Medicaid MCO opts in to have their data shared as part of the Payer-to-Payer API data exchange process, the enrollee would provide information on the Medicaid MCO which the C-SNP can use to identify and exchange data with the Medicaid MCO and vice versa. When an enrollee has multiple active plans simultaneously, such as a full-benefit dually eligible individual enrolled in a C-SNP and Medicaid MCO and has opted in to payer-to-payer data exchange, the relevant plans will share data initially and then quarterly while both coverages are active. Data to be exchanged is outlined at § 422.119, which includes adjudicated claims and appeals, encounter data from capitated providers, and prior authorizations. These data must be exchanged in a timely manner as outlined in § 422.119(b)(1)(iv)(B), maximizing the usability of the data for care coordination. These data can be used by C-SNPs, IE-SNPs, and HI-SNPs to coordinate with Medicaid FFS and Medicaid MCOs to ensure full-benefit dually eligible individuals receive services to address their needs. For example, data exchange through Payer-to-Payer API could provide C-SNPs, IE-SNPs, and HI-SNPs with information regarding Medicaid services such as LTSS, behavioral health services, DME not covered by Medicare, dental services, vision services, transportation, and caregiver support as well as service-related authorizations, providers, and contact information.

In addition to previously mentioned factors, C-SNPs, IE-SNPs, and HI-SNPs that are located in multiple States must also consider Medicaid differences by State such as cost-sharing, benefit coverage, and providers when conducting care coordination activities if this proposal is finalized. For those enrollees in Medicaid MCOs, C-SNPs, IE-SNPs, and HI-SNPs may need to know whether the State carves out any services, such as behavioral health, and the appropriate contacts for these services. These differences may impact the care coordination approach within a State.

As we mentioned previously, once C-SNPs, IE-SNPs, and HI-SNPs have identified the full-benefit dually eligible individuals in their plan and HI-SNPs have identified which of these enrollees reside in the community they must determine strategies for coordinating Medicaid-covered services in response to their needs, and methods for coordination with Medicaid. We note that there will likely be differences in the amount and types of coordination needed for enrollees based on their risk stratification level and their current needs.

Some types of coordination could include outreach to the enrollee's Medicaid MCO to inform the Medicaid MCO that the enrollee had a recent inpatient hospital admission and was discharged back to the community with services the C-SNP, IE-SNP, or HI-SNP has put in place, like home health. The C-SNP, IE-SNP, and HI-SNP may need to coordinate with the Medicaid plan and/or directly with Medicaid providers to ensure appropriate long-term services and supports, such as a personal care aide or personal emergency response system device, are in place to ensure the enrollee is safe in the community, managing any chronic conditions, and ideally avoids a readmission. A C-SNP, IE-SNP, and HI-SNP could take the same approach with enrollees receiving Medicaid via fee-for-service, such as coordinating with a section 1915(c) home-and-community based waiver services coordinator or Medicaid case worker. Colorado offers another example of potential coordination strategies for Medicaid fee-for-service enrollees used for D-SNP enrollees that could be applied to C-SNP, IE-SNP, and HI-SNP enrollees. A May 2026 Health Affairs article notes that Colorado's Medicaid agency, the Department of

Health Care Payment and Financing, leverages D-SNP admission, discharge, and care transition data to develop reports for options counseling teams and train D-SNP teams to make direct referrals to options counseling[95]. This work supports the goals shared by the Colorado Medicaid agency and D-SNPs of transitioning dually eligible individuals to the community. IE-SNPs and HI-SNPs could establish similar relationships with State Medicaid agencies to share data for Medicaid fee-for-services enrollees outside of a State Medicaid Agency contract framework.

Plans could provide assistance in many ways, including advising enrollees to call Medicaid providers and the questions to ask, assisting enrollees with medical documentation requests, identifying necessary forms to file, and referring enrollees to an organization with more expertise (such as a State ombudsman and other relevant assistance programs). Establishing contact with the Medicaid MCO, Medicaid waiver service coordinator, or Medicaid case worker could reduce the time enrollees wait to receive services as well as reduce duplication of services. C-SNPs, IE-SNPs, and HI-SNPs may want to consider including Medicaid case workers/care coordinators and Medicaid providers as part of the interdisciplinary care team (ICT) as well as sharing the plan's HRA and ICP with the Medicaid care coordinator/case manager. C-SNPs, IE-SNPs, HI-SNPs, and even D-SNPs could also consider providing their model of care or other documentation to States to provide more insight into their care coordination strategies. Depending on the complexity of the issue and the status of the enrollee, a three-way call or more intensive care coordination activities may be needed to coordinate with Medicaid providers and care managers/care coordinators. For example, populations with severe mental illness may need more intensive care coordination between Medicare and Medicaid given the disproportionately high rates of serious mental illness among dually eligible individuals. Approximately 30 percent of duals have serious mental illness (SMI), compared with approximately five percent to 10

[95] Chaise L, Dobson C, Neely R, Priebe C. Advancing Medicare-Medicaid Integration in Fee-for-Services LTSS Systems. Health Affairs. May 2026. Retrieved from: https://www.healthaffairs.org/content/forefront/advancing-medicare-medicaid-integration-fee-service-ltss-systems

percent of adults enrolled in private insurance, Medicare alone, or Medicaid alone.[96] Thirty-five percent of individuals with significant mental health concerns report not receiving treatment.[97] We are also proposing in another section to require all SNP ICTs to include behavioral health providers actively treating or coordinating care for the enrollee, as applicable. We do not seek to be overly prescriptive in the types of assistance a plan must provide, and our examples are not intended to be exhaustive.

Per § 422.101(f)(1) SNPs must conduct a comprehensive HRA that assesses the enrollee's physical, psychosocial, and functional needs within 90 days before or after the effective date of enrollment. Accordingly, plans should be positioned to identify enrollee needs that may not be covered by Medicare and instead may be covered under Medicaid shortly after enrollment. SNPs are also required to address these results in the ICP. We recommend that any identified needs from the HRA that are covered by Medicaid be noted in the ICP as well as the care coordination steps needed to assist the enrollee in obtaining these Medicaid services as preferred by the enrollee. SNPs must already have systems in place to track care coordination activities including ICP steps taken and outcomes. CMS may review this information during Medicare Part C SNP care coordination audits. We strongly recommend that C-SNPs, IE-SNPs, and HI-SNPs add tracking of care coordination activities with Medicaid to their systems to document compliance with this new Medicaid care coordination requirement as CMS may consider reviewing this requirement during SNP care coordination audits. ICPs are one such place where these SNPs may consider documenting the Medicaid care coordination activities. Finally, we recommend that C-SNPs, IE-SNPs, and HI-SNPs develop processes to train customer service staff and care coordinators on how to provide this assistance.

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[96] McGinty, E. et. al. Enrollment in Integrated Special Needs Plans Among Dually Eligible Beneficiaries with Serious Menal Illness. JAMA Open Network, June 1, 2026. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2849733

[97] Kaiser Family Foundation, "How do States Deliver, Administer, and Integrate Behavioral Health Care? Findings from a Survey of State Medicaid Programs." Available from: https://www.kff.org/mental-health/how-do-states-deliver-administer-and-integrate-behavioral-health-care-findings-from-a-survey-of-state-medicaid-programs/.

We welcome comments regarding our proposal. Specifically, we seek feedback on the 60-percent threshold for requiring C-SNP and IE-SNPs to coordinate with Medicaid, or whether we should impose a lower threshold such as the 40-percent threshold suggested by some commenters on the November 2025 RFI; whether we should use a different enrollment period than January of the current contract year; and whether we should require coordination for specific types of full-benefit dually eligible enrollees or whether we should require coordination for all full-benefit dually eligible enrollees. We seek feedback on other ways that C-SNPs, IE-SNPs, and HI-SNPs could obtain enrollee Medicaid information if the enrollee does not opt in to the API or whether we should limit the coordination to those C-SNP, IE-SNP, and HI-SNP enrollees who opt in to sharing their data via the Payer-to-Payer API as well as feedback on facilitating data exchange with State Medicaid agencies and Medicaid MCOs. We welcome commenters' perspectives on whether there are benefits to applying our proposed requirements to all I-SNPs with 60-percent or more dually eligible enrollees, including facility-based institutional SNPs (FI-SNPs) as defined at §422.2, or whether we should exclude HI-SNPs from this proposal since the enrollees in these plans predominantly enroll individuals residing in an institution. Additionally, we solicit comments on whether and how C-SNPs, IE-SNPs, and HI-SNPs are currently coordinating with Medicaid for dually eligible enrollees. We also seek feedback on potential challenges to our proposal.

2. Amend Definition of Fully Integrated Dual Eligible Special Needs Plan (§ 422.2)

D–SNPs are a type of MA plan that are intended to integrate or coordinate care for beneficiaries who are dually eligible for both Medicare and Medicaid more effectively than standard MA plans or Original Medicare by focusing enrollment and care management on dually eligible individuals. Since the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) first authorized D–SNPs' creation, subsequent legislation has been enacted that has extended their authority to operate and set forth additional programmatic requirements. In 2008, sections 164 and 165 of the Medicare Improvements for Patients and

Providers Act (MIPPA) (Pub. L. 110– 275) amended sections 1859 and 1852(a) of the Act to require D–SNPs to: limit cost sharing for certain dually eligible beneficiaries, provide each prospective enrollee, prior to enrollment, with a comprehensive written statement that describes the benefits and cost-sharing protections to which the beneficiary is entitled under Medicaid and which are covered by the plan, and contract with the State Medicaid agency to provide benefits, or arrange for the provision of Medicaid benefits, which may include long-term care services consistent with State policy, to which such individual is entitled. Notwithstanding this requirement, section 164(c)(4) of MIPPA stipulated that a State is in no way obligated to contract with a D–SNP and limit the imposition of cost-sharing on full-benefit dually eligible individuals and qualified Medicare beneficiaries. In 2010, section 3205 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) revised section 1853(a)(1)(B) of the Act to permit the Secretary to apply a frailty payment under Program of All-Inclusive Care for the Elderly (PACE) payment rules to certain D–SNPs that are fully integrated with capitated contracts with States for Medicaid benefits, including long-term care, and that have similar average levels of frailty (as determined by the Secretary) as the PACE program. Most recently, section 50311(b) of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115-123) amended section 1859 of the Act to require integration of the Medicare and Medicaid benefits provided to enrollees in D–SNPs. In particular, the BBA of 2018 requires: (1) development of unified grievance and appeals processes for D–SNPs; and (2) establishment of new standards for integration of Medicare and Medicaid benefits for D–SNPs.

CMS has promulgated regulations in accordance with legislation. In the Contract Year 2012 Medicare Advantage and Part D final rule, which appeared in the April 15, 2011 **Federal Register** on (76 FR 21432, hereafter referred to as the April 2011 final rule), we finalized a definition of fully integrated special needs plan (FIDE SNP) at § 422.2 in accordance with section 3205 of the Affordable Care Act, stating that a FIDE SNP is a CMS approved MA-PD D-SNP that, among other things, enrolls special needs individuals entitled to Medicare and

Medicaid, has a capitated contract with a State Medicaid agency that includes coverage of specified primary, acute, and long-term care benefits and services, consistent with State policy, coordinates the delivery of covered Medicare and Medicaid health and long-term care services using aligned care management and specialty care network methods for high-risk beneficiaries, and employs policies and procedures approved by CMS and the State to coordinate or integrate member materials, enrollment, communications, grievance and appeals, and quality improvement. Further, we finalized in the April 2011 final rule that a FIDE SNP must provide dually eligible individuals access to Medicare and Medicaid benefits under a single managed care organization.

In the Contract Year 2020 Medicare Advantage and Part D final rule, which appeared in the April 16, 2019 **Federal Register** (84 FR 15680), we established requirements in accordance with section 50311(b) of the BBA of 2018. In that rulemaking, we amended the definition of FIDE SNP at § 422.2 to align with the definition of D-SNP, finalized in that same rule. These amendments to the FIDE SNP definition included replacing terminology to create cohesion between regulation and statute, codifying subregulatory guidance, and amending language regarding coordination of care. In this final rule, we added language to the definition of FIDE SNP to require a FIDE SNP to provide access to Medicare and Medicaid benefits under a single entity that holds both an MA contract with CMS and a Medicaid managed care organization contract.

FIDE SNPs fully integrate care for dually eligible beneficiaries under a single managed care organization and have the highest level of integration among D-SNPs. Just like HIDE SNPs and coordination-only D-SNPs, FIDE SNPs must have a contract with the State Medicaid agency that complies with the contracting requirements in § 422.107(c). However, to be designated a FIDE SNP, a plan must also include coverage of primary, acute, and long-term services and supports including coverage of nursing facility services for a period of at least 180 days during the plan year, behavioral health benefits, and provide coverage of home health services, medical

supplies, equipment, and appliances. As of January 2026, there are 101 FIDE SNPs across 17 states.

The current requirement in § 422.2 that the same legal entity must hold the contract for the D-SNP as well as the contract for the Medicaid managed care organization (MCO) has created a high bar for eligibility for a FIDE SNP designation. While all plans that are currently designated FIDE SNPs meet the requirements set forth in the definition of FIDE at § 422.2 and the contracting requirements at § 422.107(c), there are other plans that meet all the same elements for contracting requirements at § 422.107(c) and for FIDE SNPs as outlined in the definition at § 422.2, aside from the requirement that the contracts be held under a single entity. Because these plans do not have the same legal entity, the plan is designated as a HIDE SNP.

In the interest of promoting integration, we adopted a definition of FIDE SNP in the 2020 rule that, among other things, codified longstanding subregulatory guidance that required the same legal entity to hold both contracts. Since then, CMS has received feedback indicating that this requirement places unnecessary constraints on plan flexibility and isn't necessary to promote integration as it was intended to do. To maximize plan flexibility, we are proposing to remove this requirement.

Section 1859(f)(8)(D)(i)(II) of the Act describes D-SNPs that "meet the requirements of a fully integrated plan described in section 1853(a)(1)(B)(iv)(II)," other than the requirement to have similar average levels of frailty as the PACE program. Section 1853(a)(1)(B)(iv)(II) allows for the application of a frailty adjustment for "a specialized MA plan for special needs individuals described in section 1859(b)(6)(B)(ii) that is fully integrated with capitated contracts with States for Medicaid benefits, including long-term care, and that have similar average levels of frailty (as determined by the Secretary) as the PACE program." These provisions do not require a single legal entity to hold both the MA contract with CMS and the State Medicaid agency contract, provided the SNP is fully integrated with capitated contracts with the State for Medicaid benefits.

Further, based on feedback received since the "same legal entity" requirement was codified in the regulatory definition of a FIDE SNP, we do not believe this requirement creates a plan that provides more integrated care than a HIDE SNP that meets the bar of FIDE SNP designation outside of the same legal entity requirement. As a result, we are proposing to amend the definition of FIDE SNP at § 422.2 to remove the requirement that the D-SNP provide access to Medicare and Medicaid under a single entity that holds both an MA contract with CMS and a Medicaid MCO and replace it with the same requirement applicable to contracts held by HIDE SNPs under § 422.2: the requirement that the plan provides coverage of Medicaid benefits under a capitated contract that is between the State Medicaid agency and the MA organization, the MA organization's parent organization or another entity that is owned and controlled by its parent organization, or 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. This proposed amendment to the FIDE SNP definition at § 422.2 would continue to meet the statutory requirement at section 1853(a)(1)(B) of the Act that a FIDE SNP is fully integrated with capitated contracts with States for Medicaid benefits, as the enrollees of such a plan would have access to their Medicare benefits, provided under an MA contract with CMS, and their Medicaid benefits, provided under a Medicaid managed care organization contract, under the control of a single parent organization, but would provide more contracting flexibility for plans interested in providing a FIDE SNP.

The current definition of FIDE SNPs in § 422.2 identifies, in paragraphs (2)-(6), additional requirements that a MA plan must meet to be considered a FIDE SNP. Requirements include that a FIDE SNP have a capitated contract with a State Medicaid agency that requires coverage of primary and acute care services including Medicare cost sharing, long-term services and supports including coverage of nursing facility services for a period of at least 180 days

during the plan year, behavioral health services, home health services, medical supplies, equipment, and appliances, in addition to coordinating the delivery of covered Medicare and Medicaid services using aligned care management and specialty care network methods for high-risk beneficiaries, and using integrated materials and processes for enrollment, communications, grievance and appeals, and quality improvement. FIDE SNPs must also maintain exclusively aligned enrollment, which is the requirement that, per State policy, the FIDE SNP may only enroll individuals who are enrolled in, or in the process of enrolling in, the affiliated Medicaid managed care plan. We are not proposing to amend any of the elements in paragraphs (2)-(6) of the FIDE SNP definition at § 422.2. As such, the proposed definition allowing the Medicare and Medicaid contracts to be held by separate legal entities under common organizational control would continue to require FIDE SNPs to be fully integrated with capitated contracts with States for Medicaid benefits, including long-term care, as set forth in section 1853(a)(1)(B)(iv)(II).

We note that our only proposed change would be to amend the requirement that the FIDE SNP is required to provide dually eligible individuals access to Medicare and Medicaid benefits under a single entity that holds both an MA contract with CMS and a Medicaid managed care organization contract. We are not proposing any other amendment to the FIDE SNP or HIDE SNP definitions at § 422.2. We are not proposing any substantive change to the types or amounts of benefits that are required to be offered to HIDE SNPs or FIDE SNPS and all other requirements would remain identical to what they are today.

If finalized, this amended definition would have the impact of creating more FIDE SNPs. Currently, based on internal analysis of contract year 2026 plans, we believe that there are six HIDE SNPs that, aside from the requirement that a FIDE SNP must provide dually eligible individuals access to Medicare and Medicaid benefits under a single entity holding both the MA contract with CMS and the Medicaid managed care organization contract, would meet the definition of FIDE SNP. Therefore, we believe that additional plans could be considered for frailty payments if this proposal is finalized. We believe that amending this definition will open

up the market for more plans to become FIDE SNPs and remove an unnecessary barrier for plans. But given the high bar that plans would continue to have to meet to be considered a FIDE SNP, we do not believe that there will be a substantial increase in plans that would newly meet the FIDE SNP definition under the proposed revision.

We solicit comment on all aspects of our proposal and assumptions, including whether to include in the definition of FIDE SNP the allowance for a capitated contract to be held by 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. This allowance, currently applicable to HIDE-SNPs, was finalized in the April 2025 Final Rule to address a unique scenario presented by coordinated care organization structures in Oregon, 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.

We invite comment on the effect of this proposal and request suggestions for potential refinement.

3. Update to Default Enrollment for States Transitioning from Medicaid Fee-for-Service to Medicaid Managed Care (§ 422.66)

Section 1851(c)(3)(A)(ii) of the Act provides the Secretary with authority to establish, by regulation, a process under which an individual who is enrolled in a non-MA health plan offered by an MA organization may be deemed to have made an election to enroll in an MA plan offered by that organization upon becoming entitled to Medicare benefits. This provision grants the Secretary broad discretionary authority to define the parameters of such enrollment processes, including the populations eligible for such enrollment and the conditions under which such enrollment may be effectuated.

We initially addressed default enrollment upon conversion to Medicare in rulemaking (70 FR 4606 through 4607) in 2005, indicating that we would retain the flexibility to implement this provision through future instructions and guidance to MA organizations. Such subregulatory guidance was established later that year and was applicable to contract year 2006. As outlined previously in Chapter 2 of the Medicare Managed Care Manual, now the MA and Part D Enrollment and Disenrollment Guidance, we established an optional enrollment mechanism, whereby MA organizations may develop processes and, with CMS approval, provide seamless continuation of coverage by way of enrollment in an MA plan for newly MA eligible individuals who are currently enrolled in other health plans offered by the MA organization (such as commercial or Medicaid plans) at the time of the individuals' initial eligibility for Medicare. The guidance emphasized that seamless continuation of coverage should not be limited to situations in which an enrollee becomes eligible for Medicare by virtue of age, but extended to all newly eligible Medicare beneficiaries, including those whose Medicare eligibility was based on disability. We did not mandate that MA organizations implement a process for seamless continuation of coverage but, instead, gave MA organizations the option of implementing such a process for their enrollees who were approaching Medicare eligibility. From its inception, the guidance required that individuals receive advance notice of the proposed MA enrollment and have the ability to ''opt out'' of such an enrollment prior to the effective date of coverage.

The Contract Year 2019 final rule titled, "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program" (83 FR 16440, April 16, 2018), established the regulatory framework for an enrollment process under section 1851(c)(3)(A)(ii) of the Act as it relates to enrollment of Medicaid enrollees into dual eligible special needs plans (D-SNPs) at the time of their initial coverage election period (ICEP), which was given the term "default enrollment". The framework for default enrollment was

established at § 422.66(c) and requires that the default enrollment process into D-SNPs be subject to all of the following conditions:

- Upon enrollment into the D-SNP, the individual remains enrolled in an affiliated Medicaid managed care plan and is dually eligible for Medicare and Medicaid.
- The State has approved use of this default enrollment process and provided Medicare eligibility information to the MA organization.
- The MA organization provides the individual with a notice that meets CMS requirements.
- The individual does not decline the default enrollment prior to the effective date and does not elect to receive coverage other than through the MA organization.
- CMS has approved the MA organization to use the default enrollment process before any enrollments are processed.
- The MA organization has a minimum overall quality rating from the most recently issued Star Ratings of three stars or is a low enrollment contract or new MA plan.
- The MA organization does not have any prohibition on new enrollment imposed by CMS.

In the Contract Year 2019 final rule (83 FR 16440 and 16496), we included our reasoning for proposing and finalizing this provision, stating that the option of default enrollment can be particularly beneficial for Medicaid managed care enrollees who are newly eligible for Medicare. When the parent organization of the Medicaid managed care plan also offers a D–SNP, default enrollment promotes enrollment in a plan that offers some level of integration of care, which could include acute care, behavioral health, long-term care services and supports (LTSS), including institutional care, and home and community-based services (HCBS). Since the implementation of default enrollment, our analysis of default enrollment transactions shows a high level of retention among individuals who are default enrolled. In 2025, 80 D-SNPs were approved for default enrollment. In our review of the 40,980 individuals who were default

enrolled in CY 2025, 76 percent remained enrolled in the integrated D-SNP after their enrollments were effective and 70 percent remained enrolled three months after their default enrollments were effective. Since the finalization of the Contract Year 2019 rule, a number of States have transitioned their Medicaid program from a fee-for-service (FFS) delivery system to a Medicaid managed care delivery system. We anticipate two additional states may make such a transition within the next 3 years.

During these State-initiated transitions, individuals who are in their Medicare ICEP and meet the other criteria for default enrollment cannot be default enrolled into a D-SNP newly affiliated with a Medicaid managed care plan because they are not enrolled in the Medicaid managed care plan prior to their Medicare ICEP. This is not due to any choice or action by the individual but rather is a function of the timing of the State's transition. Under current regulations, individuals who become Medicare-eligible after a State has transitioned their Medicaid beneficiaries to a managed care delivery system are eligible for default enrollment into a D-SNP, whereas individuals who become Medicare-eligible during the transition period are excluded solely because they were not previously enrolled in Medicaid managed care plan.

This system-timing issue creates a gap for individuals who are Medicare-eligible but are in the process of being transitioned from Medicaid FFS to Medicaid managed care. Those individuals cannot be enrolled via the default enrollment mechanism simply because the State has not yet completed the individual’s transition to Medicaid managed care. We believe this creates an unfair system for Medicaid enrollees who become Medicare eligible during a State’s transition to Medicaid managed care that excludes individuals based on the timing of how their Medicare eligibility date aligns with their State’s transition into Medicaid managed care. Default enrollment promotes integration between Medicare and Medicaid coverage. To alleviate this barrier and ensure that as many individuals as possible are eligible for default enrollment during a State’s transition to Medicaid managed care, we are proposing new regulation text to allow default enrollment into a D-SNP for individuals who are eligible for Medicare and who are in the

process of transitioning from Medicaid FFS into a Medicaid managed care plan affiliated with the D-SNP, as part of a State-initiated transition to Medicaid managed care. We are proposing that default enrollment under this proposed expansion must be coordinated with, and is contingent upon, the individual's concurrent enrollment into the affiliated Medicaid managed care plan, such that integrated Medicare and Medicaid coverage is effectuated simultaneously, and that an MA organization may not effectuate default enrollment under this proposal prior to the individual's enrollment in the affiliated Medicaid managed care plan. This proposal presents a narrow update to the existing default enrollment regulations. These proposed additions would only apply to default enrollment transactions that are effective the first day of the month in which a State transitions an individual from Medicaid FFS to Medicaid managed care. Beyond that point in time, the existing default enrollment regulations would apply because individuals eligible for default enrollment are already enrolled in a Medicaid managed care plan affiliated with an eligible D-SNP.

We are proposing this change pursuant to the statutory authority described in section 1851(c)(3)(A)(ii) of the Act, which states that the Secretary may establish procedures whereby an individual currently enrolled in a non-MA health plan offered by an MA organization at the time of his or her ICEP is deemed to have elected an MA plan offered by the organization if he or she does not elect to receive Medicare coverage in another way. As we highlighted previously in this preamble, default enrollment into a D-SNP that is contingent upon and concurrent with the individual's enrollment in the affiliated Medicaid managed care plan would meet the requirement that the individual be enrolled in a non-MA health plan offered by an MA organization.

We propose to add a new § 422.66(c)(2)(i)(A) to permit default enrollment when the individual is eligible for full Medicaid benefits and is concurrently transitioning from Medicaid FFS to a Medicaid managed care plan affiliated with the MA organization offering the D-SNP. The individual's concurrent enrollment into the affiliated Medicaid managed care plan and

default enrollment into the D-SNP must effectuate simultaneously. We also propose to add new § 422.66(c)(2)(i)(B)(1) to require that for any State transitioning from Medicaid fee-for-service to Medicaid managed care and seeking to initiate concurrent default enrollment, the State will identify the individuals eligible for enrollment in the affiliated Medicaid managed care plan consistent with beneficiary choice in § 438.52, including the ability to make an affirmative Medicaid plan selection, and disenrollment protections at § 438.56, including beneficiaries' rights to disenroll for cause at any time and without cause during the 90 days following the date of the beneficiary's initial enrollment into the MCO. In particular, the proposed expansion of default enrollment would retain beneficiary choice of at least two MCOs, prepaid inpatient health plans (PHIPs), or prepaid ambulatory health plans (PAHPs) consistent with § 438.52. While States would identify individuals to be default enrolled into a D-SNP affiliated with a Medicaid managed care plan, those individuals would have the opportunity to opt out of the default enrollment and make a different enrollment choice for their Medicare and Medicaid coverage. The proposal ensures that individuals subject to default enrollment retain the ability to disenroll consistent with § 438.56. States utilizing the default enrollment mechanism would only transmit eligibility information to D-SNPs for individuals who would be concurrently enrolled in the Medicaid managed care plan affiliated with the D-SNP. States could include language in their State Medicaid agency contract to approve the use of the default enrollment process. Finally, we propose to move language currently at § 422.66(c)(2)(i)(A) that defines an affiliated Medicaid managed care plan for purposes of this section to new paragraph § 422.66(c)(2)(i)(H) for clarity.

The Medicaid managed care enrollment, default, and passive processes framework at § 438.54 provides a parallel regulatory structure under which States may assign individuals to Medicaid managed care plans as part of a transition from Medicaid FFS to Medicaid managed care. Under this framework, when a State transitions its Medicaid population from FFS delivery to a managed care delivery system and elects to use a default enrollment process, individuals

who do not make an affirmative plan selection within a designated choice period are assigned using a default enrollment process to a participating Medicaid managed care plan by the State. The default assignment framework is accompanied by a set of mandatory beneficiary protections that are built directly into the regulatory structure at § 438.56. For States that elect to use a passive enrollment process, before a Medicaid passive assignment takes effect consistent with §§ 438.52, 438.54(c), and 438.10(e), individuals must receive advance written notice informing them of the proposed Medicaid managed care plan assignment, their right to make an affirmative selection of a different plan, and the process for doing so. For States that choose to limit disenrollment, consistent with § 438.56(c), Medicaid managed care plan contracts must provide that an individual may request disenrollment for cause at any time and without cause during the 90 days following the individual's initial enrollment into the Medicaid managed care plan or during the 90 days following the date the State sends the enrollment notice, whichever is later. These protections reflect the statutory requirements of sections 1932(a)(3) and (4) of the Act, which conditions a State's authority to require managed care enrollment on the provision of meaningful choice, adequate notice, and accessible disenrollment rights. The proposed amendment to § 422.66(c)(2) expressly preserves these disenrollment rights for individuals default enrolled under our proposal, ensuring that individuals subject to default enrollment retain the ability to disenroll consistent with § 438.56, which governs Medicaid managed care disenrollment rights, and with existing default enrollment protections under § 422.66(c)(2)(i)(D) and § 422.66(c)(2)(iv)(B).

The proposed amendment to § 422.66(c)(2) is designed to align the Medicare default enrollment framework with this parallel Medicaid structure, ensuring that individuals transitioning to Medicaid managed care can be simultaneously enrolled in both the affiliated Medicaid managed care plan and the D-SNP so that integrated Medicare-Medicaid coverage is not disrupted. The concurrent enrollment requirement proposed at § 422.66(c)(2)(i)(A)(*2*)(*i*), if finalized, would ensure that individuals are not default enrolled into a D-SNP before enrollment

in the affiliated Medicaid managed care plan is effectuated, thereby preserving the coordinated coverage arrangement contemplated by the default enrollment process. Without this alignment, a dually eligible individual could be enrolled in a D-SNP for Medicare coverage while remaining in Medicaid FFS, an outcome inconsistent with the default enrollment process.

The concurrent enrollment requirement implements the proposal's requirement that default enrollment into a D-SNP be coordinated with enrollment in an affiliated Medicaid managed care plan such that both the D-SNP and affiliated managed care plan enrollment effectuate simultaneously. By coordinating the Medicare default enrollment process with the applicable Medicaid managed care enrollment process, the proposed rule, if finalized, would require the two enrollment actions occur concurrently, consistent with beneficiary choice under § 438.52 and the disenrollment protections under § 438.56, thereby supporting integrated Medicare and Medicaid coverage during the transition to Medicaid managed care.

We emphasize that this proposed expansion does not diminish any existing beneficiary protections under § 422.66(c), including advance notice requirements and opt-out rights. As outlined in the current default enrollment framework, individuals identified for default enrollment under this proposed provision would receive advance written notice in plain language per § 422.66(c)(iv), and, as required by § 422.2267, in their preferred language, explaining the nature of the default enrollment, the implications for their access to care, and their right to opt out or make an alternative enrollment election.

As required under existing § 422.66(c)(2)(iv), the default enrollment notice provides information on the differences in premium, benefits and cost sharing between the individual's current Medicaid managed care plan and the D-SNP and the process for accessing care under the D-SNP; the individual's ability to decline the enrollment - up to and including the day prior to the enrollment effective date - and either enroll in Original Medicare or choose another MA plan; and a general description of alternative Medicare health and drug coverage options available to an individual in his or her ICEP. The default enrollment notice requirements provide the

beneficiary with at least a 60-day period in which to review his or her Medicare options to decline enrollment or disenroll after the enrollment is effective. CMS reaffirms that clear, accessible communication with individuals identified for default enrollment is a critical protection, particularly given the potential impact of MA plan enrollment on provider access and care continuity. We believe that this 60-day advance notice requirement under § 422.66(c)(2)(iv) provides the same type of beneficiary protections and choice as the 90-day Medicaid managed care disenrollment window under § 438.56(c). As such, the 60-day advance notice requirement under § 422.66(c)(2)(iv) complements the 90-day Medicaid managed care disenrollment window under § 438.56(c).

For individuals eligible for default enrollment into a D-SNP on the effective date the State transitions them from Medicaid FFS to Medicaid managed care, the 60-day advance notice for default enrollment under § 422.66(c) is designed to work in concert with – not in lieu of – the 90-day Medicaid managed care disenrollment window afforded to individuals under § 438.56(c). The 60-day notice that the D-SNP sends to individuals serves a dual purpose: it serves as the official communication of the D-SNP enrollment and simultaneously informs the beneficiary of their right to decline enrollment (opt-out) or to disenroll. For situations in which a State enrolls an individual into a Medicaid managed care plan, the required 60-day advance notice of default enrollment into the D-SNP provides potential enrollees with the opportunity to opt out of the default enrollment and disenroll from the affiliated Medicaid managed care plan with or without cause as the 60-day advance notice of default enrollment window is within the 90-day Medicaid disenrollment window. We believe this approach ensures that the 60-day default enrollment notice under § 422.66(c)(2)(iv) and the 90-day Medicaid managed care disenrollment window under § 438.56(c) would operate in alignment, by providing individuals with a clear and consistent understanding of their enrollment rights across both Medicare and Medicaid. We solicit comment on how best to coordinate the 90-day Medicaid managed care disenrollment window and 60-day D-SNP default enrollment notice requirements.

If finalized, these proposed revisions would strengthen the alignment between Medicare and Medicaid enrollment processes by ensuring that individuals transitioning to Medicaid managed care are not disadvantaged by the timing of State program changes. By enabling concurrent enrollment into affiliated Medicaid managed care plans and D-SNPs as part of a State-initiated transition to Medicaid managed care, the proposal promotes greater integration, continuity, and equity in coverage for dually eligible individuals. This approach preserves existing beneficiary protections while better supporting States and MA organizations in advancing person-centered, integrated care.

We solicit comment on all aspects of our proposal and assumptions. In particular, we solicit comments on how to coordinate the 90-day Medicaid managed care disenrollment period under § 438.56(c) with the 60-day default enrollment notice requirements under § 422.66(c)(2)(iv). We also solicit comment on whether there are other Medicaid managed care regulations and operational processes that we need to consider as we finalize this proposal. Finally, we solicit comment on whether States will have the capacity to approve default enrollment if the State is transitioning its payment systems and how the timing of those transitions will need to be effectuated.

C. Technical Updates for D-SNP Regulations (§§ 422.2263, 422.2267, and 423.2263)

1. Update CMS Required Materials and Content to Include the Coverage Decision Letter (§ 422.2267)

The Bipartisan Budget Act (BBA) of 2018 directed the establishment of procedures to unify Medicare and Medicaid grievance and appeals procedures to the extent feasible for dual eligible special needs plans (D-SNPs) and companion Medicaid managed care organizations beginning in 2021. On April 16, 2019, CMS finalized the 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" (84 FR 15680) (hereafter referred to as the April 2019 final rule) to implement these new statutory provisions[98]. As a result of these regulations codified at §§ 422.629 through 422.634, starting in 2021, D-SNPs that meet the definition of an applicable integrated plan (AIP) at § 422.561 were required to unify and update appeals and grievance procedures, including how enrollees are notified of their appeal rights. More discussion of these provisions can be found at in the April 2019 final rule at 84 FR 15720 through 15723.

AIPs are D-SNPs with affiliated Medicaid managed care organizations (MCOs) that must meet the unified appeals and grievances procedures defined at §§ 422.629 through 422.634. Per § 422.631(d), AIP D-SNPs are required to issue a coverage decision letter (CDL) as a result of an integrated organization determination under § 422.631 when an AIP reduces, stops, suspends, changes or denies, in whole or in part, a request for a service or item and/or Part B drug or a request for payment of a service or item and/or Part B drug that the enrollee has already received. The CDL integrates Medicare and Medicaid service decisions into one letter, minimizing confusion for full-benefit dually eligible individuals about how to appeal an adverse decision. AIP D-SNPs issue the CDL in place of the Notice of Denial of Medical Coverage (or

[98] https://www.govinfo.gov/content/pkg/FR-2019-04-16/pdf/2019-06822.pdf

Payment) (NDMCP) form (CMS-10003; 09380829) as part of requirements to unify appeals and grievance processes.

In this proposed rule, we are proposing to add a new paragraph (i) at §422.2267(e)(16), to codify existing policy to add the CDL to the CMS required materials and content as a standardized material since it is required for AIP D-SNPs. In recent years, we have received questions from stakeholders about whether the CDL is a required standardized material. Adding CDL to the list of required materials at § 422.2267(e)(16) will provide necessary clarification for stakeholders regarding the CDL. We are not making any other updates to the section. Section 422.2267(e)(16) currently addresses the CMS required materials and content of the NDMCP, which is also known as the Integrated Denial Notice. Standardized materials and content are required materials and content that must be used in the form and manner provided by CMS.

The most recent CDL model was issued on January 6, 2026.[99] We do not believe that this proposal will result in any new burden since plans already have to comply with this requirement or have an impact on unified appeals and grievances procedures. We solicit comment on the proposed technical change.

2. Updates to Align with Monthly Special Enrollment Period for Applicable Integrated Plan D-SNP Enrollees (§§ 422.2263 and 423.2263)

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 (PACE)", which appeared in the **Federal Register** on April 23, 2024, we established a new integrated care special enrollment period (SEP) for dually eligible individuals at §423.38(c)(35) and revised the quarterly Dual/LIS Eligible Monthly SEP at §423.38(c)(4). In this rulemaking, CMS created the new monthly SEP specifically for dually

[99] https://www.cms.gov/files/document/2025-coverage-decision-letter-memo.pdf

eligible individuals to enroll in fully integrated dual eligible SNPs (FIDE SNPs), highly integrated dual eligible SNPs (HIDE SNPs), and affiliated integrated plans (AIPs) and replaced the quarterly dual/LIS SEP with a simplified monthly SEP that allows dually eligible and LIS-enrolled individuals to enroll once per month into any standalone Prescription Drug Plan (PDP). Importantly, these revised SEPs would no longer permit enrollment into MA-PD plans or changes between MA-PD plans (except where another enrollment period permits).

In this proposed rule, we are including a technical change at §§ 422.2263(b)(7)(i)(A) and 423.2263(b)(7)(i)(A) to replace the current language referring to marketing to dually eligible and LIS individuals. CMS proposes to replace this language with language to refer to the current SEP for full-benefit dually eligible individuals per § 423.38(c)(35). When the quarterly dual/LIS SEP was established and subsequently proposed to be replaced by the new monthly dual/LIS SEP and integrated care SEP, a cross-reference in the existing regulatory text was not updated to reflect the revised SEP framework. As a result, the existing text continues to align with the prior quarterly SEP structure rather than the current SEP for full-benefit dually eligible individuals to make a one-time-per month election into a fully integrated dual eligible special needs plan as defined at § 422.2, a highly integrated special needs plan as defined in § 422.2, or an applicable integrated plan as defined at § 422.561. This technical change is intended to correct that oversight, ensuring that the regulation reflects the redesigned SEP structure and appropriately captures the current SEP for full-benefit dually eligible individuals under the revised policy.

We do not believe that this proposal will result in any new burden or have an impact on marketing activities related to these SEPs as §423.38(c) clearly defines the current SEPs. We want to update this language to correctly cross-reference the current SEPs and eliminate any potential confusion. We solicit comment on the proposed technical change.

D. Introduce Additional Choice and Competition with Integrated D-SNPs (§§ 422.2; 422.514). 1. Expanding the Definition of HIDE SNP (§§ 422.2 and 422.514)

Background and Policy Framework

CMS policy regarding dually eligible beneficiaries is to (1) promote integrated care; and (2) promote the principles of choice and competition in D-SNP markets as a means of encouraging innovation and ensuring beneficiaries have the opportunity to choose from a range of high-quality plans offered by competing MA organizations. First, as we stated in the C-SNP and I-SNP Request for Information (RFI) published in the November 2025 proposed rule, meaningful integration means ensuring that dually eligible beneficiaries receive seamless, coordinated care that addresses their full range of Medicare and Medicaid needs and mitigates cost-shifting incentives between the two programs. As further described below, integration, in this context, requires that a single plan or coordinated arrangement assumes clinical and financial responsibility for benefits provided under both Title XVIII and Title XIX of the Act, so that beneficiaries experience their Medicare and Medicaid coverage as a unified whole rather than as separate, fragmented programs.

Second, we recognize that the landscape of managed care contracting has evolved, and that network dynamics and organizational structures may vary across States and markets in ways that affect how plans can feasibly deliver integrated financing and benefits. CMS has received feedback from interested parties that certain regulatory policies aimed at promoting more integrated care models have had the unintended consequence of discouraging choice and competition in certain markets. We therefore believe it is appropriate to consider a range of arrangements through which MA organizations can demonstrate the clinical and financial accountability that is the hallmark of meaningful integration, rather than prescribing a single structural model that may not reflect the realities of today's managed care marketplace.

Regulatory History

To promote integration, our rulemaking has tended to rely on common ownership requirements to foster structural integration and alignment between a D-SNP and an affiliated Medicaid managed care organization (MCO), at least for purposes of defining FIDE SNPs and HIDE SNPs in § 422.2, and more recently for purposes of § 422.514(h).

The statutory foundation for these integration requirements is found in section 1859(f)(8)(D)(i) of the Act, which establishes that, beginning in 2021, D-SNPs must meet one or more integration requirements to the extent permitted under State law, including: (1) coordinating long-term services and supports or behavioral health services, or both, in accordance with a minimum set of Secretary-determined requirements; (2) meeting the requirements of a fully integrated plan in section 1853(a)(1)(B)(iv)(II) of the Act (other than level-of-frailty requirements) or entering into a capitated contract with the State Medicaid agency to provide long-term services and supports or behavioral health services, or both; or, (3) where the D-SNP and a Medicaid MCO share a common parent organization, having that parent organization assume clinical and financial responsibility for benefits provided under both Medicare and Medicaid with respect to any individual enrolled in both plans. While the statute requires a common parent organization to assume clinical and financial responsibility for Medicare and Medicaid benefits with respect to any individual enrolled in both a D-SNP and a Medicaid MCO under the common parent, it does not mandate common ownership as a prerequisite for integration — rather, common ownership has been a component of CMS's regulatory framework for FIDE SNPs and HIDE SNPs at § 422.2, and applicable integrated plans (AIPs) at § 422.561 as a mechanism through which integration is achieved. In turn, corporate structures that facilitate the common assumption of clinical and financial responsibility for both Medicare and Medicaid benefits have effectively been the standard that CMS has used to operationalize integration requirements through successive rulemakings establishing and refining the definitions of FIDE SNP and HIDE SNP at § 422.2, and AIP at § 422.561. This reliance on the assumption of clinical and financial responsibility lies at the core of integration.

This can first be seen beginning with the Contract Year 2012 Medicare Advantage and Part D final rule, which appeared in the **Federal Register** on April 15, 2011 (hereafter referred to as the April 2011 final rule; 76 FR 21432), where we finalized that a FIDE SNP must provide dually eligible individuals access to Medicare and Medicaid benefits under a single managed care organization. In the April 2019 final rule (84 FR 15700), we amended the FIDE SNP requirement to specify that access to Medicare and Medicaid benefits must be provided under a single legal entity that holds both the MA contract with CMS and a Medicaid MCO contract. In that same rulemaking, we established the definition of HIDE SNP as a type of D-SNP offered by an MA organization that has — or whose parent organization or another entity that is owned and controlled by its parent organization has — a capitated contract with the Medicaid agency in the State in which the D-SNP operates that includes coverage of long-term services and supports (LTSS), behavioral health services, or both, consistent with State policy.

As part of the April 2019 final rule, we finalized the definition of AIP as FIDE SNPs and HIDE SNPs in which Medicare and Medicaid enrollment is aligned (per the definition at § 422.2) with the companion Medicaid MCOs for those D-SNPs, thereby making it feasible for these plans to implement unified grievance and appeals processes. At that time, we limited the universe of potential AIPs to FIDE SNPs and HIDE SNPs with exclusively aligned enrollment to ensure, first, that all enrollees are covered with the same scope of benefits, and second, that the plans implementing unified grievance and appeals offered a sufficiently substantial range of Medicaid benefits to make the unification of Medicare and Medicaid processes meaningful for beneficiaries and worthwhile for States and plans (84 FR 15699 through 15717).

The April 2019 final rule finalized the definition of aligned enrollment at § 422.2, which refers to D-SNP enrollment where the enrollee's Medicaid benefits are covered under a Medicaid MCO contract between the State and: (1) the MA organization offering the D-SNP; (2) the D-SNP's parent organization; or (3) an entity that is owned and controlled by the D-SNP's parent organization. In the April 2019 final rule, we explained that this definition clarifies that financial

and clinical responsibility for the enrollee is held by the MA organization or its parent organization (84 FR 15708).

We have since received feedback reflecting that additional arrangements beyond common ownership may also facilitate the assumption of common clinical and financial responsibility for both Medicare and Medicaid benefits. Accordingly, while the integration option described in section 1859(f)(8)(D)(i)(III) of the Act is limited to a situation in which the MA organization and the affiliated MCO share a common parent organization, a D-SNP operating under an alternative corporate arrangement where the organization offering the D-SNP assumes clinical and financial responsibility for both Medicare and Medicaid benefits, such that the State Medicaid agency contract can be attributed to the D-SNP for integration purposes, may be sufficiently integrated to meet other integration options identified in section 1859(f)(8)(D)(i) of the Act. We are therefore proposing an amendment that would allow such D-SNPs to qualify as HIDE SNPs where other integration requirements are met.

We previously recognized that the assumption of clinical and financial responsibility for both Medicare and Medicaid benefits can be achieved through contractual arrangements, not only through common ownership, in the Contract Year 2023 MA and Part D final rule, which appeared in the **Federal Register** on May 9, 2022 (hereafter referred to as the May 2022 final rule; 87 FR 27704). In that rule, we amended the definition of AIP at § 422.561 to expand the range of qualifying arrangements between Medicaid managed care plans and D-SNPs. Specifically, we recognized that certain contractual arrangements between the D-SNP and the Medicaid MCO that do not meet the definition of a FIDE SNP or HIDE SNP may nonetheless satisfy the policy objectives underlying the AIP framework without requiring that the D-SNP and the Medicaid MCO share a common parent. As finalized § 422.561, we established that the following arrangement may additionally meet the definition of AIP:

● The D-SNP, by State policy, has enrollment limited to those beneficiaries enrolled in a Medicaid MCO, where--

● There is a capitated contract between the MA organization, the MA organization's parent organization, or another entity that is owned and controlled by its parent organization--

++ A Medicaid agency; or

++ A Medicaid managed care organization as defined in section 1903(m) of the Act that contracts with the Medicaid agency; and

++ Through the capitated contract, Medicaid benefits including primary care and acute care, including Medicare cost-sharing as defined in section 1905(p)(3)(B), (C), and (D) of the Act, without regard to the limitation of that definition to qualified Medicare beneficiaries, and at a minimum, one of the following: Home health services as defined in § 440.70, medical supplies, equipment, and appliances as described in § 440.70(b)(3), or nursing facility services are covered for the enrollees.

Current Landscape and Rationale for Proposed Change

Since codifying the changes at § 422.561 in the May 2022 final rule, we have become aware of other similar contracting arrangements that we believe would allow for the level of integration of clinical and financial responsibility necessary for HIDE SNPs — and possibly FIDE SNPs — but do not meet the common ownership requirements currently codified in the HIDE SNP definition. We continue to hear from interested parties that requiring common ownership under a single parent organization is not necessary to achieve meaningful integration between D-SNPs and Medicaid MCOs, and that such a requirement may discourage competition and limit beneficiary choice in certain markets.

In response to the C-SNP and I-SNP RFI published in the November 2025 proposed rule, commenters noted that CMS's current focus on structural alignment — requiring the same parent organization for both the MA organization offering the D-SNP and affiliated Medicaid MCO — reflects an outdated approach to Medicare-Medicaid care coordination. Commenters noted that technology has transformed the integration and coordination landscape through ease of data sharing and opportunities to establish delegated integration models where MA plans would lead

overall care coordination while partnering with Medicaid plans without requiring Medicare-Medicaid plan integration through common ownership.

One example of an arrangement that we believe could allow sufficient integration of clinical and financial responsibility to offer a HIDE SNP, but does not meet the current common ownership requirement, is when a State Medicaid agency has a capitated Medicaid MCO contract with an entity, and that entity has a contractual relationship with one or more MA organizations that offer one or more D-SNPs. In this arrangement, the Medicaid managed care plan has an executed Medicaid MCO contract with the State and contracts with the MA organization(s) offering the D-SNPs, with the MA organization(s) offering the D-SNPs taking on clinical and financial responsibility for both Medicare and Medicaid benefits. In this example, the MA organization(s) offering the D-SNPs would be contractually responsible for conducting the health risk assessments, establishing individualized care plans, conducting ongoing care coordination of Medicare and Medicaid benefits, reviewing and authorizing Medicare and Medicaid benefits, unifying appeals and grievance processes, and paying Medicare and Medicaid claims for enrollees, which reflects the assumption of clinical and financial responsibility for Medicare and Medicaid benefits. A second example involves two separate MA organizations that offer D-SNPs and do not have a common parent, forming a joint venture as a Medicaid MCO that has an executed Medicaid contract with the State. Each MA organization offering a D-SNP may contract with the joint venture and meet all the requirements to be a HIDE SNP or FIDE SNP, except for common parent ownership. In the second example, each MA organization offering the D-SNP would have clinical and financial responsibility for the Medicare and Medicaid benefits, meaning that the MA organization offering the D-SNP would be contractually responsible for conducting the health risk assessments (HRAs), establishing individualized care plans (ICPs), conducting ongoing care coordination of Medicare and Medicaid benefits, reviewing and authorizing Medicare and Medicaid benefits, unifying appeals and grievances processes, and paying Medicare and Medicaid claims for the enrollees. In both examples, if the

MA organization offering the D-SNP contractually assumes clinical and financial responsibility for Medicare and Medicaid benefits with respect to any individual enrolled in the D-SNP and receiving Medicaid benefits through the capitated Medicaid contract, we find it appropriate under those circumstances to attribute the State Medicaid agency contract to the D-SNP, such that the D-SNP can appropriately be considered to have entered into, and to be providing coverage of Medicaid benefits under, the capitated Medicaid contract as contemplated by section 1859(f)(8)(D)(i)(II) of the Act. We are therefore proposing to amend the HIDE SNP definition to allow for such contractual arrangements.

1. Proposed Amendment to the HIDE SNP Definition

We are proposing to broaden the HIDE SNP definition to allow for more flexible and innovative arrangements between D-SNPs and Medicaid MCOs, which could create more opportunities for organizations to serve dually eligible individuals and expand integration approaches used by States. Specifically, we are proposing to add a new paragraph (1)(iv) to the HIDE SNP definition at § 422.2 to include D-SNPs offered by an MA organization that provides coverage of Medicaid benefits under a capitated contract that meets the following requirements: the capitated contract is between the State Medicaid agency and an entity that has a contractual relationship with the MA organization that requires the MA organization to assume clinical and financial responsibility for Medicare and Medicaid benefits with respect to individuals enrolled in the D-SNP who receive their Medicaid benefits through the capitated contract. We believe this change will open the integrated D-SNP market to other organizations, which in turn will provide more beneficiary choice and promote competition.

To meet the proposed amendment to the HIDE SNP definition, D-SNPs would still need to meet all other requirements of the current HIDE SNP definition at § 422.2, including having a capitated contract covering Medicaid LTSS or Medicaid behavioral health services, as required per the integration standards at Section 1859(f)(8)(D)(i)(II) of the Act. We believe that permitting this type of joint venture contracting arrangement would retain the existing level of

integration required of a HIDE SNP while also allowing more flexibility with respect to corporate structure. This proposed definition would thereby promote competition and choice in D-SNP markets. While we recognize that similar arguments regarding contractual accountability could be applied to the FIDE SNP definition, we are not proposing to extend this change to the FIDE SNP definition at this time. Modifying the FIDE SNP definition in this manner raises distinct considerations, particularly with respect to the frailty adjustment methodology, and we believe it would be premature to make additional structural changes to the FIDE SNP definition given that we are already proposing modifications to the FIDE SNP definition in this rulemaking.

We are also proposing to broaden the aligned enrollment definition at § 422.2 to include D-SNPs meeting the proposed expanded HIDE SNP definition. Under the current definition, aligned enrollment refers to enrollment in a D-SNP of full-benefit dually eligible individuals whose Medicaid benefits are covered under a Medicaid MCO contract between the applicable State and the D-SNP's MA organization, the D-SNP's parent organization, or another entity that is owned and controlled by the D-SNPs parent organization. We propose to expand this existing definition of aligned enrollment to include enrollment in a D-SNP of full-benefit dually eligible individuals whose Medicaid benefits are covered under a capitated contract between the applicable State and an entity that has a contractual relationship with the MA organization that requires the MA organization to assume clinical and financial responsibility for Medicare and Medicaid benefits for any individuals so enrolled.

Finally, we are proposing updates to § 422.514(h) to clarify that D-SNPs meeting the proposed expanded HIDE SNP definition would be subject to the requirements at § 422.514(h). Under current policy at § 422.514(h)(1) beginning in Contract Year 2027, where an MA organization offers a D-SNP and the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid MCO that enrolls full-benefit dually eligible individuals in the same service areas (even if there

is only partial overlap of the service areas), the MA organization: (a) may only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D-SNP for full-benefit dually eligible individuals except as otherwise provided in § 422.514(h)(3); and (b) must limit new enrollment in the D-SNP to individuals enrolled in, or in the process of enrolling in, the Medicaid MCO. Per § 422.514(h)(2), beginning in Contract Year 2030, such D-SNPs must only enroll (or continue to enroll) individuals enrolled in (or in the process of enrolling in) the affiliated Medicaid MCO, except that such D-SNPs may continue to implement deemed continued eligibility requirements as described in § 422.52(d). We propose updates at § 422.514(h)(1) to apply these requirements to entities meeting the proposed expanded HIDE SNP definition and avoid creating a potential loophole to circumvent the § 422.514(h) requirements.

We solicit comments on all aspects of this proposal, including the following:

- FIDE SNP and AIP Definitions: Whether we should apply the proposed change to FIDE SNPs, and whether we should consider other updates to the HIDE SNP, FIDE SNP, and AIP definitions to capture other types of contractual arrangements that might adequately allow for D-SNP integration.

- Enrollment Restriction: Whether, similar to the definition of AIP, a contractual relationship should only be recognized in the context of an arrangement where enrollment is limited to the contracted Medicaid MCO, as a means of ensuring that the goals of integrated care are fully realized for all enrollees.

- Clinical and Financial Responsibility Standard: Whether a contractual relationship where the parent organization or MA organization offering the D-SNP assumes clinical and financial responsibility for Medicare and Medicaid benefits with respect to individuals enrolled in the D-SNP who receive their Medicaid benefits through the capitated contract is an appropriate integration standard to apply for the flexible arrangements proposed in this rulemaking. Is this the appropriate allocation of roles between the MA organization offering the

D-SNP and the Medicaid MCO where the MA organization offering the D-SNP is ultimately accountable for performance? If so, what should be the role of the Medicaid MCO with respect to operations and functions to ensure the integration of care? Also, are there risks with our proposed amendment and other guardrails CMS should consider to ensure accountability and protect beneficiaries?

- Section 422.514(h) Requirements: Whether there are any unintended consequences of applying the § 422.514(h) requirements to arrangements under the proposed expansion of the HIDE SNP definition rather than continuing to limit § 422.514(h) requirements to D-SNPs based on common ownership.

- Examples of Other Contractual Relationships: Whether there are examples of other types of contractual relationships that might meet our proposed amendment to the HIDE SNP definition and whether there are examples of other types of contractual relationships that meet some but not all our proposed requirements.

2. Request for Information on Need for Additional Flexibility in the Current Integrated Dual Eligible Special Needs Plan Policy to Expand Choice for Dually Eligible Individuals

Background and Policy Framework

The Contract Year 2025 Medicare Advantage and Part D final rule, which appeared in the **Federal Register** on April 23, 2024 (hereafter referred to as the April 2024 final rule; 89 FR 30448), included several provisions to simplify options for dually eligible individuals and promote greater alignment of dual eligible special needs plans (D-SNPs) and Medicaid managed care organizations (MCOs). In the April 2024 final rule (89 FR 30678 through 30702), we finalized a package of provisions at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h) that require that, beginning in Contract Year 2027, where an MA organization offers a D-SNP and the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid MCO that enrolls full-benefit dually eligible individuals in the same service areas (even if there is only partial overlap of the

service areas), the MA organization: (a) may only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D-SNP for full-benefit dually eligible individuals except as otherwise provided in § 422.514(h)(3); and (b) must limit new enrollment in the D-SNP to individuals enrolled in, or in the process of enrolling in, the Medicaid MCO. Per § 422.514(h)(2), beginning in Contract Year 2030, such D-SNPs must only enroll (or continue to enroll) individuals enrolled in (or in the process of enrolling in) the affiliated Medicaid MCO, except that such D-SNPs may continue to implement deemed continued eligibility requirements as described in § 422.52(d). To minimize enrollment disruption associated with achieving compliance, in the April 2024 final rule, we finalized a provision at § 422.530(c)(4)(iii) that would provide a new crosswalk exception to allow one or more MA organizations that share a parent organization and offer D-SNPs subject to the new limits to crosswalk enrollees (within the same parent organization and among consistent plan types) when the MA organization chooses to non-renew or consolidate its current D-SNPs to comply with the new rules at §§ 422.504(a)(20) and 422.514(h).

In addition, in the April 2024 final rule, we codified at § 422.514(h)(3) two exceptions to the requirements at § 422.514(h)(1) and (2) for instances where (a) the State Medicaid agency contract (SMAC) with the MA organization differentiates enrollment into D-SNPs by age group or to align enrollment in the D-SNP with the eligibility or benefit design used in the State's Medicaid managed care program; and (b) the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization offers both HMO D-SNPs and PPO D-SNPs, subject to limitations on new enrollment of full-benefit dually eligible individuals in the HMO or PPO D-SNPs not subject to § 422.514(h)(1).

We outlined in the April 2024 final rule a number of benefits expected from these changes (89 FR 30680). These included boosting the percentage of D-SNP enrollees in aligned enrollment, and – over time – exclusively aligned enrollment, increasing access to the comprehensive coordination of care, unified appeal process across Medicare and Medicaid,

continuation of Medicare services during an appeal, and integrated materials that come with enrollment in one or more of the various types of integrated D-SNPs; prompting MA organizations to consolidate plan benefit packages (PBPs) down to a single PBP for full-benefit dually eligible individuals that is aligned with their Medicaid MCO that fully or partially overlaps with the D-SNP service area; removing some incentives for agents and brokers to target dually eligible individuals; lessening assistance needed from advocates and SHIP counselors to correct enrollment issues; and simplifying provider billing and lowering the risk of inappropriate billing. For a more detailed discussion of these provisions and expected benefits, see 89 FR 30678 through 30702.

In the Contract Year 2027 Medicare Advantage and Part D final rule, which appeared in the **Federal Register** on April 6, 2026 (hereafter referred to as the April 2026 final rule; 91 FR 17384), we finalized two additional exceptions to the requirements at § 422.514(h)(1) and (2). At § 422.514(h)(3)(iii), we finalized an exception that allows an eligible MA organization, its parent organization, or an entity that shares a parent organization with the MA organization to offer one or more additional D-SNPs for full-benefit dually eligible individuals who are enrolled in Medicaid fee-for-service. We finalized related language at § 422.107(d)(1)(i) to specify that the exception at § 422.514(h)(3)(iii) is available to highly integrated dual eligible special needs plans (HIDE SNPs) and coordination-only D-SNPs that operate in a State where the State Medicaid agency does not mandate enrollment in Medicaid managed care for full-benefit dually eligible individuals. At § 422.514(h)(3)(iv), we codified an exception that would exempt MA organizations operating in U.S. Territories that have not adopted Medicare Savings Programs from the requirements at § 422.514(h)(1) that otherwise would require – beginning in Contract Year 2027 – the MA organization to only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D-SNP for full-benefit dually eligible individuals. As we articulated at 91 FR 17531, these changes addressed challenges related to implementing the § 422.514(h) provisions, which interested parties raised since we originally

codified the provisions in the April 2024 final rule. For a more detailed discussion of these provisions, see 91 FR 17529 through 17538.

We expect the current § 422.514(h) policy to reduce the number of D-SNPs each parent organization offers for full-benefit dually eligible individuals in a service area, reducing the competitive advantage that large parent organizations hold over small ones so they can offer a more comparable number of D-SNP offerings in a service area and stopping a parent organization with multiple MA organizations in a service area from diluting the market with multiple D-SNP offerings that do not meaningfully differentiate their offerings. These are policy goals for CMS. For example, in Miami-Dade County in Florida in 2026, there are 33 D-SNPs for full-benefit dually eligible individuals offered by 12 MA parent organizations. One parent organization offered 10 of these D-SNPs, a second parent organization offered eight of these D-SNPs, and the remaining parent organizations offered three or fewer D-SNPs for full-benefit dually eligible individuals. The main differentiating features of the D-SNPs offered by the same parent organization in CY 2026 are the value of flex cards and dental benefits. For CY 2027, under the current § 422.514(h) policy, these offerings for full-benefit dually eligible individuals reduced to 18 D-SNPs offered by 11 MA parent organizations, evening the competition among parent organizations.

Interested parties have raised concerns, however, that the current § 422.514(h) policy reduces beneficiary choice of D-SNPs. For example, limiting parent organizations to offer one D-SNP for full-benefit dually eligible individuals in a service area could discourage some full-benefit dually eligible individuals from enrolling in a D-SNP when they are not ready to receive both Medicare and Medicaid benefits from one parent organization.

Additionally, in a market such as Pennsylvania where coordination-only D-SNPs compete against integrated D-SNPs subject to the restrictions of § 422.514(h) as described above, interested parties have raised concern that these integrated D-SNPs are at a competitive disadvantage. These disadvantages include limitations on the potential pool of enrollees available

to plans subject to § 422.514(h) that may only enroll beneficiaries enrolled in an affiliated Medicaid MCO as compared to coordination only D-SNPs that face no such restrictions. For example, in Pennsylvania, there are three MA parent organizations that have Medicaid MCO contracts with the State and offer HIDE SNPs. Under the current § 422.514(h) policy, these three parent organizations are not allowed to offer a coordination-only D-SNPs enrolling full-benefit dually eligible individuals in the same service area as their HIDE SNP. Starting in CY 2027, any individuals newly enrolling in their HIDE SNP must be enrolled in or in the process of enrolling in the affiliated Medicaid MCO, consistent with § 422.514(h). These parent organizations cannot compete for full-benefit dually eligible individuals who are not enrolled in their affiliated Medicaid MCO whereas the coordination-only D-SNPs can compete for those individuals. Based on current experience of some of these parent organizations, individuals who enrolled in the HIDE SNP with unaffiliated Medicaid MCO enrollment become acquainted with the parent organization and change their Medicaid MCO enrollment to align with the HIDE SNP. In this example, allowing these parent organizations to offer a coordination-only D-SNP for full-benefit dually eligible individuals would improve competitiveness in the D-SNP market as well as offer an opportunity for individuals to enroll first in the coordination-only D-SNP for their Medicare coverage. As these individuals become acquainted with the parent organization, they may enroll in the HIDE SNP and affiliated Medicaid MCO to have fully integrated Medicare and Medicaid coverage.

CMS policy regarding dually eligible beneficiaries is two-fold. First, it is to promote integrated care — a goal we have long pursued through our regulatory framework for D-SNPs. Second, CMS policy is to promote the principles of choice and competition in D-SNP markets as a means of encouraging innovation and ensuring beneficiaries have the opportunity to choose from a range of high-quality plans offered by competing MA organizations.

3. Potential Policy Change for Comment Solicitation

We solicit comments on a potential policy change to address the aforementioned concerns, allow more beneficiary choice and competition in D-SNP markets, and continue to promote integrated care. In particular, we solicit comment on whether an effective solution would be an amendment to § 422.514(h) to allow D-SNPs with affiliated Medicaid MCOs to also offer a coordination-only D-SNP for full-benefit dually eligible individuals in the same service area as their D-SNP subject to the requirements of § 422.514(h). Would allowing each D-SNP with an affiliated Medicaid MCO to offer one coordination-only D-SNP sufficiently address the need to provide an additional option for full-benefit dually eligible individuals without adding D-SNPs to the market that do not offer meaningful differences? Under this idea, the coordination-only D-SNP could enroll both full- and partial-benefit duals even if the full-benefit dually eligible individuals are enrolled in an unaffiliated Medicaid MCO. This would mean that full-benefit dually eligible individuals who do not want to enroll with the same parent organization for both Medicare and Medicaid benefits could enroll in the coordination-only D-SNP for Medicare and enroll in a different parent organization for Medicaid. If we were to propose such a change, States that want to continue to limit D-SNP offerings to only D-SNPs with an affiliated Medicaid MCO could continue to do so through their SMAC.

The extent to which MA organizations could take advantage of this idea would depend on State policy. For Contract Year 2026, there are 13 States and U.S. Territories that have integrated D-SNPs and do not allow coordination only D-SNPs in any service area in the State or only allow coordination only D-SNPs for partial-benefit dual eligible beneficiaries such that the proposed exception would not apply based on State policy. Additionally, many States have made changes to their D-SNP markets for Contract Year 2027 via the executed Contract Year 2027 SMACs to comply with existing requirements at § 422.514(h). States may be reluctant to undo these changes in future years and allow coordination-only D-SNPs for full-benefit dually eligible individuals in the same service area as HIDE SNPs or AIP D-SNPs offered by the same parent organization. However, in Contract Year 2026, there are at least 11 States that have integrated D-

SNPs and allow enrollment of full benefit dually eligible individuals in coordination-only D-SNPs in the same service area as integrated D-SNPs, including Pennsylvania and South Carolina.

We solicit comments on all aspects of this potential approach. In particular,

- Would it sufficiently introduce more beneficiary D-SNP options to address interested parties' concerns?
- Would allowing a parent organization offering a D-SNP with an affiliated Medicaid MCO to offer *one* coordination-only D-SNP for full-benefit dually eligible individuals be sufficient to offer more choice for individuals? If commenters believe more than one coordination-only D-SNP should be allowed for full-benefit dually eligible individuals, how many should be allowed and what would be the meaningful differences among those coordination-only D-SNPs offered in the same service area as the D-SNP with an affiliated Medicaid MCO?
- Would the additional flexibility offered under this idea ultimately result in greater enrollment into integrated D-SNPs by providing a glidepath into an integrated D-SNP if, for example, trust and affinity develops between the beneficiary and sponsor of the coordination only D-SNP and the enrollee later chooses to enroll in the integrated D-SNP and affiliated Medicaid MCO?
- Would States – especially those that allow both integrated D-SNPs subject to existing requirements at § 422.514(h) and coordination-only D-SNPs to enroll full-benefit dually eligible individuals – view this idea as a means of effectively promoting competition between integrated D-SNPs and coordination-only D-SNPs?
- Would the advantages of the proposed changes outweigh potential risks of detracting from the original goal of the provisions codified in the April 2024 final rule?
- Are there other strategies that we could implement to promote more beneficiary choice among D-SNPs while still promoting integrated care?

VI. Reducing Regulatory Burden and Costs in Accordance with Executive Order 14192

A. Burden Reduction in the MA Application Process and MA Network Adequacy (§ 422.116)

Section 1852(d)(1) of the Act permits an MA organization to select the providers from which an enrollee may receive covered benefits, provided that the MA organization, in addition to meeting other requirements, makes such benefits available and accessible in the service area with promptness and in a manner that assures continuity in the provision of benefits. Further, § 422.112(a) generally requires that a coordinated care plan maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served.

1. Shifting Network Adequacy Reviews from the MA Application

In the "Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program" final rule, which appeared in the **Federal Register** on June 2, 2020 (85 FR 33796) (hereinafter referred to as the June 2020 final rule), CMS codified, with some modifications, network adequacy criteria and access standards (previously outlined in subregulatory guidance) at § 422.116. The provisions at § 422.116 establish standards for measuring network adequacy and access under a contracted provider network in accordance with section 1852(d)(1) of the Act and §§ 422.112(a) and 422.114(a)(1). In addition, CMS codified the then-existing policy that CMS would not deny an application based on the evaluation of the applicant's network for a new or expanding service area. Under that policy, an applicant was required to attest that it had an adequate network for access and availability of applicable provider and facility types at the time of the application for a new or expanding service area, and CMS reviewed networks for pending service areas after an application was approved but before the MA organization was operational in the new or expanded service area.

Subsequently, in the "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy

and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" final rule, which appeared in the **Federal Register** on May 9, 2022 (87 FR 27704) (hereinafter referred to as the May 2022 final rule), CMS finalized an amendment at § 422.116(a)(2)(ii) to require MA organizations to submit a compliant network for review at the time of an MA application and provide that CMS may deny an application on the basis of an evaluation of the applicant's network for the new or expanding service area.

In the May 2022 final rule, CMS explained that the timing of network adequacy submissions for pending service areas affected the timely, complete, and accurate submission of bids. CMS stated that providing network adequacy determinations before the bid deadline, within the MA application timeline, would allow organizations to make decisions regarding their intended service areas before submitting bids and would mitigate operational issues associated with service area changes after the bid deadline. In that rule, CMS also finalized a temporary 10-percentage-point credit toward the percentage of beneficiaries residing within published time and distance standards for all combinations of county designations and provider/facility specialty types specified in § 422.116(d) in the proposed contracted network for a new or expanded service area. In response to public comments, CMS also allowed Letters of Intent (LOIs) to be used in lieu of signed provider contracts—at the time of application and for the duration of the application review. These flexibilities were intended to account for the fact that the network adequacy review for an MA application for a new or expanding service area occurs almost a year before the applicable contract year begins.

When a network adequacy review is performed in conjunction with an MA application, there is a very short window of time for MA organizations to complete the application process and demonstrate compliance with network adequacy requirements. MA organizations submit provider networks for review using the Health Service Delivery (HSD) tables and submit the data through the Network Management Module (NMM) in the Health Plan Management System

(HPMS), where CMS's automated review of network adequacy, also known as the Automated Criteria Check (ACC), is triggered. MA organizations may cure deficiencies identified through the ACC by resubmitting HSD tables with additional contracted providers or facilities, or by submitting valid exception requests during CMS specified timelines. If network deficiencies remain unresolved after the cure period, CMS may issue a notice of intent to deny the application under § 422.502(c)(2). MA organizations may also withdraw counties they wanted to operate in as submitted with their application during the application review process if they are unable to satisfy the network adequacy standards for those counties. If at least one deficiency (for a county/specialty type combination) remains unresolved after CMS issues a notice of intent to deny the application, CMS may deny the application and the MA organization may request a hearing under § 422.660. If the MA organization is not successful at the hearing, they may also appeal to the CMS Administrator under § 422.692. Unless the MA organization is successful in an administrative appeal, the application is denied.

Under the current process MA organizations must submit comprehensive application materials in mid-February of the year prior to the year in which they wish to operate, CMS reviews those materials, including the network information, and issues notices of intent to deny in mid-April and denials in mid-May in order to provide MA organizations time to exercise their appeal rights. In contrast, CMS's ongoing oversight of active provider networks operates on a three-year cycle known as the Triennial Review. This annual operational review evaluates one-third of all contracts and their entire active service areas. However, unlike the stricter application-stage process that may lead to application denial, organizations found to be out of compliance with network adequacy standards during the Triennial Review may be referred for compliance and/or enforcement actions.

An adequate network requires that MA organizations meet Medicare access and availability requirements through direct contracting with network providers consistent with the prevailing community pattern of health care delivery in the areas where the network is being

offered. Since CMS began including the network adequacy review in the MA application cycle, MA organizations have had difficulty establishing networks so far in advance of the contract start date, even with the flexibilities afforded during the application process. CMS has heard from applicants that the timing of the MA application submission period is insufficient for MA organizations to build high-quality provider networks. In addition, MA applicants have suggested that the network adequacy requirements disproportionately affect smaller MA organizations seeking to expand to certain regional, rural, and medically underserved areas, thereby inhibiting competition among plans and limiting beneficiary choice.

Since implementing application-stage network adequacy reviews, CMS has denied applications for network adequacy reasons, including in circumstances when an MA organization may only be failing network adequacy for the lack of a singular provider and where approving the application could have increased competition and enrollee choice in various service areas. Although MA organizations receive the new applicant credit and may use LOIs to establish an adequate network, CMS has found that those flexibilities have not always resolved the difficulties of establishing a contracted network so far in advance and within a short window to demonstrate compliance. Additionally, CMS has observed instances where an MA organization submitted HSD tables based largely on LOIs, rather than signed contracts. That was not the intended use of LOIs, which were meant to provide flexibility rather than serve as a placeholder for a fully compliant network.

CMS has also experienced continued bid timeline challenges. For example, when an MA organization exercises its hearing rights under § 422.660, the timeline for resolving the hearing can interfere with finalizing bids and may delay plan corrections and contract execution. Delays in those pre-operational steps create downstream issues for MA and MA-PD systems, such as contracts not being included in enrollment processes, contract information not being displayed timely on Medicare Plan Finder, challenges with automatic continuation or transition of a beneficiary's enrollment from one plan to another, and beneficiary reassignments. To reduce

burden on MA organizations and CMS, and consistent with Executive Order 14192, "Unleashing Prosperity Through Deregulation" (90 FR 9065, February 6, 2025), CMS proposes to remove the regulatory requirement under § 422.116(a)(2)(ii) that applicants must demonstrate compliance with § 422.116 as part of the MA application for a new or expanded service area. CMS also proposes to remove § 422.116(d)(7), which provides for the new applicant credit and permits LOIs to be used in lieu of signed provider contracts for purposes of network adequacy review, as those flexibilities would no longer be necessary under this proposal. Instead, consistent with § 422.116(a)(2)(i), CMS would require applicants to attest during the application process that they will meet applicable provider network standards by the beginning of the contract year. CMS is proposing to make two conforming changes, to § 422.116(a)(2)(i) and to § 422.112(a)(4), to align with the network adequacy review timing in this proposal. CMS proposes to revise the language at § 422.116(a)(2)(i), to add after the first paragraph, "An organization applying for a new service area must attest upon application that at the beginning of the applicable contract year, the MA organization will be in full compliance with network adequacy standards under this section." CMS will also revise the language in § 422.112(a)(4) to state that organizations with approved service area expansions must demonstrate that the number and type of providers available to plan enrollees are sufficient to meet the needs of the population served, reflecting that service area expansion network adequacy reviews will occur once the plan is operational. CMS would also review the provider network of an MA organization with a new or expanded service area in the first year that the MA organization is operating in a new or expanded service area. This proposal would eliminate the potential need for network adequacy-based application-related hearings, while preserving beneficiary protections through attestation requirements, first-year operational network reviews, and continuing compliance and/or enforcement obligations. This approach would also lower the burden on MA organizations that may otherwise be required to submit networks for pending service areas during the application process and once again when the service area is active during a triennial network adequacy review.

MA organizations would also have approximately 8 to 9 months of additional time prior to their MA plan being in effect to contract with providers and facilities and, if applicable, to develop exception requests under § 422.116(f)(1) using CMS's longstanding rationales also proposed for codification in section III.F. of this proposed rule.

This proposal would not change existing and continuing regulatory requirements related to enrollee access and cost sharing protections. MA organizations must continue to meet the access and availability requirements at §§ 422.112(a), 422.114(a)(1), and 422.116 so enrollees have sufficient access to covered benefits. When an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs, MA organizations that offer coordinated care plans must arrange for and cover the medically necessary covered benefit outside of the plan provider network at the in-network cost sharing level under § 422.112(a)(1)(iii). In addition, MA organizations may need to make alternate arrangements if the primary care provider network is not sufficient to ensure access to medically necessary care under § 422.112(a)(2). CMS monitors the complaints tracking module, which includes beneficiary complaints through 1-800-Medicare. CMS reviews these complaints and addresses issues to ensure beneficiaries get appropriate access to needed services. If an organization does not meet CMS access standards, CMS may take compliance or enforcement actions against those organizations.

2. Consolidating Outpatient Behavioral Health Network Adequacy Requirements

In the "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" final rule, which appeared in the **Federal Register** on April 12, 2023 (88 FR 22120) (hereinafter referred to the April 2023 final rule), CMS finalized amendments to § 422.116 adding time and distance standards and minimum ratios for two new provider-specialty types, Clinical Psychology and Clinical Social Work. In the "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 Policy

and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE)" final rule, which appeared in the Federal Register on April 23, 2024 (89 FR 30448) (herein after referred to as the April 2024 final rule), CMS finalized a new facility-specialty type, Outpatient Behavioral Health (OBH), including time and distance standards and minimum provider number requirements. As a result of these changes, MA organizations must independently satisfy each of the network adequacy standards for Clinical Psychology, Clinical Social Work, and OBH. CMS also added Clinical Psychology, Clinical Social Work, and OBH to the list at § 422.116(d)(5) of specialties for which an MA organization may receive a 10-percentage-point telehealth credit if its contracted provider network includes one or more telehealth providers of that specialty type furnishing additional telehealth benefits, as defined in § 422.135, for covered services.

At the time of the April 2023 final rule, CMS received several comments that opposed the proposal to add new behavioral health specialty types to the network adequacy evaluation, citing concerns that shortages of behavioral health providers could hinder MA plans' ability to meet network adequacy standards. However, CMS determined that finalization of the proposal was appropriate at that time, indicating that the network adequacy standards are updated annually based on the supply of providers and that MA organizations unable to meet network standards have the option to submit an exception.

Since implementing separate behavioral health specialty types into the network adequacy standards, CMS has received industry feedback that the behavioral health standards may have introduced unintended consequences, such as skewed negotiating leverage and reduced provider competition and supply in MA networks, which may increase the cost of care.

While performing network adequacy reviews, CMS has also found that MA organizations have submitted some of the same Clinical Social Work and Clinical Psychology providers on their HSD tables to satisfy both the OBH time and distance and minimum number standards and

the separate Clinical Psychology and Clinical Social Work standards. For example, CMS examined network submissions by MA organizations during the formal 2025 triennial review period and found that 94.5 percent of OBH submissions were also submitted with another behavioral health specialty, meaning that the majority of MA organizations submitted the same providers under multiple behavioral health specialty types. In the April 2024 final rule, CMS stated that "MA organizations may not submit a single provider for purposes of meeting the Outpatient Behavioral Health requirement if they have already submitted that provider under another specialty. For example, MA organizations would not be permitted to submit a single provider as a psychiatry, clinical social work, or clinical psychologist provider specialty and as an Outpatient Behavioral Health facility." However, CMS has come to understand, based on analysis of fee for service Medicare claims data from August 1, 2021, through July 31, 2022, that beneficiaries use similar psychotherapy services across the behavioral health provider types CMS monitors. For example, psychotherapy services provided to individuals with mental health or substance use disorders may be similar among clinical psychology, clinical social work, and certain specialties allowable under OBH. They may also provide other services as well, such as medication monitoring or care management.

Accordingly, to reduce administrative burden and increase flexibility with network adequacy submissions, and to mitigate potential market impacts associated with redundant network adequacy specialty type designations, CMS proposes to consolidate Clinical Psychology and Clinical Social Work provider-specialty types into the OBH facility-specialty type. Under this proposal, MA organizations would be able to satisfy the OBH network adequacy standards using any combination of qualifying providers or facilities included in § 422.116(b)(2)(xiv), including clinical psychologists and clinical social workers. This would expand the pool of providers and facilities eligible to meet the OBH network adequacy requirements and directly address concerns about duplicative submissions, provider supply, and contracting leverage.

In the amended OBH facility-specialty type definition at § 422.116(b)(2)(xiv), CMS is also proposing to include certified peer support specialists and community health workers that meet the requirements for auxiliary personnel acting under the supervision of a physician (or other eligible practitioner) described at § 410.26(a)(1). Peer support specialists are qualified mental health or substance use professionals who leverage their own lived recovery experience to guide others. They provide non-judgmental mentoring, help clients navigate treatment systems, and assist in building independent living and recovery plans. Community health workers (CHWs) are frontline public health professionals who serve as a trusted liaison between healthcare systems and local communities. They improve health outcomes by helping vulnerable populations navigate care and increase health literacy. The CY 2024 Physician Fee Schedule final rule, which appeared in the Federal Register on November 16, 2023 (88 FR 78818), finalized coding and payment changes to better account for resources involved in furnishing patient-centered care involving a multidisciplinary team of clinical staff and other auxiliary personnel. These changes make Community Health Integration and Principal Illness Navigation services separately payable under original Medicare to account for resources when clinicians involve certain types of health care support staff such as community health workers, care navigators, and peer support specialists in furnishing medically necessary care. (88 FR 78920 through 78949)

While these types of health care support staff have been able to serve as auxiliary personnel to perform covered services incident to the services of a Medicare-enrolled billing physician or practitioner, the finalized codes are the first that are specifically designed to describe services involving community health workers, care navigators, and peer support specialists. The Principal Illness Navigation codes describe services involving auxiliary personnel, such as peer support specialists to better support individuals with behavioral health conditions like severe mental illness and substance use disorder. Auxiliary personnel are not independent Medicare Part B providers and their services are billed under the supervising

physician's or eligible practitioner's National Provider Identifier (NPI) when all Medicare requirements are met. CMS believes that amending the OBH facility-specialty type to include peer support specialists and CHWs would clarify that MA plans can include these providers in their networks when these provider types meet the requirements for auxiliary personnel acting under the supervision of a physician (or other eligible practitioner) described at § 410.26(a)(1). This proposed update is consistent with original Medicare and would promote MA enrollee access to such providers to address behavioral health needs.

Current regulations at § 422.116(a)(3) specify that an MA plan must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility-specialty type. As part of the proposed consolidation, CMS proposes to remove the separate time and distance standards for Clinical Psychology and Clinical Social Work from § 422.116(d)(2) and to rely on the OBH time and distance standards for the consolidated OBH category. CMS is proposing to change the base time and distance standards for OBH based on CMS's analysis of the current supply of providers as follows:

TABLE VI.A-1: Table 1 to Paragraph (d)(2)

Specialty Type	Large Metro		Metro		Micro		Rural		CEAC	
	Time	Distance	Time	Distance	Time	Distance	Time	Distance	Time	Distance
Outpatient Behavioral Health	20	10	25	15	35	25	45	35	95	85

CMS solicits comment on whether it is appropriate for clinical psychologists and clinical social workers to be consolidated into OBH for purposes of network adequacy, and whether there are any separate implications of this proposal for rural areas.

CMS determines the minimum number requirement for all provider and facility specialty types, as codified in § 422.116(e). CMS codified at § 422.116(e)(2)(iii) that all facility specialty types, except for acute inpatient hospitals, have a minimum number requirement of one. Paragraph (e)(2)(iii) refers to all facility types listed in paragraphs (b)(2)(ii) through (xiv), including OBH. Therefore, CMS does not propose any revisions to paragraph (e)(2)(iii).

CMS intends to maintain the telehealth credit under § 422.116(d)(5) for OBH. Under § 422.116(d)(5), MA plans may receive a 10-percentage-point credit towards the percentage of beneficiaries that reside within published time and distance standards for certain providers when the plan includes one or more telehealth providers of that specialty type that provide additional telehealth benefits, as defined in § 422.135, in its contracted network. CMS is proposing to remove and reserve the separate Clinical Psychology and Clinical Social Work entries at § 422.116(d)(5)(xiii) and (xxiv), respectively, because clinical psychologists and clinical social workers would be counted under the consolidated OBH category for purposes of network adequacy. The telehealth credit would continue to be available for OBH, subject to the existing requirements at § 422.116(d)(5) and § 422.135. CMS solicits comment on whether maintaining the 10-percentage-point OBH telehealth credit is appropriate for the consolidated OBH category.

3. Proposed Revision to the Network Adequacy Telehealth Credit (§ 422.116(d)(5))

Section 1852(d)(1) of the Act requires an MA organization using a network of providers to make covered benefits available and accessible to each enrollee within the plan's service area with reasonable promptness and in a manner that assures continuity in the provision of benefits. Consistent with this statutory requirement, § 422.116 establishes minimum provider and facility number requirements and maximum time and distance standards that network-based MA plans must satisfy.

Under § 422.116(d)(4), an MA plan must demonstrate that at least 90 percent of beneficiaries residing in large metro and metro counties, and at least 85 percent of beneficiaries residing in micro, rural, and Counties with Extreme Access Considerations (CEAC), have access to at least one provider or facility of each applicable specialty type within the published time and distance standards. Section 422.116(d)(5) currently provides a 10-percentage-point credit toward the applicable percentage for certain provider specialty types when an MA plan includes in its contracted network one or more telehealth providers that furnish additional telehealth benefits, as defined in § 422.135.

CMS established the telehealth credit in the June 2020 final rule to recognize the additional access and choice that contracted telehealth providers can furnish while maintaining the role of telehealth as a supplement to, rather than a replacement for, an adequate in-person provider network. See 85 FR 33796, 33855. The existing regulatory framework preserves in-person access. Under § 422.116(e)(1), a telehealth-only provider may not count toward the minimum provider number requirement. In addition, § 422.135(c) requires an MA plan furnishing additional telehealth benefits to furnish in-person access to the specified Part B service at the election of the enrollee and to advise enrollees that they may receive the service either in person or through electronic exchange.

In the April 2024 final rule, some commenters recommended that CMS increase the telehealth credit from 10 percentage points to 30 percentage points. Other commenters expressed concern that a larger credit could result in overreliance on telehealth and could reduce access to providers who furnish timely in-person services. CMS stated that the Agency would remain open to considering future adjustments to the telehealth credit based on evidence, stakeholder feedback, and the evolving role of telehealth in the delivery of health care. See 89 FR 30448, 30494.

CMS is now proposing to revise § 422.116(d)(5) to increase the current 10-percentage-point telehealth credit to a value greater than 10 percentage points such as 30 percentage points or to another appropriate level within that range of increase. Although CMS is not setting specific amendatory language for § 422.116(d)(5) in this proposed rule, CMS is describing the substance and range of the policy under consideration and soliciting comment on the appropriate amount and structure of the credit. After considering public comments, CMS may finalize an increased uniform credit of up to 30-percentage points or finalize no change to the existing 10-percentage-point credit under § 422.116(d)(5).

CMS's quantitative network adequacy standards are an important beneficiary protection to ensure that MA plans maintain sufficient contracted networks and that covered services are

geographically accessible. At the same time, in markets with limited provider supply or concentrated provider systems, an MA plan may have relatively few practical contracting alternatives for satisfying the applicable network adequacy standards. The interaction between limited provider supply and quantitative network requirements may make network development more difficult, may affect the ability of MA organizations to enter or remain in certain service areas, and may provide substantial negotiating leverage to a small number of providers or provider systems whose participation is necessary for a plan to satisfy the standards. Contracted telehealth providers may broaden the range of providers available to MA enrollees, facilitate more timely access to clinically appropriate services, and reduce geographic barriers to care. Recognizing meaningful telehealth capacity in the network adequacy methodology may support the availability of MA plan choices in areas where development of an in-person network is particularly challenging.

However, telehealth must not be treated as a complete substitute for an adequate in-person network. Certain services require a physical examination, diagnostic testing, procedures, or other in-person components. Some beneficiaries may also prefer in-person care or may be unable to use telehealth effectively because of limitations involving broadband access, technology, digital literacy, privacy, or other circumstances. The appropriate telehealth credit therefore should recognize the access value of telehealth without materially undermining required access to timely and clinically appropriate in-person care.

A 30-percentage-point credit, for example, would constitute a substantial change from the existing policy. Before application of other available network adequacy credits, a plan receiving a 30-percentage-point telehealth credit could satisfy the 90-percent standard applicable in large metro and metro counties at 60 percent. It could satisfy the 85-percent standard applicable in micro, rural, and CEAC counties at 55 percent. CMS therefore seeks feedback, including specific evidence, on whether a credit at this level — or at another level above the current 10 percent, whether 30 percent or another appropriate level within that range — appropriately reflects the

access furnished through telehealth, and conversely in-person, and what safeguards, if any, should accompany an increase.

Any increase in the telehealth credit would continue to operate within the broader network adequacy framework. CMS is not proposing any change that would permit a telehealth-only provider to satisfy the minimum provider number requirement under § 422.116(e), eliminate the requirement under § 422.135 that enrollees retain access to the covered service through an in-person visit, or relieve an MA organization of its obligation to make covered benefits available and accessible consistent with section 1852(d)(1) of the Act and §§ 422.112 and 422.116.

CMS is considering several possible structures. First, CMS could apply a uniform credit greater than 10 percent to every provider specialty type currently identified in § 422.116(d)(5) and applicable to every county type.

Second, CMS is considering an alternative approach of varying the credit by county classification. For example, a lower credit could apply in large metro and metro counties where provider supply and broadband access may differ from those in less densely populated areas, while a larger credit, such as the proposed 30 percent credit, could apply in micro, rural, or CEAC counties. Telehealth may be particularly valuable in rural and CEAC counties, where beneficiaries may otherwise face limited provider supply, substantial travel distances, and difficulty obtaining timely specialty care. An increased telehealth credit could support MA plan availability in these areas and could provide beneficiaries with access to providers who would otherwise not be reasonably available. At the same time, rural beneficiaries may be more likely to experience limitations involving broadband availability, reliable internet service, access to devices, private locations from which to receive care, transportation for necessary in-person follow-up, and digital literacy. CMS would not finalize an increased credit unless, after considering the public comments and available evidence, CMS concludes that the policy is consistent with the access requirements in section 1852(d)(1) of the Act and appropriately

protects access to in-person care. CMS is particularly interested in data concerning the effect of the current credit, and the likely effect of an increased credit, on provider contracting, appointment availability, travel burdens, beneficiary choice, health outcomes, and MA plan availability in micro, rural, and CEAC counties.

Third, CMS could vary the credit by provider specialty type, based on factors such as the clinical appropriateness of telehealth for that specialty, the extent to which services ordinarily require an in-person component, observed patterns of telehealth utilization, and provider supply. CMS has previously analyzed Medicare claims data for telehealth services to identify which provider specialty types warrant a telehealth credit. CMS considered utilization and supply of providers across specialty types over multiple years tracked through the network adequacy reviews. A uniform credit amount for all specialty types risks overlooking meaningful differences in how beneficiaries access care from different types of providers. Therefore, CMS proposes, as another alternative, to increase the credit to up to 30 percent for specialty types that had a high telehealth utilization, including but not limited to dermatology, psychiatry, neurology, otolaryngology and cardiology. Under this alternative, the remaining telehealth eligible specialty types under 422.116(d)(5) would continue to receive the 10 percent telehealth credit.

Lastly, CMS could maintain the existing 10 percent credit with no changes to the specialty types under 422.116(d)(5) based on feedback to the proposals in this proposed rule.

Section 422.116(d)(6) separately provides a 10-percentage-point credit for affected provider and facility types in a State with Certificate of Need (CON) laws or other State-imposed anticompetitive restrictions that limit the number of providers or facilities in the State or in a county. The CON credit and the telehealth credit address different circumstances: the CON credit addresses State-imposed restrictions affecting provider or facility supply, while the telehealth credit recognizes additional access furnished through contracted telehealth providers. MA organizations may receive both the 10-percentage-point CON credit and telehealth credit, if applicable.

CMS solicits comments on all aspects of the potential changes described in this section, including the alternative approaches CMS is considering, and specifically request comment on the following:

- What percentage-point credit greater than 10 would appropriately recognize the access furnished by contracted telehealth providers without undermining access to in-person care? Is a 30-percent threshold the appropriate level, or would another credit within the 10 to 30-percent range more accurately reflect the value that telehealth providers contribute to a contracted network and better achieve the goals of network adequacy and beneficiary access? CMS asks commenters to provide data or other evidence supporting the recommended amount.
- Should CMS adopt a uniform credit, or should the credit vary by county type, provider specialty type, or another factor? If the credit should vary, what methodology and values should CMS use?
- Would an increased credit reduce, maintain, or improve beneficiary access to timely in-person care? What safeguards would prevent an MA plan from using the credit as a substitute for contracting with an adequate number and distribution of in-person providers?
- What effects would an increased credit have in large metro, metro, micro, rural, and CEAC counties? In particular, would a larger credit improve access and MA plan availability in rural communities, or could it reduce the availability of local in-person providers in these areas?
- To what extent do limited provider supply, provider-market concentration, or difficulties in contracting with particular providers or provider systems prevent MA organizations from satisfying network adequacy standards? Would an increased telehealth credit meaningfully improve plan competition or help MA organizations build a network of providers, and what evidence supports that conclusion?
- Would a 30-percent telehealth credit, or another appropriate level within the 10 to 30 percent range, adequately incentivize MA plans to maintain or expand telehealth provider networks in rural and underserved communities?

- Would a 30-percent telehealth credit, or another appropriate level within the 10 to 30 percent range, have any unintended consequences that could reduce the availability or quality of telehealth services for rural beneficiaries?
- Would rural beneficiaries experience differential impacts compared to urban or suburban beneficiaries as a result of the proposed changes, and how should those differences be addressed?
- Should additional protections, incentives, or complementary policies be considered to safeguard access to telehealth services in rural areas?
- How does the proposed change align with existing federal initiatives and programs aimed at improving rural health access, including those administered by CMS and other federal agencies?

CMS solicits comments on all aspects of these proposals.

4. RFI on Network Adequacy Topics

In addition to the foregoing proposals, CMS requests comment more broadly on strategies to address negotiating leverage that may result from network adequacy requirements, particularly in behavioral health and primary care, due to shortages of providers, that may increase the cost of care for the MA program.

First, CMS seeks input on potential adjustments to time and distance standards that could increase access to behavioral health and primary care services for enrollees. Specifically, the following questions:

- Should CMS modify the time and distance standards for providers that regularly furnish telehealth services? If so, should the modification differ by county classification (for example, reducing the time and distance standards by 40 percent for urban counties and 50 percent for rural counties)?

- What are the tradeoffs between relaxing time and distance standards to expand the qualifying provider pool and the potential impact on beneficiary access to in-person care? How should CMS weigh these tradeoffs?

Second, CMS also seeks comment on potential structural changes to network adequacy requirements that may broaden the qualifying provider pool and reduce disproportionate negotiating leverage. Specifically the following questions:

- Should CMS permit nurse practitioners and physician assistants to satisfy primary care network adequacy requirements when they furnish primary care services and are licensed or certified to do so under applicable State law?
- Are there other provider types or care settings that should be eligible to satisfy behavioral health or primary care network adequacy requirements? For example, should Rural Health Clinics be eligible to meet the primary care network adequacy requirements? Should Federally Qualified Health Centers be eligible to meet the behavioral health or primary care network adequacy requirements?

CMS seeks comment on whether regulatory changes would improve access and reduce burden on MA organizations in primary care and behavioral health.

Finally, are there other policy approaches, including the utilization of super intelligence to improve access to care, not described previously that CMS should consider, to advance competition, lower costs, and preserve or strengthen beneficiary access to behavioral health and primary care services in the MA program? How should CMS approach these viewpoints given the potential tradeoffs between competition, cost reduction, and beneficiary access?

B. Deregulation of Medicare Advantage and Part D Communication Requirements (§§ 422.2262, 422.2265, 422.2267, 423.2262, 423.2265, and 423.2267)

Executive Order 14192, Unleashing Prosperity Through Deregulation, which appeared in the **Federal Register** on February 6, 2025 (90 FR 9065), directed federal agencies to identify regulations suitable for elimination in furtherance of the Administration's policy goals to promote prudent financial management and alleviate unnecessary regulatory burdens. To that end, CMS is proposing to remove four regulatory requirements from 42 CFR parts 422 and 423, Subpart V: the requirement that MA organizations and Part D sponsors submit public-facing uses of the Medicare Card Image (MCI) for CMS review (§§ 422.2262(a)(1)(xvii) and 423.2262(a)(1)(xvi)); the requirement to include specified explanatory language on envelopes (§§ 422.2267(e)(36) and 423.2267(e)(37)); the requirement that MA organizations and Part D sponsors use an exit disclaimer on their websites when users click a link that takes the user away from the plan website (§§ 422.2265(a)(1)(ii) and 423.2265(a)(1)(ii); and the requirement that MA organizations and Part D sponsors use a disclaimer on communications that mention Star Ratings (§§ 422.2267(e)(33) and 423.2267(e)(35)).

1. Removing the Requirement for CMS Approval of Plan Use of the Medicare Card Image Found In §§ 422.2262(a)(1)(xvii) and 423.2262(a)(1)(xvi)

As a part of the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Final Rule which appeared in the **Federal Register** on April 12, 2023 (hereafter referred to as the April 2023 Final Rule) (88 FR 22120), CMS finalized regulations at §§ 422.2262(a)(1)(xix) and 423.2262(a)(1)(xviii) (later redesignated as §§ 422.2262(a)(1)(xvii) and 423.2262(a)(1)(xvi) in Medicare Program; Contract Year 2027 and Certain Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program, 91 FR 17583, hereafter referred to as the April 2026 final rule) with an aim to

strengthen beneficiary protections and improve MA and Part D marketing. CMS placed discrete limits around the use of the Medicare name, logo, and Medicare card, including requiring that the use of the Medicare card image (MCI) be permitted only after review and approval from CMS.

CMS implemented these regulations in response to concerns from external stakeholders about marketing activities and documents that appeared to be from Medicare, CMS, or the Federal Government, when in fact, the documents originated from non-governmental entities. For example, CMS noted instances in which third-party internet sites included the word Medicare in the URL, television advertisements where beneficiaries might assume that the advertising was from CMS or the Medicare program, and complaints received through 1-800-MEDICARE detailing instances in which beneficiaries thought they were contacting Medicare and were in fact contacting a MA or Part D plan, its agent or broker, or other associated third-party marketing organization (TPMO). These instances heightened CMS' concern that these advertisements were inconsistent with regulations at §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(i), which prohibit MA organizations and Part D Sponsors from misleading, confusing, or providing materially inaccurate information to current or potential enrollees as well as the regulations at §§ 422.2274(c) and 423.2274(c) which require MA organizations and Part D sponsors to hold first tier, downstream, and related entities that represent the MA organization or Part D sponsor to those same standards.

Upon issuance of the April 2023 Final Rule, CMS implemented operations to manage the MCI submission and disposition process. This included developing review rubrics, approval/denial language, a policy for non-English materials, workload tracking, and communications to MA organizations, Part D sponsors, and TPMOs. Currently CMS generally approves submissions for educational use, for example, side-by-side comparisons of the MCI and the MA organizations' card. Additionally, materials that contain clear disclaimer language, for example, 'Not affiliated with or endorsed by the Federal Government or the Medicare program,' typically receive approval. Submissions which could be mistaken as endorsed by Medicare or the

Federal Government are disapproved. The MA organization or TPMO then has the option to modify the material and resubmit for rereview.

After implementing this review process, it has become apparent that CMS approves the substantial majority of MCI requests received. Among the denied submissions, the primary deficiency was a failure to make sufficiently clear that the image originated from a non-governmental entity or that it was not endorsed by the Federal Government. It has also become apparent to CMS that the requirement to pre-review MCI is overly burdensome on entities using the MCI in their material as well as on the government resources reviewing those materials. CMS already maintains robust oversight authority over marketing materials, authority that includes the ability to take action when an image is improperly attributed to a governmental entity or falsely implies Federal endorsement. The current additional layer of MCI review, that is, the individual review of the use of the MCI, has not shown to provide any meaningful protection in either detection or enforcement beyond what CMS can already provide under other existing mechanisms. Based on CMS's experience reviewing MCI submissions, CMS has determined that there is nothing inherent in the use of the MCI that warrants a separate or heightened review process compared to other communications or marketing content subject to the requirements of 42 CFR part 422, Subpart V, and 42 CFR part 423, Subpart V.

The MCI pre-review requirement stands in notable contrast to how CMS regulates other potentially sensitive elements of MA and Part D marketing materials. Numerous other components of communications and marketing materials, including plan benefit summaries, cost-sharing disclosures, provider network representations, and formulary information, carry significant potential to mislead or confuse beneficiaries, yet none of these elements are subject to the same individualized, pre-authorization review process that has been applied to the MCI. Instead, communications and marketing materials are subject to the broader oversight framework established under 42 CFR part 422, Subpart V, and 42 CFR part 423, Subpart V, including CMS's authority to review materials submitted under §§ 422.2261 and 423.2261, prohibit

misleading or inaccurate communications under §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(i), and take appropriate compliance or enforcement action where warranted. Between CMS's existing review mechanisms and processes currently in place, CMS expects that if the MCI pre-approval requirement was eliminated as proposed here, communications marketing materials that use the MCI would still receive sufficient oversight.

While CMS recognizes that the MCI pre-review requirement was adopted based on genuine underlying concerns about potentially abusive use of the MCI in marketing materials, the operational experience gained since implementation of the MCI pre-review requirement has provided CMS with additional information regarding the practical operation and effectiveness of the requirement. The fact that CMS has approved the substantial majority of MCI submissions received since the review process was established suggests that the problem the requirement was designed to address (that is, widespread or systematic misuse of the MCI in a manner likely to mislead beneficiaries into believing they were dealing with a governmental entity) has not materialized at the scale or frequency that originally prompted regulatory action. As previously noted, CMS relies on robust, generally applicable oversight mechanisms to protect beneficiaries from misleading representations across all other categories of communications marketing content, including content that directly affects beneficiary enrollment decisions and financial obligations. Based on the operational experience gained since implementation of the MCI pre-review requirement, it appears that these oversight mechanisms and general prohibitions on misleading marketing conduct will also be sufficient to address concerns related to MCI use. Imposing a unique, resource-intensive pre-review requirement exclusively on the MCI, while relying on post-submission review and enforcement for all other marketing content, creates an inconsistency that is difficult to justify on beneficiary protection grounds and is precisely the type of unnecessary regulatory burden that Executive Order 14192 directs agencies to eliminate.

CMS reviews and evaluates marketing materials in the Marketing Module of the Health Plan Management System (HPMS), as required under §§ 422.2261(a)(2) and 423.2261(a)(2). As

a part of this process, CMS uses different criteria, including material content, to focus on particular types of marketing materials. Marketing materials reviewed by CMS that include the MCI will continue to be subject to the review standards under §§ 422.2261(d) and 423.2261(d), including if the use of the MCI is misleading or confusing, as CMS did before the MCI was singled out for specialized, targeted, and individualized pre-review. In addition, if this rule is finalized and CMS later identifies concerns with the use of the MCI or would like to monitor how the MCI is being used, CMS could add MCI as a specific material content to the marketing module submission process. This would enable MA organizations, Part D sponsors, and third parties that submit marketing materials to specifically indicate if the material includes the MCI.

CMS acknowledges that there may be legitimate reasons for industry stakeholders to use the MCI in communication materials. For example, differentiating between an MA organization or Part D sponsor's card and the Medicare card, displaying the MCI when reminding beneficiaries about an upcoming MA Open Enrollment Period, or using the MCI to help beneficiaries understand how to identify their Medicare Beneficiary Identifier are examples of legitimate use of the MCI. CMS is not proposing to remove the requirement that the MCI, as well as the Medicare name, CMS logo, and products or information issued by the Federal Government, not be used in a misleading way. Rather, CMS is proposing to remove only the requirement that use of the MCI is permitted only with prior authorization from CMS.

CMS notes that existing regulations at 42 CFR 422.2262(a)(1)(i) and 423.2262(a)(1)(i) prohibit MA organizations and Part D sponsors from engaging in activities that could mislead or confuse Medicare beneficiaries and prohibit these entities from providing information that is inaccurate or misleading. Additionally, the existing regulations at 42 CFR 422.2274(c) and 423.2274(c) direct MA organizations and Part D sponsors to oversee their first tier, downstream, and related entities, as well as TPMOs, that represent the plans to ensure those entities abide by the requirements at 42 CFR Subpart V, including §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(i). Therefore, CMS has concluded that sufficient beneficiary protections already exist in regulation

and CMS' systems such that requiring CMS approval to use the MCI is unnecessary, as it does not offer enough benefit to justify continuation of the approval process. As indicated previously, CMS will leverage particular aspects of the already-established Marketing Module in HPMS if CMS becomes aware of the need for a targeted review of use of the MCI.

To ensure the use of the MCI is not misleading, CMS strongly recommends that, when MA organizations, Part D sponsors, and TPMOs representing MA organizations and Part D sponsors create materials that use the MCI, they include language, such as a disclaimer, so that a reasonable person would not incorrectly conclude that the image or message originated from, or is endorsed by Medicare, CMS, HHS, or the Federal Government. Doing so will help to keep the material in compliance with the requirement at §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(i) that prohibit MA organizations and Part D sponsors from misleading Medicare beneficiaries or misrepresenting the MA organization or Part D sponsor.

For the reasons cited previously, and in keeping with Executive Order 14192, Unleashing Prosperity Through Deregulation, CMS is proposing to amend the regulatory language found at 42 CFR 422.2262(a)(1)(xvii) and 423.2262(a)(1)(xvi) to remove the requirement that the use of the Medicare card image is permitted only with authorization from CMS.

We invite comments on this proposal.

2. Removing a Redundant Requirement for the Use of Plan Star Ratings

CMS instituted the Star Ratings program in 2007. The program was designed as a tool for consumers to quickly and reliably evaluate the quality of MA and Part D plans with ratings from one to five stars. In addition to quality, CMS hoped to drive improvements in care on the part of these plans. The program rates Cost, MA, and Part D plans on various measures including clinical care, patient experience, and drug safety. CMS has continually updated the methodology with significant refinements and changes regarding the calculation of the elements of measure that determine Star Ratings. CMS has included incentives for the Star Ratings program regarding enrollment as well, creating special enrollment periods allowing beneficiaries to enroll in plans

with 5 stars or leave plans with fewer than 3 stars outside of the normal MA enrollment periods. The utility and reliability of the Star Ratings program have made it an integral element of the MA and Part D programs. CMS has codified the regulatory requirements for the development and use of the Star Ratings program in §§ 422.160, 422.162, 422.164, 422.166, 423.182, 423.184, and 423.186. CMS has codified the regulatory requirements for use of Star Ratings in marketing materials in §§ 422.2263(c) and 423.2263(c).

As such, CMS maintains a strong interest in the integrity of the program and how Star Ratings are marketed to Medicare beneficiaries. CMS has maintained many requirements for the use of Star Ratings in advertising and member education since the institution of the program. These requirements have served as guardrails to provide plans with a picture of the purpose CMS intended the Star Ratings program to serve. The requirements, in several iterations, existed as guidance in the Medicare Managed Care Manual until January of 2021 when they were codified. On January 19, 2021, CMS issued the Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Final Rule (86 FR 5864), referred to hereafter as the January 2021 Final Rule. In this rule, CMS codified requirements for disclaimer language at §§ 422.2267(e)(31) and 423.2267(e)(33) as part of the list of MA and Part D required materials and content. These requirements indicated that the disclaimer must convey that MA organizations and Part D sponsors are evaluated yearly by CMS to determine accurate Star Ratings and that the Star Ratings are based on a 5-star rating system. The regulatory requirements also indicated that MA organizations and Part D sponsors must convey the disclaimer or the information in the disclaimer whenever Star Ratings are mentioned in marketing materials, except on small objects such as pens, rulers, or other give-away items. On May 9, 2022, in the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory

Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Final Rule (87 FR 27899), hereafter referred to as the May 2022 Final Rule, CMS amended these paragraphs by moving them without change to §§ 422.2267(e)(33) and 423.2267(e)(35). As a whole, the requirements provided regulatory instructions for the use of disclaimer language related to Star Ratings used in marketing.

Accuracy in communication of Star Ratings is essential for the reliability and operation of the program, particularly to protect beneficiaries' awareness of the quality of the plans they are choosing. Yet, there is a level of duplication between the Star Ratings requirements found under §§ 422.2263(c) and 423.2263(c) and the Star Ratings disclaimer requirements under §§ 422.2267(e)(33) and 423.2267(e)(35). The language in §§ 422.2263(c) and 423.2263(c) is more robust than the language at §§ 422.2267(e)(33) and 423.2267(e)(35). Those sections indicate that a plan is required to mention the contract year that the Star Rating represents. This indicates that the Star Rating is produced yearly. The language at §§ 422.2263(c) and 423.2263(c) also indicates that any mention of the Star Rating must be clear that the rating is out of five stars. The introductory language in §§ 422.2263(c) and 423.2263(c) also indicate that the requirements described in those sections apply whenever MA organizations and Part D sponsors use CMS-issued Star Ratings in communications and marketing materials. CMS has determined that the intended beneficiary protections inherent in the requirements regarding Star Ratings in §§ 422.2267(e)(33) and 423.2267(e)(35) are unnecessary because they are also captured under the regulatory requirements at §§ 422.2263(c) and 423.2263(c).

Taken together, the requirements at §§ 422.2263(c) and 423.2263(c) fully encompass the consumer protections that the disclaimer requirements at §§ 422.2267(e)(33) and 423.2267(e)(35) were designed to provide. The disclaimer requirements were intended to ensure that beneficiaries understand that Star Ratings are evaluated annually and are based on a five-star scale — information that is already mandated, and conveyed with greater specificity, under the

more comprehensive Star Ratings marketing requirements, which require identification of the specific contract year rather than a general reference to annual evaluation. Maintaining a separate, duplicative disclaimer requirement creates unnecessary regulatory burden for MA organizations, Part D sponsors, and CMS, and risks introducing compliance ambiguity where plans may interpret two overlapping but textually distinct standards as imposing different obligations. Furthermore, redundant disclosure requirements can undermine the clarity and readability of beneficiary-facing materials, reducing rather than enhancing the effectiveness of consumer communication. Removing the disclaimer requirement would therefore streamline compliance obligations and improve the quality of beneficiary communications while preserving the full scope of beneficiary protections already established in regulation.

Aside from the Star Ratings-specific regulatory requirements under §§ 422.2263(c) and 423.2263(c), CMS notes that the general communications requirements in §§ 422.2262(a)(1)(i) and 423.2262(a)(1)(i), which prohibit MA organizations and Part D sponsors from misleading, confusing, or providing materially inaccurate information to current or potential enrollees offer a level of protection to the use of Star Ratings in advertisements. Additionally, one of the criteria by which CMS defines marketing and identifies marketing material is the use of measuring or ranking standards. The regulatory definition at §§ 422.2260 and 423.2260 for "Marketing" includes the use of measuring or ranking standards and specifically identifies Star Ratings as an example of such standards in paragraph (2)(ii). This means that virtually all advertisements that include Star Ratings fall under the definition of marketing and therefore must abide by the more stringent requirements for marketing materials present in §§ 422.2263 and 423.2263.

To prevent confusion on the part of plans regarding the use of Star Ratings in marketing to beneficiaries, and in keeping with Executive Order 14192, Unleashing Prosperity Through Deregulation, which appeared in the **Federal Register** on February 6, 2025 (90 FR 9065), CMS is proposing to amend the regulation found at 42 CFR 422.2267(e)(33) and 423.2267(e)(35) to

remove the requirement for MA organizations and Part D sponsors to use the Star Ratings Disclaimer.

We invite comments on this proposal.

3. Removing the Requirement for Mailing Statements

On January 19, 2021, CMS issued the January 2021 Final Rule. In this rule, CMS codified requirements for mailing statements in §§ 422.2267(e)(34) and 423.2267(e)(35). Then, on May 9, 2022, in the May 2022 Final Rule, CMS amended these paragraphs by moving them without change to §§ 422.2267(e)(36) and 423.2267(e)(37). These requirements set forth language that plans must ensure is on the envelopes in which they send communications to beneficiaries. CMS provided this language intending to prevent beneficiaries from discarding or disregarding important plan communications, as plans regularly send communications to beneficiaries through the United States Postal Service (USPS).

While including information about the contents on the envelope is a best practice, CMS believes that the specific requirements in §§ 422.2267(e)(36) and 423.2267(e)(37) are overly prescriptive and unnecessary. Currently, CMS has provided only two mailing statements that MA organizations and Part D sponsors can use on an envelope, in addition to marketing language that the plan has developed and had approved or accepted for use on an envelope. These statements are: “Important [Insert Plan Name] information,” and “Health and wellness or prevention information.” As proposed, allowing MA plans and Part D sponsors to choose the language used will be more beneficiary friendly, as plans will be able to better tailor the messaging to meet the need. For the reasons cited previously, and in keeping with Executive Order 14192, Unleashing Prosperity Through Deregulation, CMS is proposing to remove the regulation found at §§ 422.2267(e)(36) and 423.2267(e)(37). CMS anticipates MA organizations and Part D sponsors will continue to include language on envelopes despite CMS removing the requirement, as it is a common industry practice, including in commercial markets, to draw the intended recipient’s attention to the type of communication inside the envelope.

We invite comments on this proposal.

4. Removing the Requirement to Notify Users When Leaving the Plan's Website

Various versions of the Medicare Managed Care Manual's instructions for MA organizations and Part D sponsors' marketing and communications chapter have included instructions for the required use of exit disclaimers, notifying users when clicking a link on the website would open or take a user to a third-party website. This long-standing requirement was established in the interest of beneficiary protection as well as the integrity of the MA and Part D programs when the internet was still in its early stages. In the January 2021 Final Rule, CMS codified these longstanding requirements for MA organization and Part D sponsor websites in §§ 422.2265(a)(1)(ii) and 423.2265(a)(1)(ii). In these regulatory provisions, CMS indicated that a plan's website must notify users that they are leaving the plan's Medicare website when the users click on a link that leads outside of the plan, such as to a first-tier or downstream entity or a third-party vendor.

As the MA and Part D programs have developed and matured, so have the use of exit disclaimers on websites. Exit disclaimers are now a longstanding and widely accepted practice to clearly notify users when they are leaving an organization's website and accessing third-party content. Organizations routinely use them to reduce potential liability, avoid the appearance of endorsing third-party content, and clearly communicate when users are leaving the organization's controlled environment. Privacy and compliance resources (for example, business websites[100] indicating common and best practices in the execution of financial business), recognize exit disclaimers as a best practice for promoting transparency, managing user expectations, and clarifying that organizations are not responsible for third-party content. Likewise, CMS understands that financial institutions frequently include third-party website disclaimers that

[100] Specifically websites from Termly (https://termly.io/), TermsFeed (https://www.termsfeed.com/), and Usercentrics (https://usercentrics.com/us/).

expressly state they are not responsible for the security, accuracy, availability, malware, viruses, or copyright compliance of external websites.

Since the use of exit disclaimers has become a common practice, and in keeping with Executive Order 14192 Unleashing Prosperity Through Deregulation, which appeared in the **Federal Register** on February 6, 2025 (90 FR 9065), CMS is proposing to remove the regulatory language found at §§ 422.2265(a)(1)(ii) and 423.2265(a)(1)(ii). Given the widespread use of exit disclaimers across both the public and private sectors, CMS anticipates that MA organizations and Part D sponsors will continue to use exit disclaimers on their websites when directing users to external websites beyond the organization's or sponsor's control.

We invite comments on this proposal.

C. Updating Agent and Broker Compensation and Oversight and Modifications to Streamline and Reduce Marketing Requirements (§§ 422.2260, 422.2271, 422.2272, 422.2274, 423.2260, 423.2271, 423.2272, and 423.2274)

CMS is proposing to make changes to its regulations governing agent and broker compensation and oversight, and training and testing requirements. CMS is also proposing to make modifications to streamline and reduce certain marketing requirements. Section 1851(h) of the Act governs the approval of marketing material and application forms for Medicare Advantage organizations. Section 1860D-1(b)(1)(B)(vi) of the Act directs that the Secretary use rules similar to and coordinated with the MA rules at section 1851(h). Sections 1851(j)(2)(D) and 1860D-4(l) of the Act require that CMS create limitations and guidelines to ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan or Part D plan that is intended to best meet their health care needs. Sections 1851(j)(2)(E) and 1860D-4(l) of the Act also require that CMS establish limitations on MA organizations and Part D sponsors using agents, brokers, and other third parties that have not completed an initial training and testing program and an annual retraining and testing program. In addition, Section 1856(b)(1) provides for the Secretary to establish by regulations and other standards to carry out other parts of the Statute regarding the Medicare + Choice (Medicare Advantage) program. Furthermore, Section 1860(D)-12(f)(1) provides that the Secretary may periodically review the standards under the section and revise the standards if the Secretary determines revisions are appropriate.

CMS is proposing changes to its regulations governing agent and broker compensation and oversight to take into consideration the ruling from the U.S. District Court for the Northern District of Texas in *Americans for Beneficiary Choice v. HHS*[101], and *Council for Medicare*

[101] *Americans for Beneficiary Choice v. United States Department of Health and Human Services*, No. 4:24-CV-00439-O, 2025 WL 2390849 (N.D. Tex. Aug. 18, 2025).

Choice v. HHS[102], as well as industry changes in compensation practices described later in this proposal. In this proposed rule, CMS is proposing to establish a transparent framework for agent and broker compensation requirements better suited to the current, more established MA and Part D markets. These proposed changes would move away from regulatory limits on MA and Part D compensation and instead move towards emphasizing data transparency and enforceable guardrails.

Agents and brokers are an integral part of the MA and Part D industries, helping millions of Medicare beneficiaries learn about and enroll in Medicare Advantage and Medicare Prescription Drug Plans (PDPs) by providing expert guidance on plan options in their local area, while assisting with everything from comparing costs and coverage to applying for financial assistance. In September 2008, CMS published the Revisions to the Medicare Advantage and Prescription Drug Benefit Programs interim final rule (73 FR 54237), hereafter referred to as the "September 2008 interim final rule". This was CMS's first regulation to establish requirements for agent and broker compensation, which included compensation limitations, training and testing, and other safeguards. In that rulemaking, CMS noted that these reforms addressed concerns that the previously unregulated compensation structure resulted in financial incentives for agents and brokers to only market and enroll beneficiaries in specific plans and not others due to larger commissions. The larger commissions potentially resulted in beneficiaries being directed toward plans that were not the best suited to meet their health care needs.

In the September 2008 interim final rule, CMS noted that "[d]epending on the circumstances, agent and broker relationships can be problematic under the Federal anti-kickback statute if they involve, by way of example only, compensation in excess of fair market value (FMV), compensation structures tied to the health status of the beneficiary (for example, cherry-picking), or compensation that varies based on the attainment of certain enrollment

[102] *Council for Medicare Choice v. United States Department of Health and Human Services*, No. 4:24-cv-00446-O (N.D. Tex. filed May 15, 2024).

targets." (73 FR 54239). These and other fraud and abuse risks existed and continue to exist among the relationships between MA organizations, Part D sponsors, and third-party marketing organizations (TPMOs), including agents, and brokers. CMS noted in the September 2008 interim final rule that the HHS Office of the Inspector General (OIG) advisory opinion process was available to parties seeking OIG's opinion as to the legality of a particular arrangement. That advisory opinion process remains available and can be found on the OIG's website at http://oig.hhs.gov/fraud/advisoryopinions.html.

In the final rule "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE)" which appeared in the **Federal Register** on April 23, 2024, (89 FR 30448), hereafter referred to as the "April 2024 final rule," CMS significantly modified the regulations governing agent and broker compensation paid by MA organizations and Part D sponsors. In the April 2024 final rule, CMS made changes to compensation requirements to address new issues in the marketplace. In that rule, we explained that the regulatory changes were prompted in part because CMS observed that there was an increase in additional payments to agents and brokers characterized as administrative payments. We noted in the April 2024 final rule that CMS had observed web-based advertisements for agents and brokers to work with, or sell, particular plans where the agents and brokers were offered bonuses and perks, such as trips and extra cash framed as allowable administrative add-ons in exchange for enrollments. CMS also noted the increase in complaints from a host of different organizations, including state partners, beneficiary advocacy organizations, and MA organizations, among others. A common theme of these complaints was that agents and brokers were being paid in excess of the maximum enrollment-based compensation allowed under the current regulation under the guise that the additional payments were for administrative services.

We also noted beneficiary complaints accusing agents and brokers of enrolling them without their consent, as well as complaints that after enrollment, beneficiaries found the plan's benefits, such as provider networks, did not align with what the beneficiary was told by the agent or broker.

The April 2024 final rule limited MA organizations and Part D sponsors, as well as TPMOs with which they contract (such as Field Marketing Organizations (FMOs)), from structuring payments to agents and brokers that allowed for separate payments that circumvented compensation caps. CMS also noted that the amounts in these separate payments appeared to be increasing. In that final rule, at a high level, CMS finalized four major changes related to agent and broker compensation: (1) establishing a flat compensation rate versus a maximum FMV amount; (2) including administrative payments, as defined under §§ 422.2274(e) and 423.2274(e), as a part of compensation; (3) increasing compensation FMV to account for the removal of administrative payments; and (4) prohibiting MA organizations and Part D sponsors from entering into contract terms with an agent, broker, or other TPMO, that have a direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best fits the health care needs of a beneficiary. At the time, CMS believed that the impact of these changes would better align with the statutory requirements to ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the plan that best fits a beneficiary's health care needs.

Following the April 2024 final rule, a lawsuit (Civil Action No. 4:24-cv-00439-O and Civil Action No. 4:24-cv-00446-O) was filed in the United States District Court, Northern District of Texas, Fort Worth Division, with the plaintiffs requesting summary judgment[103]. The plaintiffs in the case argued that CMS exceeded its statutory authority and that the final rule was

[103] *Americans for Beneficiary Choice v. United States Department of Health and Human Services*, No. 4:24-CV-00439-O, 2025 WL 2390849 (N.D. Tex. Aug. 18, 2025) and *Council for Medicare Choice v. United States Department of Health and Human Services*, No. 4:24-cv-00446-O (N.D. Tex. filed May 15, 2024).

arbitrary and capricious.[104] The court's final decision vacated the provisions within the April 2024 final rule amending §§ 422.2274(a), (c), (d), (e) and 423.2274(a), (c), (d), (e).[105] Without taking a position in this proposed rule on the persuasive effect of the court's reasoning, the fact remains CMS did not appeal the decision. However, for purposes of this proposed rule, it is important to include a discussion of the court's reasoning to help illustrate how the ruling shaped CMS's proposed changes.

As part of the ruling, the court concluded that CMS exceeded the statutory authority by setting fixed rates.[106] The court cited 42 U.S.C. 1395w-21(j)(2)(D) (section 1851(j)(2)(D) of the Act) which provides CMS the ability to set "guidelines" to "ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs."[107] The court discussed the plain language of the statute and found that there was no indication that Congress authorized CMS to establish price controls, further stating that the language in the statute allows CMS to set guidelines on the use of compensation, not the specific rate for compensation.[108] The court also ruled that CMS exceeded its authority to include administrative fees as compensation.[109] The court discussed the plain meaning of the words "compensation" and "administrative payments," specifically citing CMS's definition of "administrative payments" as "payments made for services other than enrollment of beneficiaries" such as "training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments."[110] The court stated "administrative payments are distinct from the enrollment process that agents and brokers facilitate."[111] Following the court's granting of summary judgment, CMS reverted to the compensation requirements within §§ 422.2274 and 423.2274 which had applied prior to the

[104] Id., at 7.
[105] Id., at 22.
[106] Id., at 16.
[107] Id., at 7.
[108] Id., at 10-11.
[109] Id., at 12.
[110] Id., at 12-13.
[111] Id., at 13.

April 2024 final rule; those requirements limit compensation payments to no more than the CMS-defined FMV and provide that administrative payments may not exceed the value of those services in the marketplace. However, CMS notes that the regulations finalized in the April 2024 final rule are still reflected in the CFR, even though those vacated provisions are not operative.

Since publication of the April 2024 final rule, CMS has observed additional market changes in how compensation is being used. In discussions with various state insurance commissioners, reviews of notices issued by states, agent and broker trade groups, and information provided by MA organizations, CMS has been made aware that some MA organizations and Part D sponsors have elected to stop paying initial and/or renewal compensation for some products. This has created a new market force for CMS to consider. Whereas historically the concern and regulatory focus have been on excessive compensation influencing an agent or broker's decision as to what MA or Part D plan to enroll a beneficiary, this newly emerging trend may have the opposite effect. That is, an MA organization or Part D sponsor could use a lack of compensation as a potential tactic to reduce enrollments into a given plan option, by making that option less desirable to be sold by an agent or broker as compared to the organization's other plan offerings. Under the currently applicable regulatory requirements, it is the MA organization's or Part D sponsor's decision on whether to use agents and brokers to sell their products, whether or not to pay compensation to such agents and brokers, and how much they will pay, provided that such compensation conforms with CMS's regulatory requirements, does not violate the Federal anti-kickback statute, and complies with all other applicable requirements, including all fraud and abuse laws. CMS wants to be clear that under the new requirements in this proposed rule, these decisions would remain with MA organizations and Part D sponsors, provided that any compensation offered to agents and brokers is not determined to be a base compensation outlier for enrolling beneficiaries into their plans and, moreover, that such compensation does not violate the Federal anti-kickback statute and otherwise complies with all applicable statutes, regulations, and guidance. CMS notes that the

relationships between MA organizations, Part D sponsors, and TPMOs, including agents and brokers, regarding compensation could still violate the Federal anti-kickback statute or other applicable laws and regulations, depending on the facts and circumstances.

To better align with the statute, ensure current regulations are in the best interest of the program, reflect industry practices, reduce regulatory duplication, and most importantly to ensure appropriate beneficiary safeguards, CMS is proposing changes, modifications, and re-designations of requirements currently at §§ 422.2260, 422.2272, 422.2274, 423.2260, 423.2272, and 423.2274. To better segment the various requirements, CMS is also proposing the creation of new §§ 422.2271 and 423.2271 where many of the current requirements in §§ 422.2272, 422.2274, 423.2272, and 423.2274 will be redesignated. CMS is also proposing to relocate and update existing definitions and to establish new definitions under §§ 422.2260 and 423.2260.

1. Updating Definitions under §§ 422.2260 and 423.2260

First, CMS is proposing to move the definitions at §§ 422.2274(a) and 423.2274(a) to §§ 422.2260 and 423.2260. Currently, definitions for Subpart V are split between §§ 422.2260 and 423.2260 and 422.2274(a) and 423.2274(a). CMS believes consolidating definitions for Subpart V within §§ 422.2260 and 423.2260 will streamline CMS's regulations. In this move, CMS proposes to redesignate, with minor conforming changes, the definitions for "initial enrollment year," "like plan type," "plan year and enrollment year," "renewal year," and "unlike plan type." CMS is proposing to modify the definitions of "compensation" and "fair market value" and add a definition for "base compensation outlier." Following are CMS's specific proposals for the definition of "compensation," "fair market value," and "base compensation outlier."

a. Updating the "Compensation" Definition

CMS currently defines "compensation," at §§ 422.2274(a) and 423.2274(a), to include "monetary or non-monetary remuneration of any kind relating to the sale, renewal, or services related to a plan or product offered by an MA organization…" The existing definition in

§§ 422.2274(a) and 423.2274(a) further provides examples of compensation (for example, bonuses, gifts, etc.), as well as the regulatory updates to compensation from CY 2024 to CY 2025. As previously noted, following the court's summary judgment, CMS reverted to the compensation requirements within §§ 422.2274 and 423.2274 that were in effect prior to the April 2024 final rule. Taking into consideration the court's ruling and to align with industry trends, CMS is now proposing to redefine "compensation." CMS is proposing to retain the current language regarding monetary or non-monetary remuneration for the new compensation definition but is proposing to eliminate regulatory language concerning CY 2024 and CY 2025 compensation, as well as the phrase "or services related to" which was added in the April 2024 final rule. CMS is proposing to further distinguish compensation into two types, base compensation and supplemental compensation, creating the two sub-definitions of compensation types under new paragraphs (1) and (2) at §§ 422.2260 and 423.2260, both of which must be Fair Market Value. Under new paragraph (1), CMS proposes to define "base compensation" and under paragraph (2), CMS proposes to define "supplemental compensation."[112] CMS proposes to define "base compensation" as "any monetary remuneration for the actual initial or renewal enrollment, as referenced in §§ 422.2274(a) and 423.2274(a)." In other words, base compensation is an amount paid for each enrollment into a MA or Part D plan by an agent or broker. CMS proposes to define "supplemental compensation" as "any monetary or non-monetary remuneration, above and beyond base compensation, related to the sale and renewal of a plan or product offered by an MA organization [Part D sponsor], such as bonuses, gifts, prizes or awards. Supplemental compensation is an additional incentive offered by an MA organization or Part D sponsor to agents and brokers, often tied to a performance metric. For example, an MA organization may provide supplemental compensation in the form of a bonus to agents who have a renewal retention rate of 90 percent, or a bonus based on enrollee satisfaction survey results.

[112] Office of Inspector General, U.S. Department of Health and Human Services, Medicare Advantage Compliance Program Guidance (Nov. 2024), https://oig.hhs.gov/compliance/ma-icpg/

b. Updating the “Fair Market Value” Definition

Next, CMS is proposing to modify the “fair market value” definition, currently defined at §§ 422.2274(a) and 423.2274(a). The term “fair market value” has been used since the origination of compensation requirements in 2008. “Fair market value” is currently defined as what CMS has determined could reasonably be expected to be paid for an enrollment or continued enrollment into an MA or Part D plan. Since 2008, CMS has determined a FMV maximum each year. Taking into consideration the court’s ruling and industry trends, CMS is proposing to modify this definition to no longer establish a maximum FMV for compensation. In developing the modified proposed definition, CMS looked at concepts in existing definitions of fair market value and general market value under 42 CFR § 411.351. CMS adapted the concepts found in these two definitions to re-define FMV in such a way that ensures the compensation being paid to an agent or broker reflects normal market forces, rather than favoritism, coercion, or hidden incentives, and that any such payments be based on prevailing market rates for comparable services.

CMS believes an updated definition is necessary given the changes in compensation, as outlined in this preamble, and to more closely align the MA and Part D programs with how agents and brokers are compensated in the commercial market, as well as compensation associated with assisting consumers with enrollment in Qualified Health Plans (QHPs) through the Federally Facilitated Exchanges (FFEs). Under this new FMV definition, CMS is proposing to eliminate the maximum allowable compensation structure under the current FMV definition and is proposing the updated FMV definition to state that FMV means the compensation amount (which includes base and supplemental compensation) that would be paid to a licensed insurance agent or broker at the time the parties enter into an arrangement, as the result of bona fide bargaining between well-informed parties acting at arm's length and under comparable market conditions. Furthermore, the proposed fair market value definition applies to compensation, both base compensation and supplemental compensation, including monetary and non-monetary

remuneration. Although CMS is proposing an outlier review only for base compensation, supplemental compensation must also meet the proposed fair market value standard, including consistency with prevailing market rates for comparable services. The absence of a supplemental compensation outlier methodology does not exempt supplemental compensation from that standard. As previously noted, all compensation arrangements must not violate the Federal anti-kickback statute and must comply with other applicable laws and regulations.

This proposed definition would also require that compensation be consistent with prevailing market rates for comparable services and must not reflect consideration of any business generated between the parties, except as expressly permitted by applicable law and regulation. As previously mentioned, in developing this new proposed definition, CMS utilized the concept of "bona fide bargaining between well-informed parties acting at arm's length," found in the definition of "general market value" under § 411.351. Although this definition of general market value pertains to financial relationships between physicians and entities furnishing designated health services, CMS believes that the way it frames a market value standard is equally appropriate for CMS's updated FMV definition. In proposing this updated definition, CMS sought to ensure that the resulting compensation rates reflect typical market forces and are not influenced by parties working in tandem to artificially inflate values for their mutual benefit.

Under this proposal, MA organizations and Part D sponsors would be permitted to set their own compensation amounts for initial and renewal enrollments, provided they fall within the applicable newly proposed definitions and guardrails outlined as a part of this proposed rule. CMS also notes that, based on research including discussions with MA organizations and Part D sponsors, state regulators, and agent and broker trade groups, these proposed changes better align with industry standards in other insurance markets where compensation caps are not typically utilized. In fact, as previously noted, in drafting this proposal, CMS looked at how agents and brokers who assist consumers with enrollment in QHPs offered through the FFEs are

compensated. Under this program, CMS regulations do not cap the compensation these agents and brokers receive, though under 45 CFR 156.200(f), a QHP issuer must pay the same agent and broker compensation for QHPs offered through an FFE that the QHP issuer pays for similar health plans offered outside of the exchange.

CMS originally implemented FMV caps in 2008, at a time when there were concerns that compensation rates would dramatically increase without a limit in place, which could result in problematic behaviors by some agents and brokers, ultimately leading to enrollments that did not best meet a beneficiary's health care needs. As previously noted, CMS has heard more recently from some state Departments of Insurance that MA organizations and Part D sponsors have stopped paying compensation for enrollment in some products. MA organizations and Part D sponsors stop paying compensation for various reasons which may include limiting financial losses in certain plans, or attempting to minimize the number of new enrollees in particular plans to ensure adequate access is available to current members or because an MA organization or Part D sponsor may not have the administrative capabilities to provide services to a significant number of additional enrollees. Considering the rise of some MA organizations and Part D sponsors not offering any enrollment compensation to agents and brokers for enrollments into certain plans, CMS is now concerned that agents and brokers will avoid enrolling beneficiaries into these plans.

In the release of the Contract Year 2027 Plan Benefit Package and Bid Pricing Tool Software and Related Technical Bidding Guidance for Employer/Union-Only Group Waiver Plan, CMS reminded MA organizations of the option to request an enrollment capacity limit for a given plan benefit package as part of the bid submission process. Additionally, in this proposed rule at section III.G, CMS is proposing to codify a process for how CMS will review enrollment capacity limits. In addition, CMS is proposing a minimum threshold for what would be accepted as part of the bid. CMS believes this proposed rule, if finalized, may reduce the need of MA

organizations and Part D sponsors to try to limit enrollment in particular plans by not paying compensation.

Taking into consideration the court's ruling, as well as how the broader industry uses and pays compensation, CMS also considered different alternatives for compensation. CMS considered continuing with the existing methodology which sets an FMV ceiling for compensation, adjusted each year based on MA and Part D growth factors. CMS also considered providing plans with complete flexibility to set their compensation rates, with no provision for CMS to analyze or address compensation outliers, resulting in the market determining compensation amounts without oversight to ensure compensation amounts do not result in the steerage of beneficiaries into specific plans. CMS also considered requiring MA organizations and Part D sponsors to pay the same base compensation amount across all product lines, resulting in one base compensation rate for each contract, regardless of the type of product being sold. CMS believes this latter option would provide the least amount of flexibility for MA organizations and Part D sponsors.

We solicit comments on the proposed changes to compensation, the alternatives described earlier that CMS has also considered, as well as other ideas that interested stakeholders may have for the best way to ensure the use of compensation creates incentives for agents and brokers to enroll Medicare beneficiaries into the health plan that best meets their needs.

c. Defining "Base Compensation Outliers"

CMS is proposing to add a definition for a base compensation outlier at §§ 422.2260 and 423.2260. Similar to concerns expressed in the past when FMV was originally calculated, CMS is concerned that certain MA organizations or Part D sponsors paying significantly more than other MA organizations or Part D sponsors could have an undue influence on agent and broker behavior. As noted previously, CMS is proposing to allow the market to dictate an acceptable level of base compensation. However, CMS wants to guard against an MA organization or Part

D sponsor offering a level of compensation so high that it could negatively influence an agent or broker's objectivity.

CMS is proposing that the base compensation outlier be defined as any base compensation amounts, submitted to CMS by any MA organizations and Part D sponsors to CMS, pursuant §§ 422.2271(b)(3)(ii) and 423.2271(b)(3)(ii) that are above the 3rd quartile, as calculated in a distribution, using a box plot method and determined by CMS pursuant §§ 422.2274(b) and 423.2274(b). Base compensation outliers will be determined using all base compensation amounts submitted by all MA organizations and Part D Sponsors.[113] Box plots are a graphical distribution of data split into quartiles, with the median at the center and lower and upper quartiles at the 25th and 75th percentiles. A box plot has "fences" developed using the interquartile range, which is calculated as Q3 – Q1. Any point beyond an inner fence is considered a mild outlier. Any points beyond an outer fence are considered extreme outliers.

If finalized, MA and Part D outlier analyses would be calculated separately.

2. Proposed Updates to §§ 422.2272 and 422.2274 under new 422.2271

As mentioned previously, CMS is proposing to add a new §§ 422.2271 and 423.2271. The new section at § 422.2271 will be titled "MA requirements, MA reporting requirements, and MA oversight of agent/broker/TPMO requirements" while the new section at § 423.2271 will be entitled "Part D sponsor requirements, Part D sponsor reporting requirements, and Part D sponsor oversight of agent/broker/TPMO requirements." These new sections will consist of three paragraphs: §§ 422.2271(a) and 423.2271(a) will be titled "General MA [Part D sponsor] oversight requirements," outlining the functions for which MA organizations and Part D sponsors are responsible, including establishing and implementing an oversight plan and overseeing first tier, downstream, and related entities (FDR). Sections 422.2271(b) and 423.2271(b) will be titled "MA [Part D sponsor] reporting requirements," which will outline the information, including compensation data, that MA organizations and Part D sponsors must

[113] For example, see the description here: https://www.itl.nist.gov/div898/handbook/prc/section1/prc16.htm

report to CMS. Sections 422.2271(c) and 423.2271(c) will be titled "MA [Part D sponsor] oversight of agent/broker/TPMO requirements," and will outline how MA organizations and Part D sponsors are required to ensure their FDRs, including Third-Party Marketing Organizations (TPMOs), comply with CMS requirements.

Since we are proposing new §§ 422.2271 and 423.2271, which encompasses requirements, reporting, and oversight, CMS believes, by adding §§ 422.2271 and 423.2271, the requirements for MA organizations and Part D sponsors will be clearer and more organized, grouping them into appropriate categories to create a more effective and user-friendly regulation. CMS is proposing to move a significant number of provisions from §§ 422.2272, 422.2274(b) and (c), 423.2272, and 423.2274(b) and (c) to the new §§ 422.2271 and 423.2271. CMS is also proposing to modify some of these current provisions when adding them to the new §§ 422.2271 and 423.2271. CMS is proposing to remove other provisions from §§ 422.2272, 422.2274, 423.2272, and 423.2274 in their entirety, based on redundancy or because CMS believes the provisions are not in line with Executive Order (EO) 14192, Unleashing Prosperity Through Deregulation.[114]

Currently §§ 422.2274(b), 422.2274(c), 423.2274(b), and 423.2274(c) contain introductory paragraphs regarding agent/broker requirements and MA organization and Part D sponsor oversight. CMS is proposing to remove those introductory paragraphs and add a new introductory paragraph at §§ 422.2271 and 423.2271. CMS is proposing this paragraph to state that, MA organizations [Part D sponsors] are responsible for the actions of their first tier, downstream, related entities, and TPMOs, that represent the MA organization [Part D sponsor] and must ensure the following requirements in paragraphs (a) through (c) of this section are met. Representation includes selling products (including MA plans, MA-Prescription Drug plans, Medicare Prescription Drug plans, and section 1876 Cost plans) as well as outreach to existing or

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

potential beneficiaries and answering or potentially answering questions from existing or potential beneficiaries.

a. Proposed requirements under new §§ 422.2271(a) and 423.2271(a)

Current regulations at §§ 422.2272(e) and 423.2272(e) require MA organizations and Part D sponsors to establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS. CMS is proposing to move, in its entirety, the provisions at §§ 422.2272(e) and 423.2272(e) to §§ 422.2271(a)(1) and 423.2271(a)(1).

Current regulations at §§ 422.2274(c) and 423.2274(c) require MA organizations and Part D sponsors to oversee FDRs to ensure agents and brokers abide by all applicable State and Federal laws, regulations, and requirements. CMS is proposing to move this to the newly designated paragraphs §§ 422.2271(a)(2) and 423.2271(a)(2). CMS is only proposing conforming changes to align with the proposed section.

Current regulations at §§ 422.2274(c)(11) and 423.2274(c)(11) require MA organizations and Part D sponsors to comply with State requests for information about licensed agents' and brokers' performance and require CMS to establish and maintain memoranda of understanding (MOU) with States to share compliance and oversight information with States that agree to the MOU. CMS is proposing to move the requirement related to complying with State requests for information to new §§ 422.2271(a)(3) and 423.2271(a)(3). CMS is also proposing to recharacterize the language concerning MOUs, since the critical need is to share information and the method of sharing that information is not necessarily through an MOU. As such, CMS proposes to amend the regulation text to explain that CMS will share compliance and oversight information with States about licensed agents' and brokers' performance via MOU or other appropriate means. CMS currently has MOUs with all states and will continue to work to update and maintain them as needed.

Since 2008[115], CMS has required at §§ 422.2272(a) and 423.2272(a) that, when marketing, MA organizations and Part D sponsors must "demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over." In the Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule (86 FR 5864), hereafter referred to as the "January 2021 final rule," CMS added a duplicative requirement at §§ 422.2274(c)(10) and 423.2274(c)(10), requiring MA organizations and Part D sponsors, as part of their oversight of first tier, downstream, and related entities (FDRs), to "demonstrate that marketing resources are allocated to marketing to the disabled Medicare population as well as to Medicare beneficiaries age 65 and over." To streamline duplicative requirements, CMS is proposing to consolidate, modify, and move §§ 422.2272(a), 422.2274(c)(10), 423.2274(a), and 423.2274(c)(10) to new §§ 422.2271(a)(4) and 423.2271(a)(4).

b. Requirements under new §§ 422.2271(b) and 423.2271(b)

As noted previously, CMS is proposing a new §§ 422.2271(b) and 423.2271(b) titled “MA [Part D] reporting requirements.” This proposed section will include provisions that require MA organizations and Part D sponsors to report specific information to CMS.

Current regulations at §§ 422.2272(d) and 423.2272(d) require MA organizations and Part D sponsors to report terminations of agents or brokers to the State in which the agent or broker is appointed, and the reason for termination as required by State law. Regulations at §§ 422.2274(c)(2) and 423.2274(c)(2) also require MA organizations and Part D sponsors to report agent or broker terminations to the State and the reason(s) for termination. Additionally, current regulations at §§ 422.2274(c)(3) and 423.2274(c)(3) require MA organizations and Part D

[115] 73 FR 54208

sponsors to report all enrollments made by unlicensed agents or brokers and report for cause terminations of an agent or broker to CMS.

CMS believes that all agent or broker terminations based on Federal law, CMS regulations, or relevant State laws should be reported to CMS. In addition, since agent and broker licensure is a state function, states also need to know of all agent and broker violations of Federal law, CMS regulations, or relevant State laws. To ensure both CMS and states receive information regarding these agent and broker terminations, CMS is proposing to consolidate the existing termination reporting requirements under new requirements at §§ 422.2271(b)(1) and 423.2271(b)(1) and include the requirement to report to both CMS and the applicable state. CMS is also proposing to add language requiring MA organizations and Part D sponsors to report to CMS and the State, if specified, in the form and manner prescribed by CMS, all terminations of an agent or broker as a result of a violation of Federal laws, CMS regulations, or relevant State laws, as well as any other for cause terminations of an agent or broker, and the reason(s) for such termination. CMS is also proposing that MA organizations and Part D sponsors report these terminations to CMS within 15 calendar days of the termination.

CMS believes that MA organizations and Part D sponsors reporting for cause terminations to CMS itself will strengthen CMS's ability to provide greater oversight over inappropriate marketing activities and help protect beneficiaries from harm. Specifically, MA organizations and Part D sponsors reporting these terminations within 15 days will allow CMS to track these terminations in real time and will strengthen CMS's ability to identify bad actors. CMS believes this will lessen instances of agents and brokers who have been terminated by MA organizations and Part D sponsors from continuing harmful practices elsewhere in the Medicare program and improve regulatory compliance and oversight.

CMS is also proposing to move the current requirement at §§ 422.2274(c)(3) and 423.2274(c)(3) to report all enrollments made by unlicensed agents and brokers to §§ 422.2271(b)(2) and 423.2271(b)(2). CMS is proposing to remove the current language, "and for-

cause terminations of agents or brokers," as this requirement is being consolidated in new §§ 422.2271(b)(1) and 423.2271(b)(1), as described previously.

As a part of the April 2024 final rule, CMS modified §§ 422.2274(c)(5) and 423.2274(c)(5) to align with the changes in compensation. Since the court vacated CMS's changes, CMS reverted to the pre-April 2024 final rule, which required MA organizations and Part D sponsors to report to CMS whether they intend to use agents, the types of agents being used (that is, captive, employed, independent), and the compensation-specific rates or ranges of rates. This provision also prohibited MA organizations and Part D sponsors from changing their decisions regarding agent and broker type (that is, employed, captive, or independent) and compensation until the following year. The proposed changes to compensation are as noted.

CMS is proposing to modify the language currently at §§ 422.2274(c)(5) and 423.2274(c)(5) regarding compensation and largely moving §§ 422.2274(c)(5) and 423.2274(c)(5) to new §§ 422.2271(b)(3) and 423.2271(b)(3), maintaining the requirement to report required information by the last Friday in July. CMS is proposing to move the requirement to report to CMS whether the MA organization or Part D sponsor intends to use, in the upcoming plan year, independent agents and the type of agents to new §§ 422.2271(b)(3)(i) and 423.2271(b)(3)(i).

Currently CMS requires that MA organizations and Part D sponsors provide CMS, on an annual basis, with the specific rates or ranges of rates that each will pay independent agents and brokers. At new proposed §§ 422.2271(b)(3)(ii) and 423.2271(b)(3)(ii), CMS is proposing to require MA organizations and Part D sponsors to provide CMS with more detailed data regarding the compensation that they offer to agents and brokers. Specifically, CMS is proposing to require MA organizations and Part D sponsors to report, on an annual basis, the specific amounts of the base compensation that the plan will pay independent agents and brokers for each plan, as defined by the proposed definition at §§ 422.2260 and 423.2260. By requesting this information for base compensation, CMS will be able to sufficiently review base compensation

for outliers in accordance with the proposed base compensation outlier methodology further discussed later If an MA organization or Part D sponsor wishes to change their compensation amounts during the year, as proposed in §§ 422.2274(a)(5) and 423.2274(a)(5), the MA organization or Part D sponsor will also need to report those new compensation amounts to CMS. Therefore, as proposed §§ 422.2274(a)(5)(i) and 423.2274(a)(5)(i), changes to base compensation will be compared to CMS' original base compensation outlier review.

As discussed later, CMS is proposing to review, analyze, and flag base compensation outliers. Information about the range of base compensation rates that MA organizations and Part D sponsors plan on offering in an upcoming year is not sufficient to accomplish the review of base compensation outliers proposed in this proposed rule. To implement that proposal, CMS would need to collect specific base compensation rates that MA organizations and Part D sponsors pay to agents and brokers. In a review of CY 2026 compensation data, there were 706 unique contracts and 5,546 unique plan benefit packages (PBPs). Reviewing only initial compensation, 650 of those 706 unique contracts, 92 percent of contracts, reported compensation ranges that extended from $0 to the maximum FMV. Of the 5,546 unique PBPs, MA organizations, and Part D sponsors had provided the full range of compensation rates from $0 to the maximum FMV for 5,239 PBPs. A review of CY 2025 compensation rates also shows that the vast majority of contracts had the full range of rates. Based on this data, CMS would be unable to perform meaningful analysis.

CMS is also proposing at new §§ 422.2271(b)(3)(iii)(A) through (C) and 423.2271(b)(3)(iii)(A) through (C), that MA organizations and Part D sponsors report supplemental compensation that the plan will pay independent agents and brokers for each plan, including the specific type, such as compensation, and a detailed explanation of supplemental compensation programs including payment schedules. CMS is also proposing, as discussed further later , at §§ 422.2274(a)(5) and 423.2274(a)(5), the ability for MA organizations and Part D sponsors to change supplemental compensation.

Furthermore, CMS is proposing to add a reporting requirement at §§ 422.2271(b)(3)(iv) and 423.2271(b)(3)(iv), requiring MA organizations and Part D sponsors to provide documentation, as requested by CMS. This documentation would require MA organizations and Part D sponsors to provide contracts associated with their relationships with first tier, downstream, related entities and TPMOs. CMS' review of these contracts would provide the Agency with the information necessary to ensure the use of compensation creates incentives to enroll individuals in the health care plan that best meets their needs.

c. Requirements under new §§ 422.2271(c) and 423.2271(c)

As noted previously, CMS is proposing new §§ 422.2271(c) and 423.2271(c), which will outline how MA organizations and Part D sponsors oversee agents, brokers, and TPMOs. CMS is proposing to remove the introductory paragraphs at §§ 422.2274(b) and (c) and 423.2274(b) and (c) and redesignate some of the language for the introductory paragraphs in §§ 422.2271 and 423.2271 and using other introductory language in the paragraph under the proposed new section §§ 422.2271(c) and 423.2271(c). The proposed new introductory language in §§ 422.2271 and 423.2271 is an overall statement that MA organizations and Part D sponsors are responsible for the actions of their FDRs that represent the MA organization or the Part D sponsor. The new proposed language at §§ 422.2271(c) and 423.2271(c) is introductory language requiring MA organizations and Part D sponsors "ensure agents, brokers and TPMOs who represent MA organizations [Part D sponsors] meet the requirements in paragraphs (c)(1) through (7) of this section."

Under new §§ 422.2271(c) and 423.2271(c), CMS is proposing to consolidate and streamline the requirements from §§ 422.2272(c), 422.2274(c)(1), 423.2272(c), and 423.2274(c)(1), by removing them and including similar requirements to the new §§ 422.2271(c)(1) and 423.2271(c)(1). The current provisions are largely duplicative of each other, requiring MA organizations and Part D sponsors to employ as marketing representatives only individuals who are licensed and appointed by the State to conduct marketing activities,

consistent with the appointment process provided for under State law. CMS is proposing new §§ 422.2271(c)(1) and 423.2271(c)(1), to require that MA organizations and Part D sponsors ensure that all agents and brokers who sell the plan are appropriately licensed and appointed under State law, if required. In addition, CMS is proposing to remove the reference to the Medicare Marketing Guidelines cited §§ 422.2272(c) & 423.2272(c), as the pertinent requirements are already codified in regulation.

The current regulations at §§ 422.2274(b)(2), 422.2274(c)(4), 423.2274(b)(2), and 423.2274(c)(4) require training and testing of agents and brokers. Specifically, §§ 422.2274(b)(2) and 423.2274(b)(2) require that agents and brokers be trained and tested annually and score at least 85 percent on the testing. Requirements at §§ 422.2274(c)(4) and 423.2274(c)(4) require plans to provide training and testing on Medicare rules and regulations, plan products that agents and brokers will sell, State and Federal requirements, and details specific to each plan product. Specifically, CMS currently releases training and testing guidelines on a yearly basis that cover training and testing on Medicare rules and regulations, State and Federal requirements, enrollment, appeals, as well as many other areas necessary for agents and brokers to understand Medicare Advantage and Part D. [116] To better streamline these requirements, CMS is proposing to consolidate, modify, and move §§ 422.2274(b)(2), 422.2274(c)(4), 423.2274(b)(2), and 423.2274(c)(4) to new §§ 422.2271(c)(2) and 423.2271(c)(2). Consolidating these requirements will provide clarity and will better align with CMS's overall proposals.

CMS is proposing to codify, in new §§ 422.2271(c)(2) and 423.2271(c)(2), at new paragraphs (c)(2)(i) and (ii), that MA organizations and Part D sponsors must ensure that all their agents are trained and tested on relevant Medicare rules and regulations and relevant State and Federal requirements, as well as any additional topics specified annually by CMS; requiring a

[116] https://www.cms.gov/medicare/health-drug-plans/managed-care-marketing/models-standard-documents-educational-materials

score of 85 percent or higher on tests. Additional topics being proposed in §§ 422.2271(c)(2) and 423.2271(c)(2) will be addressed in the annual training and testing guidelines. Although CMS anticipates that the training and testing guidelines will remain intact, the proposal will provide CMS with the flexibility to update training and testing guidelines as necessary, based on changes in Medicare and/or areas that CMS determines new or additional training is needed for agents and brokers. This ensures all necessary topics are covered and agents and brokers are knowledgeable in these areas. CMS is proposing to eliminate the current references to "…the plan products that agents and brokers will sell, including any details specific to each plan product…". Under this proposal, CMS' training and testing requirements would largely be maintained from year to year, including core topics, but would allow for modifications that may result from industry changes or changes that CMS identified based on the marketplace. Current regulations require that agents and brokers be trained on the plan products and any details specific to each plan product they intend to sell. Agents and brokers typically sell multiple plan products, including HMOs, PPOs, and SNP plans for several different MA organizations and/or Part D sponsors. CMS would continue to require that agents and brokers be trained and tested on the types of products available, such as HMOs, PDPs, Cost Plans, RPPOs, and SNPs, as CMS recognizes it is critical that agents and brokers know each of these products and the differences between them. Under this proposal, CMS could lessen the burden on requiring that agents and brokers be trained and tested on the details specific to each product line they sell. With agents and brokers selling multiple individual plans, it is unnecessary for CMS to require an agent or broker to be trained and tested on each specific plan benefit and cost sharing structure. CMS believes that training and testing on the nuances of cost sharing, benefits, and service areas for each individual plan is unnecessary since the agents and brokers have that information readily available when selling a plan. Additionally, it is in the best interest of the MA organization or Part D sponsor to ensure that an agent or broker is appropriately trained on unique plan

information, regardless of regulatory requirements. This proposal will significantly reduce the burden on all agents, brokers, MA organizations, and Part D sponsors.

CMS is also proposing, under new §§ 422.2271(c)(2)(iii) and 423.2271(c)(2)(iii), to add a provision permitting MA organizations and Part D sponsors to accept third-party training and testing, or training and testing from another MA organization or Part D sponsor, provided they meet the requirements in (c)(2)(i) and (ii) of this section. Agents and brokers who sell for more than one MA organization and/or Part D sponsor may be required to take training for each organization, even though the majority of the training is the same. This can result in an agent or broker taking multiple trainings that cover the same topics. CMS is proposing that MA organizations and Part D sponsors may permit their agents and brokers to take other training and testing to meet their own MA or Part D requirements, provided the training and testing encompasses all of CMS's requirements. Provided MA organizations and Part D sponsors use this option, these proposed updates to the training and testing requirements should result in a significant burden reduction for agents, brokers, TPMOs, MA organizations, and Part D sponsors, while still maintaining appropriate beneficiary protections and safeguards.

CMS is also proposing to move with slight modifications the current requirements at §§ 422.2274(c)(8) and 423.2274(c)(8), to new §§ 422.2271(c)(3) and 423.2271(c)(3). The current requirements state that marketing consulting fees cannot be charged to Medicare beneficiaries when considering enrollment into an MA or Part D plan. CMS views agents and brokers selling MA or Part D plans as an extension of the MA organization or Part D sponsor. As such, it is CMS's policy to ensure beneficiaries receive information and enrollment services provided by an MA organization or Part D sponsor without having to pay. At the same time, CMS has been made aware that some states have separate licenses, for example for health care consulting, that fall outside of the license required to be an agent or broker (or "producer" in state terms). Under new §§ 422.2271(c)(3) and 423.2271(c)(3), CMS is proposing to maintain the position that beneficiaries should not be charged fees for information regarding Medicare

products being sold by an agent, broker or TPMO. However, CMS does not intend to interfere with state laws that permit fees to be paid under a separate license, such as a health care consultant license, which are outside of CMS's purview as it applies to agent and broker oversight.

CMS is proposing to modify the new §§ 422.2271(c)(3) and 423.2271(c)(3) to say that fees may not be charged to the beneficiary, by an agent, broker or TPMO, when the agent, broker or TPMO is operating under a health insurance license under State law. By limiting CMS's requirement to health insurance licenses, CMS continues to protect beneficiaries, while not interfering with State laws governing health consultant licenses. Moreover, the proposed requirement eliminates the ambiguity associated with what constitutes "marketing consulting" fees, under the current definition.

CMS also administers the FFE and has established a framework, outlined at 45 CFR 155.220(g), for terminating agents and brokers, from participating in the FFEs, where they have engaged in certain misconduct, noncompliance, or other violations of federal law or CMS regulations. Prior to such termination, CMS conducts investigations of agents and brokers to determine the facts of the case and determine if fraud was likely to have been committed.[117] Although regulations permit agents and brokers to be terminated from the FFE programs, there are no current regulatory requirements prohibiting MA organizations and Part D sponsors from contracting with agents or brokers whose participation in the FFE has been terminated by CMS. Given agents and brokers who sell on the FFE may also sell MA and Part D products, CMS is concerned that those agents and brokers who engage in misconduct in one federal health

[117] Agents and brokers must comply with agreements with CMS under 45 CFR 155.220(d) (Exchange Agreements) in order to enroll consumers in QHPs through the FFEs or to assist them in applying for financial assistance through the FFEs. Those Exchange Agreements require registration with CMS, completion of training, and compliance with standards of conduct and other CMS requirements. If the agent or broker does not have Exchange Agreements for the plan year because CMS terminated them in accordance with 45 CFR 155.220(g), then the AB is no longer registered with the FFEs and may not assist individuals with FFE enrollments or applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs through the FFEs. Under 45 CFR 155.220(k)(1)(i), CMS may also propose to deny an agent or broker the right to enter into Exchange Agreements for future plan years.

insurance program may pose similar risks in others. CMS believes this gap exposes beneficiaries to harmful practices and undermines the integrity of the MA and Part D programs.

To address these concerns, CMS is proposing to add a new requirement at §§ 422.2271(c)(4)(i) and 423.2271(c)(4)(i), to explicitly prohibit MA organizations and Part D sponsors from entering into or maintaining contracts with agents, brokers and TPMOs who are currently terminated from participating in the FFEs by CMS. Specifically, CMS proposes to add regulatory language requiring that, as a condition of their contracts with CMS, MA organizations and Part D sponsors ensure they do not contract with an agent, broker or TPMO that is currently terminated from participation in the FFE by CMS. CMS is seeking comments on whether there are FFE specific circumstances in which an agent or broker would be terminated from the FFE program but should not be terminated from the MA and Part D programs.

In addition, CMS is proposing at §§ 422.2271(c)(4)(ii) and 423.2271(c)(4)(ii), that MA organizations and Part D sponsors must monitor the termination status with CMS's registration termination list[118] and registration completion list[119] monthly, for agents and brokers with whom they have existing contracts. CMS has considered alternative cadences for checking the termination status report, for example, every other month, or semiannually (that is every six months). CMS is specifically requesting comments as to the appropriate interval for reviewing this information.

Lastly, at §§ 422.2271(c)(4)(iii) and 423.2271(c)(4)(iii), CMS is proposing to require MA organizations and Part D sponsors terminate any existing contract with an agent or broker within 15 calendar days of determining that the agent or broker has been terminated from the FFE by CMS. CMS believes this proposal is consistent with our authority under section 1859(i)(1)(C) of the Act to specify what constitutes substantiated or suspicious activities of fraud, waste, and abuse. CMS also believes this proposal is consistent with our authority and responsibility to

[118] https://data.healthcare.gov/ab-suspension-and-termination-list
[119] https://data.healthcare.gov/ab-registration-completion-list

protect the integrity of the Medicare program and to safeguard Medicare beneficiaries from fraud, waste, and abuse by aligning the standards applicable to agents and brokers across the FFE and the MA and Part D programs.

CMS acknowledges that there are instances where previously terminated agents and brokers are reinstated to the FFE program (such as, after renewing an expired license). Reinstated agents and brokers are removed from CMS' termination lists. CMS' proposal does not prohibit an MA organization or Part D sponsor from re-contracting with an agent or broker who is no longer on CMS' termination list from the FFE programs. CMS encourages MA organizations and Part D sponsors to regularly review their terminated agents against these lists, to determine the agent or broker's current termination status. Ultimately, it is up to the MA organization or Part D sponsor to decide on whether to re-contract with agents and brokers who have been reinstated to the FFE programs.

CMS is proposing to redesignate, in its entirety, §§ 422.2274(g)(2)(ii) and 423.2274(g)(2)(ii), regarding the requirement to record all sales and marketing calls, to the newly proposed §§ 422.2271(c)(5) and 423.2271(c)(5), to align this change with other changes in this proposal.

Sections 422.2274(g)(3) and 423.2274(g)(3) require that MA organizations and Part D sponsors oversee their TPMOs by ensuring they, when directly or indirectly conducting lead generating activities for a plan, disclose to the beneficiary that their information is being provided to an agent for future contact and/or that they are being transferred to a licensed agent that can enroll them. Sections 422.2274(g)(4) and 423.2274(g)(4) require MA organizations and Part D sponsors, in their oversight of TPMOs, to ensure that personal beneficiary data collected by a TPMO for marketing or enrolling them into an MA plan is only to be shared with another TPMO when prior express written consent is given by the beneficiary. Furthermore, the requirement states that consent for sharing the data and contacting beneficiaries must be obtained through a clear and conspicuous disclosure, for each individual entity receiving the data, with the

opportunity for the beneficiary to consent to or reject sharing their personal beneficiary data. CMS is proposing to move, with minor modifications for clarity and to conform with the proposed changes, §§ 422.2274(g)(3) and (4) and 423.2274(g)(3) and (4), to newly designated §§ 422.2271(c)(6) and (7) and 423.2271(c)(6) and (7). The proposal to move these two sections is to align these requirements with the revised regulatory structure.

d. Requirements Proposed to be Removed

CMS is also proposing to remove redundancy from existing requirements. Currently, requirements at §§ 422.2274(b)(3) and 423.2274(b)(3) state that agents and brokers who represent plans must "secure and document a Scope of Appointment prior to meeting with potential enrollees." Additionally, §§ 422.2274(c)(9)(ii) and 423.2274(c)(9)(ii) require the establishment and maintenance of a system for confirming that agents and brokers complete the scope of appointment (SOA) for all marketing appointments (including telephonic and walk-in). These requirements are largely duplicative of the requirements in §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i), which currently require an agreed upon and recorded SOA. Therefore, CMS proposes to remove the duplicative and unnecessary SOA requirements currently at §§ 422.2274(b)(3), 422.2274(c)(9)(ii), 423.2274(b)(3), and 423.2274(c)(9)(ii) since the requirement to establish and maintain a system for confirming agents and brokers complete the SOA for all marketing appointments is already in regulation at §§ 422.2264(c)(3)(i) and 423.2264(c)(3)(i). In addition, the removal of these regulations will streamline requirements in line with EO 14192, Unleashing Prosperity Through Deregulation.

CMS is also proposing to remove §§ 422.2274(c)(6) and 423.2274(c)(6), which require MA organizations and Part D sponsors to have in place, on an annual basis, a full compensation structure by October 1st for the following plan year. CMS is proposing to remove these provisions to align with the overall proposed changes in the regulation, including the proposed requirement at §§ 422.2271(b)(3)(ii) and (iii) and 423.2271(b)(3)(ii) and (iii) to require MA organizations and Part D sponsors to provide actual base and supplemental compensation

amounts defined by the proposed definitions under §§ 422.2260 and 423.2260. CMS believes the proposed changes to agent and broker compensation requirements, which include the submission of actual compensation data by the last Friday in July, supersedes the need for a full compensation structure in place by October 1st. Removing these requirements is also in line with EO 14192, Unleashing Prosperity Through Deregulation.

Next, CMS is also proposing to remove the requirement at §§ 422.2274(c)(7) and 423.2274(c)(7), which requires MA organizations and Part D sponsors to oversee their FDRs and their submission of agent and broker marketing materials to HPMS. Currently, at §§ 422.2261(a) and 423.2261(a), CMS requires MA organizations and Part D sponsors to submit marketing materials into HPMS. In addition, §§ 422.2261(a)(2) and 423.2261(a)(2) further specify that marketing materials developed by TPMOs must also be submitted into HPMS. Given the duplicative nature of these requirements, CMS is proposing to remove §§ 422.2274(c)(7) and 423.2274(c)(7), in line with EO 14192, Unleashing Prosperity Through Deregulation.

CMS is also proposing to remove requirements at §§ 422.2272(b), 422.2274(c)(9)(i), 423.2272(b), and 423.2274(c)(9)(i). At §§ 422.2272(b), and 423.2272(b), current requirements state that, in marketing, MA organizations and Part D sponsors must "establish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the MA plan, and understand the rules applicable under the plan." Similarly, at §§ 422.2274(c)(9)(i) and 423.2274(c)(9)(i), CMS requires that MA organizations and Part D sponsors, through their oversight of FDRs, ensure that agents and brokers, "establish and maintain a system for confirming" that "beneficiaries enrolled by agents or brokers understand the product, including the rules applicable under the plan." CMS believes these requirements are largely duplicative with other requirements that already exist in regulations, both for ensuring the beneficiary understands the rules applicable under the plan, and for establishing and maintaining a system to confirm a beneficiary's enrollment in a plan. For example, CMS requires the pre-enrollment checklist (PECL) at §§ 422.2267(e)(4) and 423.2267(e)(4) which requires plans to provide a

standardized communications material to prospective enrollees so that enrollees understand important plan benefits and rules. For telephonic enrollments, the contents of the PECL must be reviewed with the prospective enrollee prior to the completion of the enrollment. The PECL requires references to information on the evidence of coverage (EOC), provider directory, pharmacy directory, formulary, premiums, copayments, coinsurance, emergency and urgent coverage, plan-type rules and the effect on current coverage. CMS believes that this checklist, which must be reviewed with prospective enrollees prior to the completion of enrollment, sufficiently covers what a beneficiary needs to understand prior to enrolling with a plan.

Furthermore, other required materials at §§ 422.2267 and 423.2267 ensure that documents, such as the enrollment notice, EOC, and the provider directory, are sent to new enrollees within required timeframes. These documents clearly provide beneficiaries with sufficient information about their enrollment in a plan. CMS notes that there are also various beneficiary protections in place, including the possibility of providing special enrollment periods when appropriate, or, if warranted, processing a retrospective enrollment to place the beneficiary back into their prior coverage, if a beneficiary makes an adverse enrollment decision based on misrepresentation or otherwise non-compliant sales tactics.

Similarly, CMS is proposing to remove the requirement at §§ 422.2274(c)(12) and 423.2274(c)(12), which requires that plans, in their oversight of their FDRs, ensure that, prior to an enrollment, CMS's required questions and topics regarding beneficiary needs in a health plan choice are fully discussed. CMS believes this requirement duplicates the PECL requirement at §§ 422.2267(e)(4) and 423.2267(e)(4), which requires the PECL to be presented to enrollees before enrollment so prospective enrollees understand plan rules, including provider directories, premiums, copayments, effect on current coverage as well as other topics. Furthermore, CMS believes the proposed MA organization and Part D sponsor oversight requirements in §§ 422.2271 and 423.2271 will provide additional protections to beneficiaries in that MA organizations and Part D sponsors will ensure enrollees are fully informed of the details

regarding their enrollment into an MA or Part D plan. Therefore, having both requirements, that is to cover what is required under §§ 422.2274(c)(12) and 423.2274(c)(12), as well as being required to provide the PECL or read its content may be unnecessary and confusing for agents, brokers, and beneficiaries alike. Removing these duplicative requirements is also in line with EO 14192, Unleashing Prosperity Through Deregulation.

CMS is proposing to remove §§ 422.2274(c)(13) and 423.2274(c)(13). These provisions currently require MA organizations and Part D sponsors to ensure that, beginning with contract year 2025, no provision of a contract with an agent, broker, or other TPMO has a direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best fits the health care needs of a beneficiary. CMS is proposing to remove this requirement in light of the court's ruling as detailed previously.

CMS is proposing to remove §§ 422.2274(g)(1), 422.2274(g)(2)(i), 423.2274(g)(1), and 423.2274(g)(2)(i). Sections 422.2274(g)(1) and 423.2274(g)(1) require that MA organizations and Part D sponsors, when doing business with a TPMO, either directly or indirectly through an FDR, when a TPMO is not an FDR, ensure that the TPMO adheres to applicable MA organizations' and Part D sponsors' requirements. CMS is proposing to remove this requirement because it is duplicative and unnecessary. CMS's definition of TPMO at §§ 422.2260 and 423.2260 "means organizations and individuals, including independent agents and brokers, who are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment (the steps taken by a beneficiary from becoming aware of an MA [Part D] plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § 422.2, but may also be entities that are not FDRs but provide services to an MA [Part D] plan or an MA [Part D] plan's FDR." This definition is inclusive of both entities that are and are not FDRs and is referenced throughout these requirements. Therefore, MA organizations and Part D sponsors are already required to

ensure that TPMOs they directly or indirectly contract with adhere to all MA and Part D requirements. Additionally, this language is also reiterated in newly proposed requirements in the introductory paragraphs §§ 422.2271 and 423.2271, which state that "MA organizations [Part D sponsors] are responsible for the actions of their first tier, downstream, related entities (FDRs) and TPMOs, that represent the MA organization [Part D sponsor] and must ensure the following requirements in paragraphs (a) through (c) of the section are met." Removing these requirements is also in line with EO 14192, Unleashing Prosperity Through Deregulation.

Regulations at §§ 422.2274(g)(2)(i) and 423.2274(g)(2)(i) require FDRs and TMPOs to disclose subcontracted relationships used for marketing, lead generation, and enrollment to the MA organizations and Part D sponsors. CMS finalized this requirement in "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" which appeared in the **Federal Register** on May 9, 2022 (87 FR 27704), hereafter referred to as "May 2022 final rule." In the final rule, CMS stated these oversight requirements were meant to ensure MA organizations and Part D sponsors do not utilize TPMOs as means of evading their own compliance responsibilities, and thus these oversight requirements were intended to require plans to ensure TPMOs adhere to any requirements that apply to the plans themselves.[120] However, as previously noted, CMS has duplicative requirements stating that MA organizations and Part D sponsors are responsible for the actions of their contracted entities. In addition, the subcontracting arrangements, including disclosure requirements, entered into between MA organizations and Part D sponsors, and FDRs and TPMOs for the purpose of marketing, lead generation, and enrollment, are business decisions for which MA organizations and Part D sponsors are responsible. Removing these requirements is also in line with EO 14192, Unleashing Prosperity Through Deregulation.

[120] https://www.federalregister.gov/d/2022-09375/p-1294

Finally, CMS is proposing to remove §§ 422.2274(g)(2)(iii) and 423.2274(g)(2)(iii) as the requirement for TPMOs to report staff disciplinary actions and violations "to the plan" is the responsibility of the MA organization or Part D sponsor to oversee. CMS believes MA organizations and Part D sponsors are in the best position to monitor their TPMOs and make the determination themselves regarding reporting of TPMOs disciplinary actions and violations. In addition, MA organizations and Part D sponsors, under current regulations at §§ 422.2272(e) and 423.2272(e), must establish and implement an oversight plan that monitors agent and broker activities, which CMS would expect to include monitoring disciplinary actions TMPOs take regarding their agents and brokers. As mentioned earlier, CMS is proposing to retain but re-designate §§ 422.2272(e) and 423.2272(e) to new proposed regulations at §§ 422.2271(a)(1) and 423.2271(a)(1)). Furthermore, as mentioned earlier, CMS is proposing to require at new §§ 422.2271(b)(1)(ii) and 423.2271(b)(1)(ii), that MA organizations and Part D sponsors report to CMS, in the form and manner prescribed by CMS, within 15 calendar days of termination, all for cause terminations of an agent and broker and terminations due to violations of Federal law, CMS regulations, or relevant State laws and the reasons for termination. Removing these requirements is also in line with EO 14192, Unleashing Prosperity Through Deregulation.

e. Modified Compensation Requirements for Existing §§ 422.2274 and 423.2274

As previously noted, compensation requirements were initially implemented in the September 2008 interim final rule. Since 2008, there have been significant changes in how MA organizations and Part D sponsors market and enroll Medicare beneficiaries into their Part C and Part D plans. Prior to the initial compensation requirements, including FMV, in the September 2008 interim final rule, MA organizations were paying excessively high compensation, potentially resulting in beneficiaries being enrolled in a plan based on compensation and not based on the plan best met the beneficiary's health care needs. Except for the changes in compensation for CY 2025, which were subsequently vacated by court order, CMS's policies governing compensation for agents and brokers in the MA and Part D programs have largely

been unchanged, even though industry practices have changed substantially and the MA and Part D programs have matured.

In proposing new compensation regulations, CMS reviewed how compensation is treated for agent-assisted QHP enrollments. CMS also reached out to State Insurance Commissions and MA organizations for information regarding commercial plans and specific payment amounts for Medicare health plans. For agent-assisted QHP enrollments, CMS does not set compensation rates; rather, it generally allows the market to determine the value of the services provided by agents and brokers.[121] QHP issuers determine how much compensation will be paid to agents and brokers for each consumer enrollment through the FFEs. For QHP issuers, CMS generally allows the market to determine compensation rates.[122] CMS does not regulate other payments, such as administrative payments or override payments, instead letting the market also drive the value of those services. CMS, in discussions with State Departments of Insurance, was also informed that states generally do not set compensation rates for commercial products. As with the compensation QHP issuers offer to agents and brokers who assist consumers with enrollment in coverage through the FFEs, states let the marketplace determine the value of an enrollment in a commercial health plan.

CMS also sought specific compensation data from a small sampling of MA organizations based on various sizes and service areas for contract year 2026. This effort was undertaken to obtain more specific data on how much MA organizations pay and to whom they pay compensation. CMS's request was completely voluntary, with more than half of the MA organizations asked choosing to participate. CMS requested MA organizations provide contract year 2026 actual compensation payment amounts at the plan level, if different rates were paid.

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[121] Center for Consumer Information and Insurance Oversight (CCIIO), Centers for Medicare & Medicaid Services (CMS), "2026 Final Letter to Issuers in the Federally-facilitated Exchanges," (January 15, 2025), page 27, *available at*: https://www.cms.gov/files/document/final-2026-letter-issuers.pdf

[122] CMS's oversight of the compensation agents and brokers receive for assisting with consumer enrollments through the FFEs is very limited. Under 45 CFR 156.200(f), a QHP issuer must pay the same agent and broker compensation for QHPs offered through an FFE that the QHP issuer pays for similar health plans offered off the exchange FFE.

Furthermore, CMS requested specific amounts if MA organizations paid different amounts based on other factors including specific agents/agencies or types of products sold (for example, PPO vs. HMO).

CMS reviewed data collected from MA organizations and observed a range of compensation structures, including uniform compensation rates throughout the year, midyear changes to $0 compensation, and differing compensation rates by plan type. In some contracts, full compensation was paid for D-SNP enrollments while $0 compensation applied to standard HMO or PPO enrollments under the same contract. CMS believes the variability observed across organizations and contracts could result in differing financial incentives depending on the product being recommended and, in some circumstances, could raise concerns about the potential for compensation differences to influence agent and broker recommendations. CMS believes these observations provide additional support for the proposal, discussed later in this section, to require consistent compensation for like product lines (for example, HMO) across contracts, which could help reduce the potential influence of compensation differences on recommendations.

CMS is proposing to modify the introductory paragraph of current §§ 422.2274 and 423.2274 to align with the proposed changes noted later. The current introductory paragraph refers to the requirements in paragraphs (a) through (f), identifying which paragraphs are applicable to MA organizations and Part D sponsors who use agents and brokers to sell their plans and to MA organizations and Part D sponsors who make payments to third parties. CMS is proposing to revise the introductory paragraph to accurately reflect the proposed revisions to §§ 422.2274 and 423.2274.

Currently, the regulations at §§ 422.2274(d) and 423.2274(d) state that MA organizations and Part D sponsors must ensure they meet the requirements in paragraphs (d)(1) through (5), which address general rules and types of compensation, in order to pay compensation and that the compensation requirements only apply to independent agents and brokers. CMS proposes to

redesignate §§ 422.2274(d) and 423.2274(d), titled "compensation requirements" as §§ 422.2274(a) and 423.2274(a) to align with our other proposals. CMS is also proposing to make modifications to the introductory paragraph at §§ 422.2274(a) and 423.2274(a), which currently states that if MA organizations and Part D sponsors use agents and brokers paragraphs (a) through (e) must be met. CMS is proposing to modify the language to state that MA organizations and Part D sponsors must comply with the requirements in paragraphs (1)-(8) of §§ 422.2274(a) and 423.2274(a) in paying and recovering compensation, as that more accurately reflects the specific requirements in new proposed paragraphs (1)-(8), further described later.

CMS is proposing to remove in their entirety the requirements, in §§ 422.2274(d)(1)(i) and 423.2274(d)(1)(i), that MA organizations and Part D sponsors may only pay agents or brokers who meet certain requirements. CMS is proposing at §§ 422.2271(c) and 423.2271(c) that MA organizations and Part D sponsors must ensure agents and brokers meet specified requirements. CMS believes these new proposed requirements cover the current language at §§ 422.2274(d)(1)(i) and 423.2274(d)(1)(i).

Although vacated by the court, current regulations at §§ 422.2274(d)(1)(ii) and 423.2274(d)(1)(ii) state that, beginning in contract year 2025 MA organizations and Part D sponsors would be limited to amounts outlined in this section. Based on the court's ruling, CMS is proposing to remove §§ 422.2274(d)(1)(ii) and 423.2274(d)(1)(ii). Additionally, CMS is proposing to redesignate §§ 422.2274(d)(1)(iv) and 423.2274(d)(1)(iv) to §§ 422.2274(a)(6) and 423.2274(a)(6).

Current regulations at §§ 422.2274(d)(1)(iii)-(iv) and 423.2274(d)(1)(iii)-(iv) state that MA organizations and Part D sponsors may determine their payment schedule and may only pay compensation for the number of months a beneficiary is enrolled in the plan. CMS is proposing to redesignate §§ 422.2274(d)(1)(iii) and 423.2274(d)(1)(iii) to §§ 422.2274(a)(2) and 423.2274(a)(2) with clarifying edits. CMS is proposing to maintain the requirement that MA organizations and Part D sponsors may determine their compensation payment schedule but

proposes to remove the language currently in §§ 422.2274(d)(1)(iii) and 423.2274(d)(1)(iii) which provide examples of payment schedules, such as monthly or quarterly. Additionally, CMS is proposing to remove the language in §§ 422.2274(d)(1)(iii) and 423.2274(d)(1)(iii) that payments must be during the year of the beneficiary's enrollment, which were originally implemented to ensure agents and brokers were paid timely. MA organizations and Part D sponsors contract with their downstream entities. In general, CMS does not interfere with these contracts and should not regulate payment schedules between MA organizations and Part D sponsors with agents and brokers. CMS believes the agent and broker and the MA organization or Part D sponsor should determine and negotiate an appropriate payment schedule.

Next, CMS is proposing to redesignate and modify the introductory language at §§ 422.2274(d)(2) and (3) and 423.2274(d)(2) and (3). The newly redesignated language will be at §§ 422.2274(a)(3) and (4) and 423.2274(a)(3) and (4). Since CMS is proposing to modify the definition of FMV, CMS is proposing to eliminate the reference in these requirements to pay compensation at or below FMV, as CMS is proposing to no longer establish a maximum FMV for compensation.

CMS is not proposing any additional changes to the existing requirements at §§ 422.2274(d)(2)(i) and (ii) and (3)(i) and (ii) and 423.2274(d)(2)(i) and (ii) and (3)(i) and (ii) and proposes to maintain the other requirements regarding initial and renewal enrollments provided within these subparagraphs. CMS is proposing to redesignate §§ 422.2274(d)(2)(i) and (ii) and 423.2274(d)(2)(i) and (ii) to §§ 422.2274(a)(3)(i) and (ii) and 423.2274(a)(3)(i) and (ii) and redesignate §§ 422.2274(d)(3)(i) and (ii) and 423.2274(d)(3)(i) and (ii) to §§ 422.2274(a)(4)(i) and (ii) and 423.2274(a)(4)(i) and (ii).

CMS is proposing to add a new requirement at §§ 422.2274(a)(1), requiring MA organizations to pay the same base compensation to all agents and brokers for the same product line under a contract. This requirement would only be applicable to MA organizations based on their product lines. Since Part D sponsors only offer one product line, CMS is proposing to add a

new requirement at § 423.2274(a)(1), that the Part D sponsor would be required to pay the same compensation for all plans under that contract. To further explain, an MA organization would be required to pay the same base compensation to all agents and brokers for all HMO plans offered under each contract. If the MA organization also has a PPO plan under the same contract as the HMO plan, the MA organization would be able to pay a different base compensation rate for that PPO than it does for the HMO, provided the MA organization pays all agents and brokers the same base compensation amount for that PPO. To reiterate, the same base compensation must apply to all enrollments for a particular product line offered under a contract. For purposes of this regulatory requirement, CMS is proposing to define a "product line" as one of the following: HMO, PPO, PFFS, RPPO, MSA, and Cost plans. CMS separated the various product lines that an MA organization may offer along these lines because each of these product lines have different rules, such as having to go in-network (HMO), or having the option of going in or out of network with different cost sharing (PPO). CMS is proposing this requirement to ensure an agent or broker does not steer a beneficiary into a particular plan, within a product line, based on compensation.

Since CMS does not require plans to compensate agents and brokers, CMS is considering including in this proposed requirement at §§ 422.2274(a)(1) and 423.2274(a)(1), that, MA organizations and Part D sponsors, may either pay the same base compensation for all PBPs of a similar product line as described previously, or they may pay $0 base compensation for any of those PBPs. CMS notes that the same base compensation or $0 would be the only permitted variations in base compensation across the same product lines. In other words, CMS would permit plans to offer either a specified base compensation amount or $0 for all their PBPs of a similar product line. As an example, if a plan has 3 HMO PBPs, a plan could pay agents and brokers $200 for two of their HMO PBPs and $0 for the final HMO PBP in base compensation.

In drafting this proposal, CMS also considered different types of compensation guardrails. The Agency considered requiring the same base compensation amount for all plans

across all product lines under the same contract. In this scenario MA organizations would only be permitted to pay one base compensation amount for every product line, which includes all plans, for those plans in which the MA organization chooses to pay base compensation. For instance, if one MA organization has two HMOs, one PPO, and one Private Fee-for-Service plan, the MA organization would have to pay the same base compensation for all four plans, if base compensation is paid at all.

CMS also considered requiring MA organizations and Part D sponsors to pay the same base compensation across plans operating within the same geographic service area or counties. For example, an MA organization or Part D sponsor may offer three plans, regardless of product line, that operate in the same four counties (Counties A, B, C, and D). Under this approach, the MA organization or Part D sponsor could establish different base compensation amounts by geographic area. It could pay one base compensation amount in County A, a different amount in County B, and another amount in Counties C and D. Within each designated geographic area, the MA organization or Part D sponsor would be required to pay the same base compensation amount for all three plans – regardless of product line - operating in the same county. Accordingly, all three plans would be required to have the same base compensation amount in County A; all three plans would be required to have the same, base compensation amount in County B; and all three plans would be required to have the same, base compensation amount in Counties C and D. The base compensation rates in each of those counties could differ.

Finally, CMS considered whether these six plan types (HMO, PPO, PFFS, RPPO, MSA, and Cost plans) are the appropriate plan types, or if other delineations are more appropriate, such as designating SNPs as a different type of plan and even further designating each SNP (D-SNP, I-SNP, and C-SNP) as different plan types. CMS is soliciting comments and suggestions as to whether these proposed guardrails are necessary, if the proposed guardrails are the most appropriate, or whether one of the alternatives to the proposed guardrails will best ensure that the

use of compensation creates incentives for enrolling a beneficiary into a plan that best meets their health care needs or whether different guardrails would better serve the beneficiary.

To conform with the proposed changes, CMS is proposing to redesignate, without modifications, §§ 422.2274(d)(4) and (5) and 423.2274(d)(4) and (5) to §§ 422.2274(a)(7) and (8) and 423.2274(a)(7) and (8).

The current regulations at §§ 422.2274(c)(5) and 423.2274(c)(5) contain compensation reporting requirements, which CMS has proposed earlier to be moved and modified to new §§ 422.2271(b)(3) and 423.2271(b)(3). This existing requirement also prohibits MA organizations and Part D sponsors from changing their compensation rates and ranges following the last Friday in July. Although the current requirement at §§ 422.2274(c)(5) and 423.2274(c)(5), does not permit changes to be made after the July deadline, this prohibition has not resulted in a strict prohibition of changes. As described previously, many MA organizations and Part D sponsors have traditionally submitted an intended compensation range of $0 for the minimum and FMV for the maximum, meaning that they could change their compensation throughout the year, provided they pay a compensation rate between the minimum and maximum range provided. With CMS proposing to collect the actual base compensation amounts, that plans will pay to independent agents and brokers, and supplemental compensation, CMS wants to ensure MA organizations and Part D sponsors retain the flexibility to make midyear changes to compensation amounts allowed within the current regulatory requirements. Therefore, CMS is proposing to redesignate and modify this section of existing requirements at §§ 422.2274(c)(5) and 423.2274(c)(5) to §§ 422.2274(a)(5) and 423.2274(a)(5), to permit MA organizations and Part D sponsors to change their compensation rates.

CMS proposed, in §§ 422.2274(a)(1) and 423.2274(a)(1), that MA organizations and Part D sponsors pay the same base compensation based on product line. If finalized as proposed, an MA organization or Part D sponsor who modifies their base compensation amount during the year, must apply that change to all PBPs under the same product line under a contract. As an

example, if an MA organization has three different HMO plans under a contract, the MA organization must adopt the updated compensation level for all three HMOs. Since Part D sponsors only have one product type, the same changes must be made to all plans under that contract. As previously discussed, CMS is considering whether MA organizations and Part D sponsors should be permitted to make an individual change in compensation for a plan within a product line, if that change is to $0 compensation. For example, if an MA organization has three HMO plans under the same contract, for which the compensation rate for all three HMO plans is $350 for an initial enrollment, CMS is considering permitting the MA organization to change the compensation rate to $0 only for one of the HMO plans, without being required to change the compensation rate for either of the other two HMO plans under that same contract. CMS is soliciting comments on the proposal and this alternative.

CMS is also proposing, at §§ 422.2274(a)(5) and 423.2274(a)(5), to require that MA organizations or Part D sponsors who plan to change their base and/or supplemental compensation during the year, must provide advanced notice of these changes to CMS, and that those changes must be made in the form and manner prescribed by CMS. The Health Plan Management System (HPMS) is the current system used to collect plan submitted compensation data. Any changes in compensation would be effective 30 days after the change is made. CMS solicits comments on the proposed 30-day timeframe and whether CMS should consider a shorter timeframe, such as 15 days, or a longer timeframe, such as 45 days, or should not allow base and/or supplemental compensation to be changed once submitted. Importantly, CMS strongly encourage plans to communicate any compensation changes with their agents, brokers and TPMOs as early as practicable.

CMS is also proposing minor changes to the existing requirements at §§ 422.2274(d)(4) and (5) and 423.2274(d)(4) and (5) which address other compensation and compensation recovery requirements. CMS is proposing to remove §§ 422.2274(d)(5)(iv)(B)(*1*) and (*2*) and 423.2274(d)(5)(iv)(B)(*1*) and (*2*), as they are addressed in existing regulation text in

§§ 422.2274(d)(5) and 423.2274(d)(5). Regulations at §§ 422.2274(d)(5) and 423.2274(d)(5) currently state that plans must recover a pro-rated amount of compensation, equal to the number of months a beneficiary is not enrolled for both initial and renewal enrollments. Sections 422.2274(d)(5)(iv)(B)(*1*) and 423.2274(d)(5)(iv)(B)(*1*) effectively re-states this by requiring that the MA organization or Part D sponsor must recover the number of months a member is not enrolled if the enrollment was an initial enrollment and the full compensation had already been paid. Sections 422.2274(d)(5)(iv)(B)(*2*) and 423.2274(d)(5)(iv)(B)(*2*) goes on to provide an example of the scenario, described at §§ 422.2274(d)(5)(iv)(B)(*1*) and 423.2274(d)(5)(iv)(B)(*1*). Given that the requirements at §§ 422.2274(d)(5) and 4232.2274(d)(5) clearly state that plans must recover a pro-rated amount for both initial and renewal enrollments, CMS does not believe §§ 422.2274(d)(5)(iv)(B)(*1*) and (*2*) and 423.2274(d)(5)(iv)(B)(*1*) and (*2*) are necessary.

CMS is proposing to redesignate all other regulatory changes in §§ 422.2274(d)(4) and (5) and 423.2274(d)(4) and (5) to §§ 422.2274(a)(7) and (8) and 423.2274(a)(7) and (8). CMS believes these requirements are necessary to ensure agents can be appropriately compensated depending on what types of plan(s) beneficiaries enroll in. CMS believes charge-backs are also necessary to ensure an agent is not paid for the months a beneficiary is no longer enrolled or when a beneficiary disenrolls within the first three months of an enrollment (rapid disenrollment), which can signify that the agent did not enroll the beneficiary in the plan that best met their health care needs.

CMS is also proposing to modify and redesignate §§ 422.2274(e)(1) and 423.2274(e)(1) as §§ 422.2274(c) and 423.2274(c). CMS is also proposing to remove §§ 422.2274(e)(2) and 423.2274(e)(2), based on the court's ruling that administrative fees may not be included in compensation. In the April 2024 final rule, CMS eliminated separate payments for administrative services by including those payments into the calculation of enrollment-based compensation. However, the court ruling determined that administrative payments were not part of compensation and could not be considered compensation. Taking the court's ruling into

consideration, CMS is proposing to revert back to the regulatory language in place prior to the April 2024 final rule, with slight modifications to streamline the regulatory language. CMS is proposing that administrative payments may be based on enrollments provided the payments are at or below the value of those services in the marketplace. CMS is proposing to keep the previous examples including, but not limited to, training, testing, customer service, and health risk assessments.

e. Base Compensation Outlier Review Requirements

CMS is proposing new §§ 422.2274(b) and 423.2274(b), which states that CMS reviews all base compensation submissions to identify outliers as defined at §§ 422.2260 and 423.2260. CMS is proposing to conduct an outlier analysis to ensure the base compensation amounts are within FMV, as described earlier in this proposal. CMS proposes to deny base compensation amounts that are determined to be base compensation outliers, as defined in §§ 422.2260 and 423.2260. Similar to concerns expressed in the past when the compensation requirements were first developed[123], CMS is concerned that certain MA organizations or Part D sponsors paying significantly more than other MA organizations or Part D sponsors could have an undue influence on an agent or broker. This guardrail will ensure agents and brokers are not enrolling a beneficiary in a plan based on an unusually high base compensation.

As previously discussed, CMS is proposing to determine base compensation outlier amounts annually, following the proposed compensation data submission by the last Friday of July. Following submission CMS proposes to identify any base compensation outliers for MA organizations and Part D sponsors separately. That is, the MA organization outlier review would include MA only plans and MA plans that include Medicare prescription drug coverage, and stand-alone Part D plans will be a part of the separate Part D sponsor outlier review. CMS is proposing to notify MA organization and Part D sponsors of their base compensation outlier status prior to the start of marketing, October 1 of each year , with the aim of providing sufficient

[123] 73 FR 54237

time for them to modify base compensation as needed to bring the base compensation outlier amounts within the acceptable range. MA organizations and Part D sponsors who fail to modify base compensation below the CMS determined outlier amount would be prohibited from paying base compensation until the submitted amount is below the CMS threshold. This prohibition would only apply to the product line's submitted base compensation rates that are above the FMV, and would not apply to other product lines that were not considered base compensation outliers.

Base compensation outlier amounts would not be recalculated if, at other times of the year, MA organizations or Part D sponsors change their base compensation. Any revised base compensation would be reviewed against CMS' initial base compensation outlier analysis for that plan year to ensure that it is not an outlier. If the updated base compensation amount is identified as an outlier, CMS would deny the base compensation, requiring a resubmission by the MA organization or Part D sponsor.

CMS does not propose to permit MA organizations or Part D sponsors to request a re-review or provide a reconsideration process. Since the proposal is based on a review of all base compensation amounts submitted by all MA organizations and Part D sponsors, as part of the annual submission process described in CMS's proposed regulation text at §§ 422.2271(b)(3) and 423.2271(b)(3), base compensation outliers will be determined using the box plot method described earlier and will result in in the final outlier determinations. Since the data is reported to CMS, the Agency cannot influence what constitutes an outlier. Therefore, no re-review or reconsideration process is necessary given outlier numbers will be determined by the box plot method and not changed or influenced by CMS. CMS notes that if there were an error on CMS's calculation of the outlier, CMS would recalculate the outlier and notify MA organizations and Part D sponsors.

As previously stated, CMS proposes using a box plot method. CMS developed the following example to help explain the methodology. For purposes of the example, consider the following values as having been submitted to CMS as base compensation amounts.

TABLE VI.C-1: EXAMPLE 1 AGENT/BROKER BASE COMPENSATION AMOUNTS

Agent/Broker Base Compensation Amounts
$150
$200
$200
$200
$240
$250
$300
$300
$400
$8,000

Using the example data in Table VI.C-1, CMS would first determine the quartile values. The following values were calculated for quartiles 1 and 3, along with the median. The value for the first quartile (the 25th percentile) is the median for the lower half of the data. The median in Table VI.C-2 represents the 50th percentile and is the median for the full data set. The value for the third quartile (the 75th percentile) is the median of the upper half of the data.

TABLE VI.C-2: QUARTILES IN EXAMPLE 1 DATA

Quartile 1 (25th percentile)	$200
Median (50th percentile	$245
Quartile 3 (75th percentile)	$300

CMS proposes that any data points in the distribution above the third quartile (that is, anything above the 75th percentile) will be considered a base compensation outlier. This will ensure base compensation amounts among organizations are more closely aligned and will help to avoid possible steerage of beneficiaries into particular plans based on base compensation. In the example, because the third quartile value is $300, CMS would consider the following compensation amounts outliers:

TABLE VI.C-3: EXAMPLE 1 BASE COMPENSATION AMOUNTS THAT ARE OUTLIERS

Outlier Agent/Broker Base Compensation Amounts
$400
$8,000

In this example, CMS does not consider the base compensation amounts of $300 as outliers because those are equal to the third quartile value but not greater than it.

CMS recognizes that there are other ways to calculate outliers using a box plot and considered using the upper inner fence of the box plot distribution as the marker for what is considered an outlier.[124] In the example, the upper inner fence and upper outer fence were as follows:

TABLE VI.C-4: UPPER INNER FENCE AND UPPER OUTER FENCE FOR EXAMPLE 1 DATA

Upper Inner Fence	$450
Upper Outer Fence	$600

Using either of these values as the threshold to determine outliers in the example, the only outlier would be the reported compensation value of $8,000. CMS chose not to propose this approach and instead proposed using the third quartile value because CMS believes that capturing anything above the third quartile is necessary to provide sufficient guardrails for the MA and Part D programs. However, CMS welcomes comments on using the upper inner fence or upper outer fence of the box plot distribution as the marker for what CMS would consider an outlier.

For the base compensation outlier review, CMS proposes to conduct two separate outlier analyses based on location. CMS currently has four distinct FMV compensation rates (National, CT/PA/DC, CA/NJ, and PR/VI) to reflect the differences in these geographic areas rates. Under the new proposed base compensation outlier review, CMS proposes to condense these distinct

[124] The inner and outer fences in a box plot are calculated values often used in describing box plots. The inner fence is calculated using the following formula: Q3 + (1.5 x Interquartile Range). The outer fence is calculated using the following formula: Q3 + (3 x Interquartile Range). For additional information about box plots, see https://www.itl.nist.gov/div898/handbook/eda/section3/boxplot.htm.

FMV compensation rates into a review of the current National, CT/PA/DC, and CA/NJ rates, and these base compensation values will make up the "National" outlier review. In addition, CMS is proposing a separate base compensation outlier review for PR/VI. CMS believes the existing base compensation amounts across all services areas, excluding Puerto Rico and the US Virgin Islands, are within an acceptable range, and that combining all the other areas would not significantly skew the data nor substantially affect base compensation in the marketplace. Based on this, CMS is proposing to identify base compensation outliers for the National rates separately from base compensation for the PR/VI rates. CMS welcomes comments on this approach.

In the proposed base compensation outlier analysis, CMS proposes to exclude all $0 compensation submissions from the distribution of data used to calculate outliers. CMS developed an example incorporating $0 compensation submissions for consideration. Table VI.C-5 includes the same example records from Example 1, but also includes 4 $0 compensation submissions.

TABLE VI.C-5: EXAMPLE 2 AGENT/BROKER BASE COMPENSATION AMOUNTS

Agent/Broker Base Compensation Amounts
$0
$0
$0
$0
$150
$200
$200
$200
$240
$250
$300
$300
$400
$8,000

This would change the quartile values as follows:

TABLE VI.C-6: QUARTILES IN EXAMPLE 2 DATA

Quartile 1 (25th percentile)	$37.50

Median (50th percentile	$200
Quartile 3 (75th percentile)	$287.50

With the change of the third quartile to $287.50, CMS would consider the following compensation amounts represented in Table VI.C-7 as outliers.

TABLE VI.C-7: EXAMPLE 2 BASE COMPENSATION AMOUNTS THAT ARE OUTLIERS

Outlier Agent/Broker Base Compensation Amounts
$300
$300
$400
$8,000

As illustrated in the example, including $0 compensation amounts in the outlier review affected the outlier analysis, resulting in CMS identifying more outlier compensation amounts than in its proposed methodology. With the increase in MA organizations and Part D sponsors electing to pay $0 compensation, CMS believes that removing the $0 compensation from the outlier calculation is reasonable. However, CMS solicits comments on whether $0 should be included in the proposed outlier analysis, or whether CMS should consider other values to exclude from its outlier analysis.

As an alternative to box plots, CMS also considered the use of standard deviations to determine base compensation outliers. In using a standard deviation method, CMS considered both using the mean and the median, depending on whether the base compensation rates are normal or skewed data. Using the mean is highly sensitive to extreme outliers, potentially increasing both the calculated mean and the standard deviation, whereas using the median is much less affected by extreme outliers. CMS contemplated defining outliers as observations more than two standard deviations from the mean. CMS also considered not looking at outliers at all. As such, CMS is soliciting comments on whether the proposed method of defining compensation base outliers is appropriate, or whether another method, such as using a standard deviation method (and how many standard deviations from the mean) would be better for

defining an outlier, or whether there are other suggested methods to determine compensation outliers.

f. Supplemental Compensation

Section 1851(j)(2)(D) of the Act requires the Secretary to establish guidelines to ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs. As a component of agent and broker compensation, supplemental compensation may affect these incentives and, therefore, may affect the plans that agents and brokers market or recommend to beneficiaries. CMS notes that compensation being proposed under supplemental compensation, such as bonuses, gifts, etc., are considered part of the current compensation definition and are historically subject to CMS' FMV. This proposal separates base compensation and supplemental compensation into two categories to account for the different types of compensation paid to agents and brokers. CMS' proposal eliminates the previous FMV cap on the rate paid for an enrollment and instead identifies outliers based on determining the FMV for base compensation, as submitted by MA organizations and Part D sponsors. Since base compensation is defined as a monetary amount, a base compensation outlier review is substantially easier than an outlier review for supplemental compensation, which can be monetary or non-monetary. CMS recognizes that significant differences in supplemental compensation among plans could create financial incentives that affect an agent's or broker's recommendations. However, at this time, CMS does not believe the Agency has sufficient information to propose an oversight mechanism for supplemental compensation akin to the outlier review process proposed for base compensation.

CMS has not historically received information indicating how MA organizations and Part D sponsors design and provide for bonuses, gifts, etc. Given CMS' current lack of data regarding these arrangements, regulating supplemental compensation at this time is challenging. CMS's understanding is that MA organizations and Part D sponsors structure supplemental

compensation programs in substantially different ways often tied to performance metrics, including financial bonuses based on factors such as enrollee retention, enrollee satisfaction, quality measures, or other performance metrics. In addition, some MA organizations and Part D sponsors have offered, or may be interested in offering, non-monetary supplemental compensation, such as gifts, trips, awards, or other benefits. CMS's understanding is that these arrangements differ in their structure, frequency, eligibility requirements, valuation, and the metrics used to determine whether an agent or broker receives supplemental compensation that is fair market value. Moreover, an MA organization's or Part D sponsor's compensation arrangements must not violate the Federal anti-kickback statute and must comply with all other applicable laws and regulations.

For these reasons, CMS is not proposing to establish an outlier threshold or validation process for supplemental compensation at this time. Instead, CMS believes it is appropriate to first pursue the proposed supplemental compensation reporting requirements discussed earlier and as proposed in §§ 422.2271(b)(3)(iii) and 423.2271(b)(3)(iii). If finalized, CMS would implement those reporting requirements and evaluate the information collected under those requirements. The initial year of reported supplemental compensation would be contract year 2028, allowing CMS to better understand the types of supplemental compensation agents and brokers receive, the frequency and monetary value of such compensation, the metrics or conditions used to determine supplemental compensation, and variation in compensation arrangements across MA organizations and Part D sponsors.

After gaining experience with the reporting requirements and reviewing the data collected, CMS could evaluate whether supplemental compensation arrangements raise concerns, warranting additional oversight and, if so, whether an outlier analysis or another approach would be appropriate. Any such analysis would need to account for the substantial variation in supplemental compensation arrangements and ensure that comparisons are sufficiently meaningful. CMS would also need to consider whether MA organizations and Part D sponsors

should be evaluated separately, whether comparisons should occur at the organization, plan, agent or broker, geographic, or national level, and how non-monetary compensation and compensation tied to different performance metrics should be valued and compared.

While CMS is not proposing a supplemental compensation outlier methodology in this rule, the Agency recognizes the supplemental compensation may influence the plan or plans an agent or broker recommends to a beneficiary. To protect beneficiaries, CMS believes additional guardrails need to be put in place for supplemental compensation. The Agency considered different alternatives as described later in this proposal. CMS is soliciting comments on the potential supplemental compensation guardrail approaches identified earlier. CMS is providing these examples to illustrate potential future approaches and solicit comment; they do not represent an exhaustive list, nor do they represent proposed outlier thresholds or methodologies. The Agency is also interested in other approaches to ensure supplemental compensation results in an agent or broker recommending the plan that best meets the health care needs of a beneficiary.

One possible approach could be to examine the highest amount of supplemental compensation that an agent or broker could receive under an organization's or sponsor's compensation arrangement. Another possible approach could be to collect supplemental compensation using monetary or value ranges, or "buckets." Such an approach could provide more information regarding the distribution of supplemental compensation while potentially reducing reporting burden compared with reporting each individual payment. However, the usefulness of this approach would depend on how the ranges are established and whether compensation arrangements can be meaningfully compared within and across those ranges.

CMS could also examine differences in supplemental compensation among plans offered by the same MA organization or Part D sponsor. Such an analysis could help identify circumstances in which substantially greater supplemental compensation is associated with enrollment in a particular plan. Alternatively, CMS could consider comparisons across

organizations or sponsors on a broader geographic or national basis. Each approach presents challenges because differences in compensation may reflect differences in plan characteristics, markets, performance metrics, or compensation structures rather than incentives to steer beneficiaries toward particular plans.

Another approach could focus on supplemental compensation received by individual agents or brokers relative to their peers. Such an approach could potentially identify unusually high payments, but determining an appropriate peer group would be particularly important. Differences in enrollment volume, geographic market, experience, performance, retention, or other factors could result in legitimate differences in supplemental compensation. CMS could also consider whether information regarding actual supplemental compensation payments should be evaluated together with information regarding enrollments facilitated by agents and brokers. This information could help CMS better understand the relationship, if any, between supplemental compensation and enrollment activity. However, such an approach would require additional data collection and could raise questions regarding the appropriate level of reporting and analysis. A related approach could examine aggregate supplemental compensation and enrollment. CMS could, for example, collect the total supplemental compensation paid by an MA organization or Part D sponsor and the total number of enrollments facilitated by agents and brokers during the applicable period. CMS could then calculate supplemental compensation on a per-enrollment basis and evaluate variation across organizations or sponsors. Although this approach could reduce the need for agent-level reporting, aggregate measures may obscure substantial variation among individual compensation arrangements and may not account for supplemental compensation tied to outcomes other than enrollment.

Similarly, CMS is interested in whether organizations, sponsors, or plans that do not offer supplemental compensation should be included in any future analysis. Including zero supplemental compensation amounts could substantially affect averages, distributions, or statistical thresholds, particularly where supplemental compensation is not widely used.

Reporting supplemental compensation, as a newly proposed concept, if finalized, will provide CMS information on how many MA organizations or Part D sponsors elect to use supplemental compensation as a part of the total agent and broker compensation package.

As this discussion illustrates, designing a meaningful outlier methodology requires carefully balancing the need to identify potentially concerning supplemental compensation arrangements against the reality that differences in supplemental compensation often reflect legitimate variation in plan characteristics, market conditions, and agent or broker circumstances. CMS believes that collecting data under the reporting requirements proposed in this rule, if finalized, would be an important first step, and we look forward to stakeholder input that will help inform whether and how a future outlier methodology could be developed in a way that is both effective and appropriately tailored to the diversity of supplemental compensation arrangements in the marketplace.

CMS solicits comments on all parts of supplemental compensation outliers. In particular, CMS seeks comments on whether supplemental compensation arrangements could create incentives that warrant additional CMS oversight; what information CMS would need to determine whether such concerns exist; whether the reporting requirements described in this rule would provide sufficient information for that purpose; and what additional data, if any, would be necessary. CMS also seeks comments on whether any of the illustrative approaches described previously could provide a meaningful method for identifying potentially concerning supplemental compensation arrangements, what limitations or unintended consequences those approaches might present, and whether commenters recommend alternative approaches.

CMS further solicit comments on the appropriate unit of comparison for any future analysis, including whether comparisons should be made at the MA organization or Part D sponsor, plan, agent or broker, geographic, or national level; how CMS could account for differences in the structure and purpose of supplemental compensation arrangements; how non-monetary compensation should be valued; whether organizations or plans that do not offer

supplemental compensation should be included in an analysis; and whether actual compensation and enrollment data would provide useful information sufficient to justify the additional reporting burden. CMS will consider stakeholder feedback in determining whether additional rulemaking or other action concerning supplemental compensation is warranted.

g. Referral Fee Requirements

CMS is proposing to remove limitations on referral fees, currently at §§ 422.2274(f) and 423.2274(f). Referral fee limitations were originally established in October 2011. At that time, CMS was made aware of excessive referral fees, upwards of what the maximum FMV ($402) for compensation was at that time. Moreover, with a cap placed on compensation, there was a concern that referral fees were being used as a means of circumventing the existing compensation requirements. CMS implemented a cap on referral fees to address these concerns and to limit the incentives of agents to enroll beneficiaries into particular plans, without regard to whether the plan met the beneficiary's health care needs.[125] Similar to the changes being proposed in this proposed rule regarding limitations on compensation, CMS believes that the marketplace should determine the value of a referral. MA organizations and Part D sponsors are in the best position to determine to whom referrals should be paid and the amount of referral that should be paid. Unlike the compensation reporting requirements being proposed at this time, CMS is not proposing to collect referral fee data, nor will CMS be establishing regulations to identify referral fee outliers. However, CMS will still review complaints and take appropriate action if violations occur such as agents or brokers steering or cherry-picking beneficiaries based on referral fees. CMS reiterates that if this proposed change is adopted, MA organizations and Part D sponsors would still be required to remain in compliance with all fraud and abuse laws, including the Federal anti-kickback statute.

Finally, as an alternative to finalizing the changes proposed in this section, CMS is considering amending §§ 422.2274 and 423.2274 to remove the vacated provisions and restore

[125] HPMS Memo, October 19, 2011, "Excessive Referral Fees for Enrollments".

the corresponding regulatory text in effect prior to the April 2024 final rule. This alternative would align the CFR with the agent and broker compensation and oversight requirements that CMS is currently applying. CMS solicits comments on this alternative as well as all the proposals discussed in this section.

D. Removing the Requirement for a TPMO Disclaimer (§§ 422.2267 and 423.2267)

As a part of the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency final rule, which appeared in the Federal Register on May 9, 2022 (hereafter referred to as the May 2022 final rule) (87 FR 27704), and as a part of a broader effort to address concerns with TPMOs, CMS finalized regulations at §§ 422.2267(e)(41) and 423.2267(e)(41) to improve regulatory oversight of Third-Party Marketing Organizations (TPMOs). One provision required Medicare Advantage (MA) organizations and Part D sponsors to ensure that TPMOs with which MA organizations and Part D sponsors directly or indirectly do business verbally convey a standardized disclaimer during sales calls with beneficiaries. The disclaimer, as finalized, consisted of the following statement: "We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area. Please contact Medicare.gov or 1-800-MEDICARE to get information on all of your options."

The following year, CMS issued the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program; and Programs of All-Inclusive Care for the Elderly final rule, hereinafter referred to as the April 2023 final rule (88 FR 22120). In this final rule, CMS amended §§ 422.2267(e)(41) and 423.2267(e)(41), revising the existing disclaimer to require TPMOs to notify the beneficiary of the number of organizations and the number of plans the TPMO offers in the beneficiary's service area. This disclaimer is only applicable for TPMOs that sell on behalf of more than one MA organization or Part D sponsor.

In the April 2023 final rule, CMS also added State Health Insurance Assistance Programs (SHIPs) as a source of information for beneficiaries in the disclaimer and required TPMOs to convey the applicable disclaimer within the first minute of a sales call, among other

requirements, for the TPMO to communicate the disclaimer through other electronic means or materials. Specifically, any TPMO, as defined under §§ 422.2260 and 423.2260, that sells plans on behalf of more than one MA organization or Part D sponsor, must electronically convey the TPMO disclaimer when communicating with a beneficiary through email, online chat, or other electronic means of communication, prominently display the disclaimer on TPMO websites, and include the disclaimer in any marketing materials, including print materials and television advertisements, developed, used, or distributed by the TPMO.

Most recently, as part of the Medicare Program; Contract Year 2027 and Certain Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program final rule which appeared in the Federal Register on April 6, 2026, (hereafter referred to as the April 2026 final rule) (91 FR 17384), CMS finalized regulations at §§ 422.2267(e)(41) and 423.2267(e)(41), updating the TPMO disclaimer requirements by changing the timing of verbal disclosure from the first minute of the call to "prior to the discussion of any benefits," and removing the reference to SHIPs from the disclaimer. The requirements in §§ 422.2267(e)(41)(i), (iii), (iv), and (v) and 423.2267(e)(41)(i), (iii), (iv), and (v) did not change. In the April 2026 final rule, CMS received numerous comments from stakeholders urging CMS to completely rescind the TPMO disclaimer requirement. In response, CMS noted that eliminating the TPMO disclaimer was not proposed and thus, out of scope for removal in the April 2026 final rule. However, CMS committed to taking the commenters' input under advisement.

In the April 2026 final rule, CMS also discussed the findings noted in the April 2023 final rule about the review of sales and enrollment calls. As noted in that April 2023 final rule, the review found that only one plan option from one MA organization was discussed in over 80 percent of the calls. CMS used the call monitoring findings to justify the changes in the April 2023 final rule, specifically creating a new disclaimer for TPMOs that contracted with every MA

organization or Part D sponsor in a service area. CMS continued to believe that these findings should be considered when refining regulations, including the April 2026 final rule.

CMS created the TPMO disclaimer to address a concern that TPMOs were not providing beneficiaries with information about all their health care plan options, which is a practice viewed as potentially misleading. However, industry stakeholders have indicated in subsequent meetings with CMS that it is common industry practice for agents and brokers to evaluate plan offerings based on a beneficiary's unique needs and present the plan or plans they believe will best meet the beneficiary's health care needs. CMS previously viewed the absence of information about all plan options available in the beneficiary's service area as evidence that beneficiaries were being denied information necessary to make an informed choice, thus necessitating the disclosure information in the TPMO disclaimer. However, CMS now recognizes that the complaints observed in the aforementioned sales calls may not reflect the majority of agent and broker interactions with beneficiaries. CMS also recognizes that limiting the number of plans presented to a beneficiary may reduce beneficiary confusion by appropriately excluding plans that are not for a beneficiary suited (for example, a chronic care special needs plan for a beneficiary with no health issues). The current TPMO disclaimer fails to recognize that the agent or broker may be able to provide more efficient and understandable advice to beneficiaries by researching multiple options and presenting the plan or plans that appear best suited to meet the beneficiary's health care needs.

Further, as it applies to the TPMO disclaimer, CMS recognizes that the call monitoring findings discussed in the April 2023 and April 2026 final rules should be interpreted in the context of the data source from which they were derived. The calls reviewed by CMS were drawn from marketing misrepresentation complaints in the Complaints Tracking Module (CTM) and, accordingly, reflected calls often involving non-compliance with CMS's marketing requirements under subpart V of parts 422 and 423. Those complaint-based calls were appropriately considered in identifying problematic marketing practices. However, because the

calls were selected based on complaints, they were not intended to represent a random or comprehensive sample of all beneficiary interactions with agents and brokers or to establish that the TPMO disclaimer would have addressed the underlying causes of the non-compliance.

CMS now believes that, in many instances, the conduct reflected in those calls was more attributable to ill-intentioned or ill-informed agents and brokers failing to accurately disclose the full scope of the products to the beneficiary or steering them toward an option despite reasonable indications that it was not in the beneficiary's best interest —conduct already addressed through existing marketing requirements—rather than the absence of a TPMO disclaimer. As a result, the finding that more than 80 percent of calls discussed only one plan may reflect the characteristics of complaint-based calls rather than the broader population of sales calls conducted by well-intentioned and informed agents and brokers. As previously mentioned, CMS recognizes that it may be common industry practice for agents and brokers to evaluate a beneficiary's unique health care needs and recommend the plan or plans they reasonably believe are the best fit, rather than discussing every available plan. Accordingly, CMS recognizes that the trend identified in the earlier call monitoring findings of agents and brokers discussing only one recommended plan, standing alone, may not have been indicative of inappropriate marketing or beneficiary harm, and that is therefore unclear whether requiring the TPMO disclaimer would have remedied the concerns reflected in the complaint-based calls.

CMS's conclusion is further supported by a more recent review of approximately 25 calls associated with marketing misrepresentation complaints submitted to 1-800-MEDICARE between January 2026 and March 2026. Although CMS acknowledges the limited sample size, the review identified recurring concerns involving beneficiaries' inability to access preferred providers because those providers were outside the plan's network, failures to clearly explain that a beneficiary's existing coverage would end, and agents and brokers not providing complete information regarding plan benefits and cost sharing. During these calls, however, beneficiaries did not inquire about other available plans, even when agents provided the TPMO disclaimer

informing beneficiaries that additional options were available, as required. These findings suggest that the beneficiary complaints were driven by incomplete or misleading information regarding the recommended plan, rather than by a lack of awareness that other plans existed. Accordingly, where an ill-intentioned or ill-informed agent or broker limits the information provided to a beneficiary or otherwise fails to comply with CMS's marketing requirements, CMS now questions whether requiring the TPMO disclaimer meaningfully changes the outcome of the interaction. Instead, the more effective means of addressing these concerns may be through enforcement of existing marketing requirements that prohibit misleading or incomplete communication and require appropriate oversight of agents and brokers.

CMS also considered the practical burdens associated with the TPMO disclaimer in reassessing whether it remains an appropriate regulatory requirement. The disclaimer imposes compliance obligations on TPMOs, MA organizations, and Part D sponsors, including requirements to incorporate prescribed language into verbal and electronic communications, train agents and brokers on its use, monitor compliance, and update marketing materials and systems when the disclaimer is revised. Although each of these obligations may be modest in isolation, together they create ongoing administrative and operational burdens that are warranted only if the disclaimer provides meaningful benefits to beneficiaries.

CMS also believes the disclaimer may unnecessarily interrupt what is intended to be a trust-based discussion between a beneficiary and an agent or broker. Requiring agents and brokers to deliver a standardized disclosure before engaging in a substantive discussion of a beneficiary's health care needs may delay the conversation and divert attention from information that is more relevant to the beneficiary's enrollment decision. As discussed previously, CMS now understands that it is common industry practice for well-intentioned and informed agents and brokers to evaluate a beneficiary's individual circumstances and recommend the plan or plans they reasonably believe best meet the beneficiary's needs. In that context, a disclaimer emphasizing that the agent or broker does not offer every available plan may create unnecessary

confusion without providing information that meaningfully improves the beneficiary's ability to make an informed enrollment decision. Because CMS no longer believes the TPMO disclaimer effectively addresses the conduct underlying beneficiary complaints, CMS believes these burdens outweigh any incremental benefit provided by the disclaimer.

CMS continues to believe that protecting beneficiaries from misleading or confusing marketing practices remains a fundamental objective of the Medicare marketing regulations. However, based on the information discussed previously, CMS no longer believes that the TPMO disclaimer is the appropriate regulatory mechanism to further that objective. Instead, CMS believes that other existing requirements under §§ 422.2262(a)(1)(i), 423.2262(a)(1)(i), 422.2274(c), and 423.2274(c), and proposed requirements under 42 CFR parts 422 and 423 subpart V more effectively target the causes of beneficiary complaints and will allow the agency to continue to pursue entities that continue to mislead beneficiaries by providing inaccurate or incomplete information while avoiding a disclosure requirement that has not demonstrated meaningful benefits for beneficiaries.

For example, §§ 422.2274(c) and 423.2274(c) require MA organizations and Part D sponsors to oversee first tier, downstream, and related entities (FDRs) that represent the MA organization or Part D sponsor to ensure agents and brokers abide by all applicable State and Federal laws, regulations, and requirements. Protections are provided through MA organizations and Part D sponsors monitoring TPMOs to ensure they are abiding by all requirements. CMS notes that in section I.B.11 of this proposed rule CMS is proposing significant changes to §§ 422.2274(c) and 423.2274(c). However, under this proposal the requirement to oversee FDRs would remain, but would be redesignated to new proposed §§ 422.2271(a)(2) and 423.2271(a)(2).

Likewise, the broad provisions at §§ 422.2262 and 423.2262, already prohibit TPMOs from engaging in marketing practices that are misleading, confusing, or provide materially

inaccurate information to beneficiaries. Thus, CMS believes the TPMO disclaimer requirement is a redundant application of the general marketing regulations already in place.

Beyond the broad anti-misleading provisions at §§ 422.2262 and 423.2262, CMS notes that existing regulations establish a comprehensive framework requiring transparency in beneficiary communications. Under §§ 422.2262(a) and 423.2262(a), CMS prohibits plans from engaging in a defined set of actions, which establish clear boundaries for plan conduct. Taken together, these provisions create overlapping layers of protection. A TPMO operating in compliance with these existing requirements would, by definition, already be communicating its limitations to beneficiaries in a truthful and non-deceptive manner. As noted, the disclaimer requirement, as originally conceived, was a reactive measure designed to address a specific gap in beneficiary awareness at a particular point in the program's development. The regulatory landscape has since matured considerably. Moreover, in this rule under "Enhancing Agent and Broker Compensation and Oversight," CMS is proposing extensive changes to the existing agent/broker compensation and oversight structure, as addressed in section VI.C of this proposed rule. An example of these proposed changes includes requiring MA organizations to pay the same compensation to agents and brokers for similar product types offered under a contract, intended to reduce the use of compensation to influence enrollment decisions. In addition, beneficiaries can take advantage of certain important beneficiary protections such as potential SEPs, including retrospective enrollments, when appropriate, if a beneficiary makes an adverse enrollment decision based on misrepresentation or otherwise non-compliant sales tactics. CMS believes that the guardrails included in the Enhancing Agent and Broker Compensation and Oversight provision, coupled with existing beneficiary protections, render the TPMO disclaimer unnecessary.

Based on information identified in calls, beneficiary protections already in place, and additional proposed guardrails, CMS believes the disclaimer is no longer necessary. Therefore, for the reasons cited previously, and in keeping with Executive Order 14192, Unleashing

Prosperity Through Deregulation, which appeared in the **Federal Register** on January 31, 2025 (90 FR 9065), We are proposing to rescind the regulatory language found at §§ 422.2267(e)(41) and 423.2267(e)(41).

We invite comments on this proposal.

E. Expanding Electronic Delivery of Required Enrollee Communications (§§ 422.2267 and 423.2267)

On January 19, 2021, CMS issued the Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule (86 FR 5864), referred to hereafter as the January 2021 final rule. In this rule, CMS codified requirements in 42 CFR §§ 422.2267(d)(2)(i) and 423.2267(d)(2)(i) permitting MA organizations and Part D sponsors, without prior authorization from the enrollee, to mail a hard copy notice informing enrollees how to electronically access the Evidence of Coverage (EOC), Provider and Pharmacy Directories, and Formulary. The notice must also explain how enrollees may request hard copies of those materials. Since the January 2021 final rule, electronic delivery of materials has become more common across the health care and insurance sectors. CMS believes many enrollees increasingly expect access to plan materials through websites, portals, and other electronic channels. Based on CMS's experience administering §§ 422.2267(d)(2)(i) and 423.2267(d)(2)(i), CMS has not identified complaints suggesting that enrollees' access to the Evidence of Coverage (EOC), Provider and Pharmacy Directories, or Formulary has been materially impaired by providing these materials electronically, provided that a hard-copy notice is furnished and enrollees retain the right to request paper copies.

CMS is proposing to expand the scope of required materials and content eligible for electronic delivery without prior authorization from the enrollee. Currently, §§ 422.2267(d)(2) and 423.2267(d)(2) permit electronic delivery in two circumstances. First, under §§ 422.2267(d)(2)(i) and 423.2267(d)(2)(i), MA organizations and Part D sponsors may mail new and current enrollees a notice describing how to electronically access the EOC, Provider and Pharmacy Directories, and Formulary without obtaining prior authorization from the enrollee, subject to the notice and hard-copy request requirements in those paragraphs. Second, under §§

422.2267(d)(2)(ii) and 423.2267(d)(2)(ii), MA organizations and Part D sponsors may provide any required material or content electronically with prior authorization from the enrollee, provided the entity satisfies the requirements in those paragraphs.

CMS is proposing to revise §§ 422.2267(d)(2) and 423.2267(d)(2) to permit MA organizations and Part D sponsors to electronically deliver required materials and content described in §§ 422.2267(e) and 423.2267(e), without prior authorization from the enrollee, unless another CMS regulation, CMS-required model or standardized material, or other applicable law specifies a different form or manner of delivery.

CMS is proposing to consolidate the current requirements at §§ 422.2267(d)(2)(i) and (ii) and 423.2267(d)(2)(i) and (ii) into revised §§ 422.2267(d)(2) and 423.2267(d)(2). CMS proposes to maintain a notice requirement for new and current enrollees, unless the enrollee has already opted into receiving electronic communications. CMS also proposes to require MA organizations and Part D sponsors to honor an enrollee's request to receive one or more required materials in hard copy, including a one-time or permanent request, until the enrollee elects electronic delivery again.

Under proposed §§ 422.2267(d)(2)(i) and 423.2267(d)(2)(i), the MA organization or Part D sponsor would be required to mail a notice to all new and current enrollees that includes the information specified in proposed paragraphs (d)(2)(i)(A) through (C), unless the enrollee has already opted into receiving electronic communications and the notice is furnished electronically under proposed paragraph (d)(2)(ii).CMS is also proposing to remove or consolidate requirements in current §§ 422.2267(d)(2)(i) and (ii) and 423.2267(d)(2)(i) and (ii) that would be duplicative under the revised structure. Specifically, CMS proposes to remove the current provisions authorizing one notice for multiple materials or multiple notices, establishing timing rules for notices for prospective-year materials, and allowing notices to be sent throughout the year to new enrollees. CMS believes these provisions would no longer be necessary because the required materials and content listed in §§ 422.2267(e) and 423.2267(e) already include

applicable timing and delivery requirements. CMS is also proposing to remove §§ 422.2267(d)(2)(ii)(A) and 423.2267(d)(2)(ii)(A), which currently require prior consent to receive electronic documents, because this proposed regulation would change the default method of delivery for required materials from hard copy to electronic delivery, subject to the notice and hard-copy request protections described in this section. Current §§ 422.2267(d)(2)(i)(D) and (E), 423.2267(d)(2)(i)(D) and (E), 422.2267(d)(2)(ii)(B) and (C), and 423.2267(d)(2)(ii)(B) and (C) require the notice or electronic-delivery process to include instructions for accessing materials, the date materials will be available if not currently available, and a process for requesting hard copies. CMS proposes to move, consolidate, and modify these requirements in proposed §§ 422.2267(d)(2)(i)(A) through (C) and 423.2267(d)(2)(i)(A) through (C). CMS also proposes to retain the requirement that hard-copy requests may be material specific, one time, or permanent until the enrollee chooses to receive electronic materials again.

CMS recognizes that some enrollees have already opted into receiving materials electronically. CMS proposes new §§ 422.2267(d)(2)(ii) and 423.2267(d)(2)(ii) to permit the notice required by proposed paragraph (d)(2)(i) to be furnished electronically to a new or current enrollee who has opted into electronic communications before delivery of the notice.

CMS is proposing to remove the specific requirements at §§ 422.2267(d)(2)(ii)(D) and 423.2267(d)(2)(ii)(D) that require a process for automatic mailing of hard copies when electronic versions or the chosen media type is undeliverable. In place of that prescriptive requirement, CMS proposes to require MA organizations and Part D sponsors to have a reasonable process to identify undeliverable electronic communications and furnish the applicable required material or notice in hard copy or another enrollee-selected available format when electronic delivery is unsuccessful.

Finally, CMS recognizes that certain State Medicaid agencies require D-SNPs, through State Medicaid agency contracts or other applicable State requirements, to furnish specific required materials or content in a particular form or manner, including by mail or otherwise in

hard copy. CMS does not intend this proposal to supersede those State requirements. Accordingly, CMS is proposing to add §§ 422.2267(d)(2)(iv) and 423.2267(d)(2)(iv) to clarify that nothing in the electronic delivery provisions authorizes a D-SNP to electronically deliver required materials or content when an applicable State Medicaid agency contract requirement or other applicable State requirement specifies a different form or manner of delivery. D-SNPs would remain responsible for complying with all applicable State requirements governing the delivery of required materials and content.

In developing this proposal, CMS also considered whether expanding the existing subset of materials eligible for electronic delivery without requiring prior enrollee authorization would serve as a reasonable alternative to the more comprehensive approach proposed here. CMS is soliciting public comments on whether limiting electronic delivery to a defined subset of required materials is more appropriate than a broader framework and, if so, which specific documents should be included in that subset or excluded from electronic delivery without prior authorization.

F. Treatment of Compound Drug Products (§ 423.120)

Multi-ingredient compounds are products extemporaneously prepared by pharmacies to provide drug therapies that are not commercially available as finished products approved by the Food and Drug Administration (FDA) in the same dose, formulation, and/or combination of ingredients. In the April 15, 2011 final rule titled, "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes" (76 FR 21432) (hereinafter referred to as the Contract Year 2012 final rule), CMS codified requirements at § 423.120(d) related to how Part D plan sponsors must treat multi-ingredient compounds in the Part D program. Those requirements specify at § 423.120(d)(1)(i) and (ii) that only compounds that contain at least one ingredient that independently meets the definition of a Part D drug, and that do not contain any ingredient that is covered under Part B as prescribed and dispensed or administered, may be covered under Part D. Compounds meeting both criteria are referred to as Part D compounds. The Contract Year 2012 final rule also established requirements related to when Part D compounds must be considered formulary drugs for purposes of determining enrollee cost sharing, and when transition rules apply (see § 423.120(d)(1)(iii) and (iv)).

The Contract Year 2012 final rule also codified a requirement at § 423.120(d)(2) that Part D plan sponsors establish consistent rules for beneficiary payment liability for ingredients of a Part D compound that independently meet the definition of a Part D drug, and for non-Part D ingredients. Specifically, for low income subsidy-eligible individuals (LIS), Part D plan sponsors are required to apply the copayment amount described in § 423.782 for a Part D compound based on whether the most expensive ingredient that independently meets the definition of a Part D drug is a generic or brand name drug (see § 423.120(d)(2)(i)). Finally, at § 423.120(d)(2)(ii), CMS specified that Part D plan sponsors must—through their contract with the pharmacy—prohibit pharmacies from balance billing the enrollee for the cost of any non-Part D ingredient of a Part D compound, including drugs described under § 423.104(f)(1)(ii)(A).

CMS's intent in codifying the balance billing prohibition for non-Part D ingredients was to provide transparency to Part D enrollees with respect to out-of-pocket costs associated with covered Part D compounds, and to establish a more straightforward approach for enrollees, Part D sponsors, and pharmacies, without interfering with the ability of pharmacies to negotiate prices that provide adequate reimbursement for compounds. We noted in the Contract Year 2012 final rule our belief that Part D sponsors and pharmacies have negotiated how Part D compounds are priced in general and that such prices adequately account for any non-Part D ingredients, which usually account for a small portion of the overall cost, regardless of how an individual paid claim represents payment for individual ingredients (76 FR 21523).

While we continue to believe this is true with respect to most Part D compounds, we have observed in recent years situations involving covered Part D compounds with substantial non-Part D ingredient costs, including costs that far exceed those of the Part D ingredient(s). In these limited situations, standard practices whereby the plan absorbs the costs for the non-Part D ingredients (without charging the enrollee or reporting the non-Part D costs to CMS) or reimburses the pharmacy for the non-Part D ingredients as part of the dispensing fee, are both inadequate and improper.

Existing Part D compound policies are intended to ensure enrollee access to Part D drugs when there is no commercially available formulation to meet an individual's specific treatment needs, such as an allergy to an inactive ingredient or a need for a different dosage form or custom dosage requirements. The prohibition on balance billing for non-Part D ingredients is not meant to be a vehicle by which Part D enrollees can obtain drugs that are otherwise not payable under Part D, nor is it intended to leave Part D plan sponsors or pharmacies that agree to provide Part D compounds with significant non-Part D expenses for these claims.

While the existing policy prohibiting balance billing for the cost of non-Part D ingredients was intended as an enrollee financial protection, when the financial impact on the

pharmacy is significant, it understandably deters pharmacies from providing compounding services for multi-ingredient compounds that include Part D drugs.

Only costs associated with covered Part D drugs, as defined at § 423.100, can be paid for under the Part D benefit. As such, longstanding CMS policy limits Part D coverage of Part D compounds to only: (1) the ingredient costs associated with the ingredients that independently meet the definition of a Part D drug; and (2) any dispensing fees, as defined at § 423.100, which can include the costs associated with preparing the compound such as labor costs and costs of inactive, non-Part D ingredients necessary to prepare the compound (for example, flavored compounding syrup). Because of the scenarios described earlier and our concerns with how our current policy on balance billing operates in those scenarios, we propose to revise our policy to remove the requirement that Part D plan sponsors' contracts with network pharmacies must prohibit balance billing for the cost of non-Part D ingredients, effective for plan years beginning January 1, 2028. Specifically, we propose to add the phrase, "For plan years beginning before January 1, 2028," at § 423.120(d)(2)(ii) to eliminate the prohibition on balance billing beginning with the 2028 plan year.

Under our proposal, only the requirement to prohibit balance billing would be removed. This proposal would not prevent Part D plan sponsors and pharmacies from continuing to negotiate reimbursement for Part D compounds under their contracts, and Part D sponsors may choose to continue to prohibit balance billing. We are proposing this change to address a specific scenario involving non-Part D ingredients that represent a substantial portion of the costs for a Part D compound. Outside of that scenario, and because the costs associated with preparing the compound are included in our definition of dispensing fees, CMS expects that Part D compounds would generally continue to be available to enrollees without additional out-of-pocket costs if this proposal is finalized.

We propose to make additional technical corrections to improve accuracy and readability of § 423.120(d) by striking the word "both" and adding the word "for" in the introductory text at

paragraph (d)(2) and revising paragraph (d)(2)(i) to refer to "subsidy eligible individuals (as defined at § 423.4)" instead of "low income subsidy-beneficiaries".

We estimate that this proposal, if finalized, would have a negligible overall impact on the government, Part D sponsors, and pharmacies. Since 2011, compounds have accounted for significantly less than one percent of total PDEs and total Part D drug spend.

We seek comment on whether and how the prohibition on balance billing for non-Part D ingredients of Part D compounds has impacted Part D sponsors, pharmacies, and Part D enrollees, our proposed changes, and our estimate on anticipated effects if this proposal is finalized.

VIII. Technical Changes

A. Adding Population Density Combinations to Rural County Designation - Technical Change (§ 422.116)

Section 1852(d)(1)(A) of the Act allows MA organizations to select the providers from which an enrollee may receive covered benefits, provided that the MA organization, in addition to meeting other requirements, makes such benefits available and accessible in the service area with promptness and in a manner that assures continuity in the provision of benefits. Section 1852(d)(1)(D) of the Act requires MA organizations to provide access to appropriate providers for medically necessary treatment and services. In § 422.116, CMS codified the statutory requirements by requiring organizations to demonstrate that they have an adequate contracted provider network that is sufficient to provide access to covered services in accordance with access standards.

Network adequacy is assessed at the county level, including county-equivalents, across all geographic areas in the United States and its territories. CMS uses the county level for purposes of determining the number and type of providers and facilities, based on time and distance, that an MA organization must contract with to ensure there is adequate access to Part A and B services for beneficiaries. The five county type designations: Large Metro, Metro, Micro, Rural, or CEAC (Counties with Extreme Access Considerations) are codified at § 422.116(c).

County type designations are updated annually using Census population size data and population density estimates using the criteria specified in § 422.116(c). Before CMS codified the county-type designation methodology at § 422.116(c)(4), the CMS Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance[126] identified counties with population size of less than 10,000 persons and a population density of 10 through 4,999.9 persons per square mile as Rural. The initial codified regulatory text in the Medicare Program; Contract Year 2021

[126] https://www.cms.gov/files/document/medicare-advantage-and-section-1876-cost-plan-network-adequacy-guidancepdf

Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program which appeared in the **Federal Register** on June 2, 2020 (85 FR 33796), hereinafter referred to as the June 2020 final rule, mistakenly identified counties with a population size of less than 10,000 persons and a *population density of 50 through 999.9 persons per square mile* as Rural; inconsistent with the density range reflected in the CMS's Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance. Specifically, the codified text inadvertently omitted the counties with a population size of less than 10,000 persons and population densities of 10 through 4,999.9 persons per square mile. In practice, CMS has continued to classify counties falling within these population size and density combinations as rural. This proposal is a technical correction to align § 422.116(c)(4)(ii) with the methodology CMS has historically used to classify these counties and no additional operational impact is added to the network adequacy standards.

CMS proposes to modify the definition of "rural" at § 422.116(c)(4)(ii), to include the inadvertently omitted population size and density criteria currently classified as a rural county and revise the population size of less than 10,000 persons to include a population density between 10 persons per square mile and less than or equal to 4999.9 persons per square mile.

B. Updating I-SNP Crosswalk Terms – Technical Change (§ 422.530)

This proposal would amend 42 CFR 422.530(b)(2)(ii) by replacing the current Institutional Special Needs Pan (I-SNP) subtype terminology with updated terminology that reflects the definitions finalized in the April 2024 final rule (89 FR 30448). The proposed amendments would replace references to "Institutional SNP," "Institutional Equivalent SNP," and "Institutional/Institutional Equivalent SNP" with the terms defined at § 422.2: Facility-based Institutional Special Needs Plan (FI-SNP), Hybrid Institutional Special Needs Plan (HI-SNP), and Institutional-Equivalent Special Needs Plan (IE-SNP).

SNPs are MA coordinated care plans authorized under section 1859(f) of the Act and designed to provide targeted care to, and limit enrollment to, specific groups of special needs individuals as defined at § 422.2. I-SNPs are a category of SNPs that restrict enrollment to individuals who reside in an institution or who require an equivalent level of care.

As part of the April 2024 final rule, CMS finalized four definitions at § 422.2 to clarify the specific standards applicable to I-SNPs.

These definitions clarify the standards applicable to I-SNPs and distinguish the three I-SNP subtypes from each other and from other MA plans and other MA SNPs. The I-SNP subtype definitions rely on the definitions of "institutionalized" and "institutionalized-equivalent" in § 422.2, including the list of eligible facilities in the definition of "institutionalized."

Under § 422.530(a)(1), a crosswalk is the movement of enrollees from one plan (or plan benefit package (PBP)) to another plan (or PBP) under a contract between the MA organization and CMS. MA plans may crosswalk enrollees only in the circumstances specified in § 422.530(b), or through an approved exception under § 422.530(c).

Currently, § 422.530(b)(2)(ii) sets forth the following permissible I-SNP crosswalk scenarios using the prior subtype terminology:

● Renewing Institutional SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

● Renewing Institutional Equivalent SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

● Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional SNP.

● Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional Equivalent SNP.

● Non-renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to another Institutional/Institutional Equivalent SNP.

These provisions use terminology that predates the April 2024 final rule and must be updated to reflect the new Institutional Special Needs Plan (I-SNP) subtype definitions now codified at § 422.2.

CMS is proposing to amend § 422.530(b)(2)(ii) by replacing the current I-SNP subtype terminology with updated terminology consistent with the definitions finalized in the April 2024 final rule. The amended text of § 422.530(b)(2)(ii) would be revised to read as follows:

● The following crosswalk scenarios are permissible for I-SNPs:

++ Renewing Facility-based Institutional special needs plan (FI-SNP) that transitions enrollees to a Hybrid Institutional special needs plan (HI-SNP).

++ Renewing Institutional-equivalent special needs plan (IE-SNP) that transitions enrollees to a HI-SNP.

++ Renewing HI-SNP that transitions eligible enrollees to a FI-SNP.

++ Renewing HI-SNP that transitions eligible enrollees to an IE-SNP.

++ Non-renewing HI-SNP that transitions eligible enrollees to another HI-SNP.

The proposed amendments are necessary to ensure regulatory consistency between the crosswalk provisions at § 422.530(b)(2)(ii) and the updated I-SNP subtype definitions finalized

in the April 2024 final rule. Without these conforming amendments, the crosswalk provisions would continue to reference outdated terminology that does not correspond to the defined I-SNP subtypes, creating potential confusion for MA organizations and beneficiaries.

The proposed amendments do not alter the substantive crosswalk policies currently in effect. Rather, they would update the terminology used to describe the permissible crosswalk scenarios to align with the new I-SNP subtype definitions. The permissible crosswalk scenarios under this proposal correspond to the same types of transitions currently permitted under § 422.530(b)(2)(ii). CMS does not anticipate burden impacts for this technical update and is not scoring this update in the COI section. In addition, this update is not expected to have any economic impact on the Medicare Trust Fund.

C. Effect of a Plan's Dismissal of a Reconsideration Request - Technical Correction (§ 422.582)

We are proposing a technical correction to § 422.582(i) related to the effect of a MA organization's dismissal of a standard reconsideration request. We propose to change the incorrect cross-reference of § 422.590(h) to the correct cross-reference of § 422.590(i), which is the provision related to requests for review of a dismissal by the independent entity. If this technical change is finalized, § 422.582(i) will state that the MA organization's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(i) or the decision is vacated under paragraph (h) of § 422.582.

D. Two-Year Post Acquisition Transition to Comply with Substantial Differences and Three Plan Limit Requirements – Technical Change (§ 423.265)

Generally, § 423.265(b)(2)(i) requires that Part D bids submitted by Part D sponsors reflect "differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions." Similarly, § 423.272(b)(3)(i) states that CMS will approve a bid "only if it finds that the benefit package or plan costs represented by that bid are substantially different" as required under § 423.265(b)(2). The regulation at § 423.272(b)(3)(ii) allows a PDP sponsor 2 years to meet the substantial differences requirement at §§ 423.265(b)(2) and 423.272(b)(3)(i) when the PDP sponsor or its parent organization recently purchased (or otherwise acquired or merged with) another PDP sponsor. Additionally, § 423.265(b)(3) requires that potential Part D sponsors' bid submissions "include no more than three stand-alone prescription drug plan offerings in a service area and must include only one basic prescription drug plan offering." CMS is proposing a technical correction to clarify that the 2-year post-acquisition transition period for substantial differences between bids at § 423.272(b)(3)(ii) applies to the substantial differences requirement and three plan limit at § 423.265(b)(2) and (3).

CMS adopted the 2-year post-acquisition transition period for PDP sponsors to meet the substantial differences requirement at § 423.272(b)(3)(i) when it enacted the substantial differences requirement in the final rule entitled "Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" that appeared in the **Federal Register** on April 15, 2010 (75 FR 19678). In adopting the 2-year transition period, CMS determined that the 2-year transition period provided "ample time for organizations and sponsors to ensure that benefit packages are sufficiently different and to notify enrollees of any changes" (75 FR 19739). CMS' experience in the 16 years since adopting the rule has confirmed that determination to be accurate.

CMS has consistently applied the 2-year transition period to both the substantial differences requirements at §§ 423.265(b)(2) and 423.272(b)(3)(i) and the three plan limit at § 423.265(b)(3). CMS is proposing to codify this longstanding policy by adding new paragraph (b)(6) to § 423.265, explicitly applying the transition period at § 423.272(b)(3)(ii) to the requirements at § 423.265(b)(2) and (3).

As this technical change codifies longstanding policy, CMS anticipates no additional burden from adopting this provision.

E. Technical Corrections to General Payment Provisions and Retroactive Adjustments and Reconciliations (§§ 423.315 and 423.343)

We are proposing an update, along with several technical changes, to part 423, subpart G.

Section 423.315 sets forth the general payment provisions for the Medicare Part D program. Paragraph (d) describes the low-income subsidies, specifically, the premium and cost-sharing subsidies, paid on behalf of certain subsidy-eligible individuals. The provision refers to "additional coverage above the initial coverage limit." Beginning with plan year 2025, the Medicare Part D redesign eliminated the initial coverage limit. *See* section 1860D-2(b)(3)(A) of the Act. Additionally, as it applies to plan years prior to 2025, we do not believe that the reference to the initial coverage limit is necessary. Therefore, we propose to remove the clause "including additional coverage above the initial coverage limit," from the provision to reflect the current structure of the Medicare Part D program.

Section 423.315(d) states that low-income cost-sharing subsidy payments are reconciled to actual allowable reinsurance costs. However, reconciliation of low-income cost-sharing subsidy payments is addressed separately in § 423.343(d) and is based on eligible low-income cost-sharing subsidy costs rather than allowable reinsurance costs. Therefore, we propose to remove the erroneous reference to allowable reinsurance costs and add a reference to total low-income cost-sharing subsidy costs.

The next technical corrections proposed would amend § 423.315(d), previously discussed, and § 423.343(d)(2), which refers to the reconciliation of low-income cost-sharing subsidy payments. Both sections reference § 423.782 in connection with low-income cost-sharing subsidy payments made on behalf of low-income subsidy eligible individuals. While § 423.782 describes beneficiary eligibility for and entitlement to low-income cost-sharing subsidies, it does not establish the methodology under which CMS makes such payments to Part D sponsors. The payment methodology is set forth in § 423.329(d). We therefore believe that § 423.329(d) is the more appropriate reference for purposes of describing CMS payments.

Accordingly, we propose to amend §§ 423.315(d) and 423.343(d)(2) to remove references to § 423.782 and instead refer to § 423.329(d).

Section 423.343 describes the reconciliation of reinsurance payments, low-income cost-sharing payments, and selected drug subsidy payments. Paragraph (c)(2), which pertains to reinsurance; paragraph (d)(2), which pertains to the low-income subsidy; and paragraph (e)(2), which pertains to the selected drug subsidy, are similar. Each paragraph discusses additional payments made to Part D sponsors and the recovery of payments from Part D sponsors as a result of each reconciliation. Notably, each of these paragraphs contains the same technical error.

The provisions state that CMS may make additional payments by adjusting monthly payments throughout the remainder of the payment year following the coverage year. However, the corresponding recovery language authorizes recoveries through adjustments made throughout the remainder of the coverage year. Because reconciliation necessarily occurs after the close of the coverage year, there is no remaining portion of the coverage year during which recoveries could occur. This discrepancy is a drafting error. The recovery portion of the provision was intended to mirror the timing specified for additional payments. Indeed, with respect to § 423.343(c) and (d), the preamble to our final rule, Medicare Program; Medicare Prescription Drug Benefit states, "[w]e would then either make lump-sum payments or adjust monthly payments throughout the remainder of the payment year following the coverage year to pay out or recover this difference." See 70 FR 4194, 4316 (January 28, 2005).

The selected drug subsidy payment provision at § 423.343(e)(2) mirrors the language in § 423.343(c)(2) and (d)(2), and as a result, carried the error forward when the provision was codified in our final rule Medicare Program; Contract Year 2027 and Certain Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program, 91 FR 17384 (April 6, 2026).

Accordingly, we propose to amend § 423.343(c)(2), (d)(2), and (e)(2) by replacing, in each of these paragraphs, the phrase “throughout the remainder of the coverage year” with “throughout the remainder of the payment year following the coverage year”.

VIII. Aligning Data and Value to Nurture Competition and Efficiency in Medicare Advantage (ADVaNCE MA) Model

A. Introduction and Background

1. Introduction and Goals of the ADVaNCE MA Model

Under the authority of section 1115A of the Act, the CMS Innovation Center proposes to implement and test a mandatory, 10-year model: the Aligning Data and Value to Nurture Competition and Efficiency in Medicare Advantage (ADVaNCE MA) model. We are proposing the ADVaNCE MA model would begin January 1, 2029, and end December 31, 2038, with bid submissions for the first year of the model, calendar year (CY) 2029, due in June 2028. In addition, there would be a pre-implementation period beginning on June 8, 2027, the CY 2028 bid deadline, and ending December 31, 2028, during which pre-performance contracting and operational activities required for appropriate implementation would occur.

MA covers more than half of all Medicare beneficiaries. The ADVaNCE MA model is designed to test potential avenues to further incentivize quality improvement among MA organizations, promote local competition, reduce program expenditures, and address concerns for potential fraud, waste, and abuse or avoidable costs to the Medicare program.[127,128,129,130,131] The ADVaNCE MA model would test approaches to addressing some of the structural

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[127] Mark Duggan, Amanda Starc, and Boris Vabson, "Who Benefits When the Government Pays More? Pass-Through in the Medicare Advantage Program," Journal of Public Economics 141 (September 2016): 50–67, https://doi.org/10.1016/j.jpubeco.2016.07.003.

[128] Curto, Liran Einav, Jonathan Levin, and Jay Bhattacharya, "Can Health Insurance Competition Work? Evidence from Medicare Advantage," Journal of Political Economy 129, no. 2 (February 2021): 570–606, https://doi.org/10.1086/711951. This article notes that the "Medicare Advantage program generates substantial surplus to participants (of $217 per enrollee-month), but that approximately two-thirds of this surplus is captured by insurers."

[129] Daria Pelech, "Paying More for Less? Insurer Competition and Health Plan Generosity in the Medicare Advantage Program," Journal of Health Economics 61 (September 2018): 77–92, https://doi.org/10.1016/j.jhealeco.2018.07.002.

[130] U.S. Department of Health and Human Services, Office of Inspector General, Medicare Advantage: Questionable Use of Health Risk Assessments Continues To Drive Up Payments to Plans by Billions, Report No. OEI-03-23-00380 (October 2024), https://oig.hhs.gov/reports/all/2024/medicare-advantage-questionable-use-of-health-risk-assessments-continues-to-drive-up-payments-to-plans-by-billions/.

[131] U.S. Department of Health and Human Services, Office of Inspector General, CMS Potentially Overpaid Medicare Advantage Organizations $462 Million Based on Certain Unsupported Acute Stroke Diagnosis Codes, Report No. A-02-23-01020 (May 28, 2026), https://oig.hhs.gov/reports/all/2026/cms-potentially-overpaid-medicare-advantage-organizations-462-million-based-on-certain-unsupported-acute-stroke-diagnosis-codes/.

mechanisms in question through three core components:

● CMMI Inferred Risk Adjustment Model: Explore, through shadow testing, an innovative risk adjustment methodology that builds upon the current CMS Hierarchical Condition Category (HCC) risk adjustment model by integrating multiple, existing data sources already available to CMS, including Original Medicare (OM) claims data, MA encounter data, enrollment data, and new technologies. The learnings from the shadow test are expected to inform future risk adjustment policy.

● The Diamond Ratings System: A redesigned quality program implemented in Mandatory States (defined below) would replace the current MA and Part D Star Ratings and Quality Bonus Payment (QBP) system with a localized, cohort-based, quality framework that incentivizes continuous improvement; enables beneficiaries to make meaningful, geographically relevant plan comparisons in their local areas; and promotes competition in the Medicare Advantage program;

● Targeted Supplemental Benefits for Low-Income Subsidy (LIS)-Eligible Individuals: New regulatory flexibilities would allow MA organizations to offer certain supplemental benefits, currently mostly available to qualifying chronically ill beneficiaries, to Part D LIS-eligible individuals. These benefits have a focus on high-value preventive care and serious illness support through nutrition, caregiver supports, and transportation for non-medical needs that aim to improve quality outcomes; and

● Dialysis Carveout for Beneficiaries with End-Stage Renal Disease: CMS is considering, but not currently proposing, to exclude payment for dialysis services from MA for beneficiaries with end stage renal disease (ESRD) as a component of the ADVaNCE MA Model. Under this concept, for beneficiaries with ESRD, dialysis providers would bill OM directly and be reimbursed through the ESRD Prospective Payment System (PPS). If finalized as a part of the ADVaNCE MA model, in future rulemaking, additional details with respect to interactions under the ESRD PPS would be provided.

Sections 1102(a) and 1871(a)(1) of the Act provide the Secretary with the authority to implement regulations necessary to administer the Medicare program. In addition, section 1115A of the Act authorizes the Secretary to test innovative payment and service delivery models that reduce program expenditures while preserving or enhancing the quality of care furnished to beneficiaries. Section 1115A(b) of the Act authorizes the Secretary to select and test payment and service delivery models subject to the requirements and considerations specified in that subsection. The proposed ADVaNCE MA model would be tested pursuant to the model selection criteria of section 1115A(b)(2)(A) of the Act.

The CMS Innovation Center, under its statutory authority, is proposing the ADVaNCE MA model to test alternative approaches to payment and service delivery in MA for purposes of evaluating whether these approaches would improve or maintain quality, while reducing program expenditures. Goals of the ADVaNCE MA model include spurring local plan competition, enhancing beneficiary choice and value, and protecting taxpayers by safeguarding against improper payments and fraud, waste, and abuse. On the whole, savings are also anticipated, for instance, through the removal of "double bonus counties" and through supplemental benefit offerings that existing medical literature supports will decrease hospitalizations and improve enrollee health, the ADVaNCE MA model would be primarily evaluated on two factors: (1) the quality of care furnished through the model, and (2) changes in expenditures.

The ADVaNCE MA model is grounded in the CMS Innovation Center's 2025 Strategic Direction, which established three inter-related pillars to build healthier lives and Make America Healthy Again: (1) promote evidence-based prevention; (2) empower people to achieve health goals; and (3) drive choice and competition. These pillars are anchored in the Center's statutory obligation to protect taxpayers.[132] The alignment of each ADVaNCE MA model core component with these strategic pillars is detailed throughout this introductory section.

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[132] Centers for Medicare & Medicaid Services, "Strategic Direction," CMS Innovation Center (originally posted May 13, 2025; last modified March 16, 2026), https://www.cms.gov/priorities/innovation/about/strategic-direction.

2. Core Components of the ADVaNCE MA Model

The ADVaNCE MA model proposes to test innovations in three areas of Medicare Advantage: (1) risk adjustment, (2) quality, and (3) supplemental benefits. As a fourth component, CMS is also considering, but is not currently proposing, to test coverage changes for dialysis services. The following subsections describe each core component of the model followed by a consolidated summary of stakeholder input that has informed the proposed model.

a. Risk Adjustment

The Medicare Payment Advisory Committee (MedPAC)[133] and several academic researchers[134,135] have observed that CMS' current HCC-based risk adjustment model produces risk scores that may not fully reflect beneficiaries' actual health status and care needs, increasing payments under the MA program. Shadow testing an alternative risk adjustment methodology that may better reflect actual health status is, therefore, a critical component for CMS in any comprehensive MA innovation effort. Risk adjustment shadow testing will start in CY 2028 during the pre-implementation period, with other model components following in CY 2029 during the model performance period.

b. Quality

MA organizations have made significant investments in quality improvement since the establishment of the MA and Part D Star Ratings and, later, the QBP system. This engagement

[133] Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, chap. 12, "The Medicare Advantage Program: Status Report" (March 2026), https://www.medpac.gov/wp-content/uploads/2026/03/Mar26_Ch12_MedPAC_Report_To_Congress_SEC.pdf.
[134] J. Michael McWilliams, "Risk Adjustment in Medicare Advantage Needs Fixing—There's Just One Catch," Annals of Internal Medicine 178, no. 5 (May 2025): 739–740, https://doi.org/10.7326/ANNALS-25-00549.
[135] Curto, Vilsa E., Eran Politzer, Timothy S. Anderson, John Z. Ayanian, Jeffrey Souza, Alan M. Zaslavsky, and Bruce E. Landon. "Coding intensity variation in Medicare Advantage." *Health Affairs Scholar* 3, no. 1 (2025): qxae176. https://academic.oup.com/healthaffairsscholar/article/3/1/qxae176/7958334

has resulted in quality gains for enrollees as demonstrated in research,[136,137,138,139,140,141] including by the Congressional Budget Office (CBO),[142] that has suggested that alternatives to the current bonus incentives may produce improvements in clinical quality, administrative effectiveness, or both. Consequently, the ADVaNCE MA model seeks to test an alternative way to display quality measures to enrollees while testing rebate and benchmark incentives for cost and quality with more robust and fair competition among plans.

Sections 1860D-4(e) and section 1854(b)(1)(C) of the Act,[143] contain the statutory framework for the MA and Part D Star Ratings and QBP System and the rebate provisions for MA plans based on the quality ratings system established under section 1853(o) of the Act. The statute establishes the applicable percentage quality increases under the MA benchmark methodology and specifies how plans that fail to report data are treated for purposes of the quality determination. Under the ADVaNCE MA model, CMS would test modifications to the quality determinations under section 1853(o) of the Act for participating MA organizations, using the Secretary's authority under section 1115A of the Act and, as necessary, the waiver authority under section 1115A(d)(1) of the Act, solely for purposes of testing the model.

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[136] Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System, chap. 3, "Replacing the Medicare Advantage Quality Bonus Program" (June 2020), https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch3_reporttocongress_sec.pdf.

[137] Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System, chap. 3, "Replacing the Medicare Advantage Quality Bonus Program" (June 2020), https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch3_reporttocongress_sec.pdf.

[138] Adam A. Markovitz, John Z. Ayanian, Devraj Sukul, and Andrew M. Ryan, "The Medicare Advantage Quality Bonus Program Has Not Improved Plan Quality," Health Affairs 40, no. 12 (December 2021): 1918–1925, https://doi.org/10.1377/hlthaff.2021.00606.

[139] Timothy J. Layton and Andrew M. Ryan, "Higher Incentive Payments in Medicare Advantage's Pay-for-Performance Program Did Not Improve Quality but Did Increase Plan Offerings," Health Services Research 50, no. 6 (December 2015): 1810–1828, https://doi.org/10.1111/1475-6773.12409.

[140] Robert A. Berenson and Laura Skopec, The Medicare Advantage Quality Bonus Program: New Ideas and New Conversations, Urban Institute (March 2024), https://www.urban.org/sites/default/files/2024-03/The%20Medicare%20Advantage%20Quality%20Bonus%20Program%20New%20Ideas%20and%20New%20Conversations.pdf.

[141] Ankur Gupta, et al., "Medicare Advantage Plan Star Ratings and County Social Vulnerability," JAMA Network Open 7, no. 7 (July 2024): e2424089, https://doi.org/10.1001/jamanetworkopen.2024.24089.

[142] Congressional Budget Office, "Reduce Quality Bonus Payments to Medicare Advantage Plans," Options for Reducing the Deficit: 2019 to 2028 (December 13, 2018), https://www.cbo.gov/budget-options/2018/54737.

[143] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3201, 124 Stat. 119, 454 (2010) (codified as amended at 42 U.S.C. § 1395w-23).

The current MA and Part D Star Ratings methodology is a rigorous process that converts performance on individual quality measures into Star Ratings. The methodology is intended to help beneficiaries understand differences in quality performance between contracts. The methodology has cut-points that are annually recalculated based on the distribution of all MA contract performance data. CMS seeks to balance the goals of supporting beneficiary decision-making and incentivizing quality improvement and competition.[144,145,146]

The current Star Ratings calculations aggregate performance at the contract level, which can make it difficult for beneficiaries to make decisions based on plan quality performance in their geographic region if the contract covers a large geographic area. Contract level aggregation also may not incentivize competition at the local level. To address this, the ADVaNCE MA model seeks to evaluate quality at the State level. The ADVaNCE MA model seeks to enable dual eligible special needs plans (D-SNP)-specific comparisons based on quality, and more specific geographically based quality rankings to inform beneficiary choice. The ADVaNCE MA model presents an opportunity to explore whether a different approach to quality measurement could complement the existing framework, support greater transparency, broaden benefit availability, and bolster a more dynamic competitive environment across MA organizations of all sizes.

c. Supplemental Benefits

The current statutory and regulatory framework at 42 CFR Part 422 Subpart F allows MA organizations to offer supplemental benefits not available under OM (Parts A and B). When a MA organization's MA bid falls below the applicable MA benchmark, the difference between the MA bid and the MA benchmark results in a rebate, representing a share of the savings generated,

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[144] Andrew Anderson and Mark K. Meiselbach, "Fluctuating Star Ratings and Medicare Advantage Bonuses," JAMA Health Forum 6, no. 10 (October 24, 2025): e254398, https://doi.org/10.1001/jamahealthforum.2025.4398.
[145] Andrew Anderson, Rajesh Satpathy-Horton, and Mark Katz Meiselbach, "Medicare Advantage Star Rating Quality Gains Were Concentrated in a Narrow Set of Clinical and Medication Measures, 2015–25," Health Affairs 45, no. 4 (April 2026), https://doi.org/10.1377/hlthaff.2025.00946.
[146] David J. Meyers, "Measuring Quality for Patients With High Needs in Medicare Advantage," JAMA Health Forum 7, no. 3 (March 2026): e260333, https://doi.org/10.1001/jamahealthforum.2026.0333.

which must be used to provide enrollees with additional benefits, which may include benefits in the form of reduced cost-sharing, or lower premiums.[147] MA organizations may offer additional supplemental benefits which are paid for through premiums or cost-sharing. These supplemental benefits are an important feature of MA plan design and can support beneficiary choice and competition by providing necessary medical benefits.The ADVaNCE MA model proposed to test allowing MA organizations to direct three supplemental benefits to additional beneficiaries. The three supplemental benefits—caregiver supports, healthy food and produce, and transportation for non-medical needs—are broad in scope, potentially affecting many needs of eligible enrollees. Under the model, these three evidence-based, prevention-forward supplemental benefits could be offered specifically to LIS-eligible individuals; this is a high-needs population that stands to benefit from targeted, high-value benefit design.

d. Dialysis Payments

ESRD is a condition of permanent kidney failure that requires ongoing dialysis or a kidney transplant to sustain life. The 21st Century Cures Act[148] allowed beneficiaries with ESRD to enroll in MA beginning in 2021. For these beneficiaries, an MA organization covers outpatient maintenance dialysis. MA organizations reimburse in-network dialysis facilities according to negotiated contract rates. We are considering, but are not currently proposing, changing coverage requirements for ADVaNCE MA model participants such that outpatient maintenance dialysis provided to beneficiaries with ESRD would be covered by OM and reimbursed under the ESRD PPS, rather than by the beneficiary's MA organization. Under such a policy, beneficiaries would remain enrolled in their MA plan and the MA organization would remain responsible for the beneficiary's other basic benefits and any supplemental benefits offered under the plan. If proposed, we would expect that this payment change could be expected to reduce inefficient

[147] These supplemental benefits can be funded through the rebate mechanism when a plan bids below its benchmark allowing provision of supplemental benefits which may be offered at $0 additional premium to enrollees. The vast majority of plans already bid below the benchmark. See Medicare Payment Advisory Commission, *The Medicare Advantage Program: Status Report* (January 2026), https://www.medpac.gov/wp-content/uploads/2026/01/Tab-N-MA_Status-Jan-2026.pdf

[148] 21st Century Cures Act, Pub. L. No. 114–255, 130 Stat. 1033 (2016).

spending associated with higher MA dialysis prices, encourage competition among dialysis providers, and allow MA organizations to direct more resources towards the non-dialysis needs for beneficiaries with ESRD.

e. Interested Parties' Input

Over the past several years, CMS has solicited extensive public input on the MA program. The themes that have emerged consistently across multiple forums directly informed the design of the ADVaNCE MA model. We detail those efforts in this section.

In 2022, CMS released the "Medicare Program; Request for Information on Medicare" (hereinafter "2022 RFI on Medicare"), which received more than 4,000 responses.[149] The 2022 RFI on Medicare sought input on various aspects of MA, including how to strengthen the program, how to drive innovation to promote person-centered care, and how to support affordability and sustainability in MA. Respondents broadly called for reforms that emphasize whole-person care, reward prevention and chronic disease management, improve quality transparency at a local level, and better support beneficiary plan selection based on quality and cost. Respondents also urged CMS to provide more meaningful, geographically relevant quality information to beneficiaries and raised concerns about misleading marketing practices.

In 2024, CMS released the "Medicare Program; Request for Information on Medicare Advantage Data" (hereinafter "2024 RFI on MA Data").[150] Information was requested on any aspect of data related to the MA program including, but not limited to, directories and networks, prior authorization and utilization management, denials and appeals, use of algorithms, supplemental benefits, and enrollment. Respondents included beneficiary advocates, MA plans and plan associations, providers and provider associations, researchers and policy organizations, quality-measurement organizations, community-based organizations, and others. Many

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[149] Centers for Medicare & Medicaid Services, "Medicare Program; Request for Information on Medicare," 87 FR 46918 (August 1, 2022), https://www.federalregister.gov/documents/2022/08/01/2022-16463/medicare-program-request-for-information-on-medicare.

[150] Centers for Medicare & Medicaid Services, "Medicare Program; Request for Information on Medicare Advantage Data," 89 FR 5907 (January 30, 2024), https://www.federalregister.gov/documents/2024/01/30/2024-01832/medicare-program-request-for-information-on-medicare-advantage-data.

recommended improvements in data collection methods to provide more timely, comprehensive, and accurate information for assessing quality and cost across contracts and called for increased transparency and expanded use of MA encounter data to support value-based care.

In March 2024, the Federal Trade Commission (FTC), Department of Justice (DOJ), and HHS jointly released a Request for Information on Consolidation in Health Care Markets.[151] Of the submissions received, 72 specifically addressed MA consolidation. Respondents identified concerning trends including lower quality outcomes, higher premiums and cost sharing, provider pressure to engage in upcoding, broker steerage, predatory marketing, and anti-competitive market dynamics. Respondents recommended reforms to address perceived gaming of quality scores and Medical Loss Ratio (MLR) calculations, advocated for increased price and quality transparency, and to address broker practices that limit competition.

Most recently, in section 1.B.6 of the November 2025 proposed rule, "Medicare Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program," CMS issued a Request for Information on Future Directions in Medicare Advantage (Risk Adjustment and Quality Bonus Payments).[152] This request for information (RFI) sought comprehensive input from MA organizations, beneficiary advocates, healthcare providers, and technology and industry experts on modernizing the MA program. Commenters generally expressed strong support for quality interventions, such as removing double bonus counties and achieving budget neutrality, as these could help to address negatively perceived aspects of Star Ratings and reduce spending disparities between MA and OM. There was also some support for improved risk score calculations including incorporating Super Intelligence (SI) or next-generation models. But while

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[151] Department of Justice, Department of Health and Human Services, and Federal Trade Commission, "Request for Information on Consolidation in Health Care Markets," Docket No. ATR 102 (February 29, 2024), https://www.regulations.gov/document/FTC-2024-0022-0001.

[152] Centers for Medicare & Medicaid Services, "Medicare Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program," 42 CFR Parts 422 and 423 (November 28, 2025), https://www.federalregister.gov/documents/2025/11/28/2025-21456/medicare-program-contract-year-2027-policy-and-technical-changes-to-the-medicare-advantage-program

commenters acknowledged the potential of these models to improve upon the existing CMS-HCC risk adjustment model, they urged that any such models be transparent and accessible while undergoing rigorous testing before implementation.

Taken together, this input from interested parties reflects a broad and consistent call for the types of reforms proposed to be tested in the ADVaNCE MA model: localized quality measurement, improved beneficiary decision-making tools, targeted supplemental benefits for high-need populations, and modernized risk adjustment.

3. Mandatory Nature of the ADVaNCE MA Model

We propose the ADVaNCE MA model as a mandatory test, in Mandatory States, as we believe doing so is essential to evaluate the ability of the ADVaNCE MA model to improve quality of care and reduce program expenditures. We also believe a mandatory test is appropriate because the ADVaNCE MA model would test changes to MA payment, quality incentives, and risk adjustment that are intended to operate across local markets and, therefore, require broad participation within select geographic areas. As such, we believe that requiring MA organizations with eligible plans in Mandatory States to participate would reduce the potential for self-selection bias, improve the representativeness of participating MA organizations across geographic areas, and support sufficient participation to generate meaningful results. We discuss specific proposals relating to mandatory participation and Mandatory States in more detail in section VIII.D. of this proposed rule.

We also believe that a mandatory test of this model is appropriate because there are several limitations when conducting a voluntary test. In a voluntary model test, participants may be able to choose to join the model after the performance period has already begun depending on model parameters. This can present significant evaluation challenges. As noted in the Fourth Evaluation Report of the Medicare Advantage Value-Based Insurance Design (VBID) model–the only prior CMS Innovation Center model test focused on the MA program, which concluded in 2025–VBID participation increased substantially over time (from 144 plans in 2020 to 1,400 in

2024), resulting in the majority of VBID plans being first-year implementers throughout the model timeline, limiting the ability of evaluation results to "fully capture VBID's long-term effects on outcomes."[153] The evaluation report also found that the significant rise in VBID model population contributed to other evaluation limitations. That is, "self-selection into the model presented particular challenges for D-SNPs. By 2023, the majority of eligible D-SNPs had joined the model test, leaving a smaller and possibly a skewed selected sample of nonparticipating D-SNPs to serve as comparators."[154] In short, a continued influx of model participants each year (and decline in available comparators) could limit our ability to evaluate the impact of the ADVaNCE MA model, and is why, in part, we are proposing a mandatory framework.

Depending on the terms of the model, a voluntary model test may also permit participants to cease their model participation before the end of the model performance period. CMS has noted that, "in some cases, voluntary participation can limit potential savings and impede evaluation due to selection bias as participants may opt in if they project that the financial incentives in the model are in their favor and drop out when potential losses are projected."[155] As noted previously, in VBID, the participants could shift year to year with contracts participating in the model one year but not the next, which caused problems for the evaluation. Under the ADVaNCE MA model, all applicable MA plan types in a Mandatory State would be required to participate, as discussed in section VIII.D.2.a of this proposed rule. This ensures maximum consistency and fuels the ability of the model to meet its goals and the mission of the CMS Innovation Center to identify, test, and scale new ways to pay for and deliver better healthcare.

Moreover, the CBO previously noted that the CMS Innovation Center has greater potential to meet its statutory obligations related to program cost and quality were it to shift to

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[153] Dmitry Khodyakov, Evaluation of the Medicare Advantage Value-Based Insurance Design Model: 2020–2024, report no. PR-A4406-2 (RAND Health, March 2026), https://www.cms.gov/priorities/innovation/data-and-reports/2026/vbid-report-2020-2024.

[154] Dmitry Khodyakov, Evaluation of the Medicare Advantage Value-Based Insurance Design Model: 2020–2024, report no. PR-A4406-2 (RAND Health, March 2026), https://www.cms.gov/priorities/innovation/data-and-reports/2026/vbid-report-2020-2024.

[155] Centers for Medicare & Medicaid Innovation, Innovation Center Strategy Refresh (Centers for Medicare & Medicaid Services, October 2021), https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper.

mandatory models, stating "[The CMS Innovation Center] might also achieve larger savings in its second decade if it reduced the potential for selective participation by shifting from voluntary to mandatory models."[156] That is, voluntary models may be more susceptible to attrition and volatility, particularly since high-volume participants may choose to cease model participation prior to the end of the model test period (due to market, financial, or regulatory factors, for example), exacerbating sample size and selection bias issues over time. The ADVaNCE MA model would be prone to many of the drawbacks of voluntary models, which is in part, why we are proposing it as a mandatory model.

We believe a robust and consistent evaluation of the ADVaNCE MA model necessitates sustained participation in the ADVaNCE MA model, which would be fostered by a mandatory model design. Such participation over time also can aid the statistical calculations underlying the evaluation of the Diamond Ratings system that require sufficient participation over multiple years to generate reliable, population-level results, as proposed at § 516.200(a) and described in section VIII.F.

4. Summary

The proposed aspects of the model described in this section build on information gathered from the RFIs described above.

a. Risk Adjustment

The ADVaNCE MA model proposes to shadow test a CMMI Inferred Risk Adjustment Model that builds upon the current HCC framework by integrating multiple, additional data sources already available to CMS, including OM claims data, MA encounter data, enrollment data, and new technologies. The shadow test will begin during the pre-implementation period and run in parallel with the existing risk adjustment methodology; at this time, we are not proposing risk adjustment related payment changes under the ADVaNCE MA model to be tied to

[156] Congressional Budget Office, Federal Budgetary Effects of the Activities of the Center for Medicare & Medicaid Innovation (September 2023), https://www.cbo.gov/system/files/2023-09/59274-CMMI.pdf.

shadow test results. The purpose of the shadow test is to generate learnings about how new approaches may improve the accuracy of risk adjustment, determine if its use reduces susceptibility to upcoding, and test if its use better reflects beneficiaries' actual health status and care needs. These learnings are expected to inform future risk adjustment policies in the ADVaNCE MA model. The specific design of the CMMI Inferred Risk Adjustment Model is described in detail in section VIII.E of this proposed rule.

b. Diamond Ratings System

The Diamond Ratings system for the ADVaNCE MA model would test an innovative design for quality assessment and quality based payment. A key mechanism for achieving this is measuring quality at a more granular geographic level in cases in which contracts previously spanned multiple states. This approach would spur local quality improvement, help beneficiaries make meaningful, geographically relevant plan comparisons, and encourage plans to more meaningfully compete on the basis of quality of care. The Diamond Ratings system would also test if replacing the payment thresholds in the current, statutorily based QBP adjusted benchmark methodology can create more incentives for plans to improve quality by more directly linking incremental performance differences with incremental payment impacts and utilizing ranking rather than threshold based rewards through a more competitive funding environment among all plans. The specific design of the Diamond Ratings system is described in detail in section VIII.F of this proposed rule.

c. Supplemental Benefits

To test potential alternatives to the supplemental benefit structure described earlier in section VIII.G.3.(d) of this proposed rule, we propose to allow targeting of certain supplemental benefits to LIS-eligible individuals under the ADVaNCE MA model. That is, ADVaNCE MA model participants would be allowed to target certain supplemental benefits specifically to Part D LIS-eligible individuals, as defined at 42 CFR 423.34(b)(2). This is intended to assess whether such flexibilities would enable ADVaNCE MA model participants to support access to

preventive care and address drivers of unnecessary healthcare expenditures and adverse health outcomes for high-need beneficiaries, and whether doing so would reduce program expenditures and improve overall quality of care. The ADVaNCE MA model expands the offering of benefits available through Special Supplemental Benefits for the Chronically Ill (SSBCI), by making certain supplemental benefits available to LIS-eligible individuals. This would level the playing field for disparately resourced MA organizations since some may currently face challenges implementing existing supplemental benefit authorities due to limited funding, staffing, and/or data systems. As proposed in § 516.300(a)(1)(i) through (iii), the ADVaNCE MA model would allow MA organizations to offer the following supplemental benefits to LIS-eligible individuals:

- Healthy food and produce.
- Transportation for non-medical needs (TNMN).
- Supports for caregivers of enrollees.

Of these three benefits, healthy food and produce and TNMN are currently allowable only as SSBCI. We believe that testing these flexibilities could empower enrollees and caregivers, encourage innovative and value-driven benefit designs, improve quality, reduce avoidable healthcare utilization, and encourage more meaningful competition. These benefits may have cascading impact, not only among MA organizations but among healthy food and transportation vendors, also resulting in improved quality of care for enrollees. For example, based on responses to our 2024 RFI on MA Data as well as external research, CMS believes enabling smaller, more local MA organizations to offer certain prevention-oriented benefits could reduce barriers to relationships between MA organizations and smaller, local vendors (such as family-operated grocers, local farmers, and community transportation providers).[157,158] The inclusion of such vendors in MA organizations' supplemental benefit networks may impact

[157] Centers for Medicare & Medicaid Services, "Medicare Program; Request for Information on Medicare Advantage Data," 89 FR 5907 (January 30, 2024), https://www.federalregister.gov/documents/2024/01/30/2024-01832/medicare-program-request-for-information-on-medicare-advantage-data.
[158] Na'amah Razon, Laura M. Gottlieb, and Taressa Fraze, "Essential Not Supplemental: Medicare Advantage Members' Use of Non-Emergency Medical Transportation (NEMT)," Journal of General Internal Medicine 38, no. 16 (December 2023): 3566–3573, https://doi.org/10.1007/s11606-023-08321-1.

their continued operation and/or competition on price and quality with larger, national vendors (which more national MA organizations may contract with) to better ensure supplemental benefit access across multiple States/non-contiguous service areas.

d. Dialysis Payments

We are considering, but are not currently proposing, a policy to carve-out outpatient dialysis payments from the MA benefit for beneficiaries with ESRD that live in Mandatory States. Since the 21st Century Cures Act allowed beneficiaries with ESRD to enroll in MA, as of December 2024, 55 percent of the Medicare beneficiaries with ESRD were enrolled in MA. Currently, MA organizations negotiate dialysis payment rates directly with facilities rather than using the OM ESRD PPS rates. However, there are two dominant providers who control 75 percent of market share, meaning they have significant leverage over the payment rates in MA. A 2026 MedPAC study indicated MA organizations pay, on average, 22 percent more for dialysis treatment than OM, a trend that has occurred for many years.[159] The goal of this policy would be to lower MA dialysis costs without reducing access to dialysis for beneficiaries. We request comments on this potential policy, including its costs, benefits, and other impacts, as well as any alternative approaches that would achieve the desired policy aims of reducing spending in this area, promoting choice and competition, and best serving the needs of beneficiaries with ESRD.

5. Alignment with the CMS Innovation Center's Strategic Vision to Make America Healthy Again

The CMS Innovation Center's 2025 Strategic Direction established a vision to build healthier lives grounded in three pillars: (1) promote evidence-based prevention; (2) empower people to achieve health goals; and (3) drive choice and competition. These pillars are anchored

[159] Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, chap. 12, "The Medicare Advantage Program: Status Report" (March 2026), https://www.medpac.gov/wp-content/uploads/2026/03/Mar26_Ch12_MedPAC_Report_To_Congress_SEC.pdf.

in the CMS Innovation Center's statutory obligation to protect taxpayers.[160] As detailed throughout this proposed rule, the ADVaNCE MA model is designed to operationalize each of these pillars. Table I-1 summarizes the proposed innovations of the ADVaNCE MA model for each of the three pillars and supporting principle of protecting taxpayers.

a. Promote Evidence-Based Prevention

The CMS Innovation Center's prevention pillar incentivizes model participants to promote access to timely preventive services and encourages investments in chronic disease management. It expands the use of beneficiary engagement incentives tied to health promotion and sustained lifestyle changes and encourages the use of metrics to track preventive outcomes, including metrics focused on reducing the progression of chronic illness.

The ADVaNCE MA model progresses this pillar by allowing plans to target certain supplemental benefits aimed at promoting prevention: healthy food and produce, TNMN, and supports for caregivers of enrollees. Healthy food and produce and TNMN–currently available only to chronically ill MA beneficiaries who qualify for SSBCI–have the potential to prevent the onset of chronic illness and delay progression of existing chronic conditions. Additionally, supports for caregivers of enrollees may prevent beneficiaries (especially those who are experiencing advanced illness or functional and cognitive decline) from disease progression that might otherwise require more intensive institutional care. These flexibilities are intended to test if CMS can realize improved health outcomes and reduced Medicare expenditures for high-needs beneficiaries by directly tying these alternative benefit designs to health prevention and long-term, sustained lifestyle changes.

b. Empower People to Achieve Health Goals

The CMS Innovation Center's empowerment pillar focuses on equipping people with tools, information, and processes that better connect them to their health data and support

[160] Centers for Medicare & Medicaid Innovation Center, "CMS Innovation Center 2025 Strategy to Make America Healthy Again," Strategic Direction, Centers for Medicare & Medicaid Services, last modified March 2026, https://www.cms.gov/priorities/innovation/about/strategic-direction.

informed health decisions. This includes increasing data access, aligning financial incentives with health outcomes, and publishing data on provider, plan cost, and quality performance to support beneficiary decision-making.

The ADVaNCE MA model advances this pillar in two ways. First, the Diamond Ratings system would test whether reporting an MA parent organization's performance at the State level by cohort and delivering localized comparative quality data to beneficiaries enables more informed plan selection. Second, the supplemental benefit flexibilities for LIS-eligible individuals, including targeting of healthy food and produce, TNMN, and supports for caregivers of enrollees, are intended to assess whether such benefits may empower beneficiaries and caregivers to engage in prevention-based activities and enable beneficiaries to remain in the community longer.

c. Drive Choice and Competition

The CMS Innovation Center's competition pillar promotes stronger market-based incentives that encourage providers and MA organizations to deliver higher-value care and expands information on high-value coverage options to stimulate beneficiary choice and competition.

The ADVaNCE MA model advances this pillar through the Diamond Ratings system, which is designed to encourage stronger local-level competition among MA organizations by measuring and reporting quality at the State level by cohort, and by utilizing forced ranking. This alternative, more localized framework, is intended to provide beneficiaries with meaningful and clear quality comparisons between MA organizations and create direct incentives for MA organizations to compete on quality within the Mandatory States. Additionally, the supplemental benefit flexibilities proposed under the ADVaNCE MA model are intended to promote competition among healthy food and transportation vendors through contracts with MA organizations that are offering targeted benefits to LIS-eligible individuals, driving value.

Finally, in considering moving MA dialysis payments to OM, we hope to drive competition in the dialysis market.

d. Protecting Taxpayers

All three pillars of the CMS Innovation Center's Strategic Direction are anchored in the obligation to protect taxpayers. The ADVaNCE MA model moves this forward by: (1) shadow testing a CMMI Inferred Risk Adjustment Model; (2) refining quality reporting and payment; (3) testing whether permitting MA organizations to target to LIS-eligible individuals reduces the future costs of chronic disease through preventive supplemental benefits; and (4) considering changes to dialysis payment structure.

TABLE I-1: ADVaNCE MA MODEL ALIGNMENT WITH CMS INNOVATION CENTER STRATEGIC VISION

CMS Innovation Center Strategic Pillar	ADVaNCE MA Model Implementation Hypotheses
Promote Evidence-Based Prevention	Supplemental benefits targeted to LIS-eligible individuals for nutrition, caregiver supports, and transportation for non-medical needs (TNMN) would directly tie benefit design to health prevention and long-term lifestyle changes, aiming to improve the health status and outcomes for high-need beneficiaries.
Empower People to Achieve Health Goals	The Diamond Ratings system reports MA parent organization's performance at the State level, providing localized quality data to support informed beneficiary plan selection. LIS-targeted benefits for nutrition, transportation, and caregiver support would equip additional beneficiaries and caregivers to engage in prevention and enable beneficiaries to remain in their community.

Drive Choice and Competition	The Diamond Ratings system would measure and report quality at the State level by cohort, spurring local MA parent organization competition. Supplemental benefit flexibilities are intended to expand the market and promote competition among healthy food and transportation vendors, driving value for LIS-eligible individuals. The potential dialysis payment change that could appear in a future proposed rule would address a distortion in the market for beneficiaries with ESRD by replacing MA rates with OM payments to reduce market leverage by dialysis organizations.
Protecting Taxpayers (Supporting Principle)	Shadow testing of the CMMI Inferred Risk Adjustment Model is designed to generate learnings that could inform efforts to enhance the accuracy of future risk adjustment models. The Diamond Ratings system is designed to increase alignment of MA quality payments with high-quality care delivered. Preventive supplemental benefits are designed to reduce the future costs of chronic disease. Carving-out beneficiary dialysis payments from MA to be paid under the ESRD PPS and, thereby, adjusting MA benchmarks would protect taxpayer dollars.

B. Definitions

We propose at § 516.5 to define certain terms for the ADVaNCE MA model. We also propose that the definitions applicable to CMS Innovation Center models at 42 CFR 512.110, along with certain revisions to those definitions as identified in this notice of proposed rulemaking, would also apply to the ADVaNCE MA model.

For the purpose of the ADVaNCE MA model, we propose the following definitions be applicable unless otherwise stated:

ADVaNCE MA contract means an eligible contract type (Health Maintenance Organizations (HMOs), Local Preferred Provider Organizations (PPOs), Private Fee-for-Service Plans (PFFSs), Chronic Condition Special Needs Plans (C-SNPs) and Dual Eligible Special Needs Plans (D-SNPs) operating with service areas in a Mandatory State.

ADVaNCE MA Diamond Ratings system ("Diamond Ratings system") means the quality assessment and payment framework described in Subpart C of proposed part 516.

ADVaNCE MA model participant means a Medicare Advantage organization, as defined in 42 CFR 422.2, that operates one or more eligible plans within a Mandatory State.

ADVaNCE MA Individual Measure Diamond means an individual quality measure's numeric rating as calculated in the Diamond Ratings system and as described in § 516.215(c)(1).Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures are displayed to the nearest whole Diamond. Non-CAHPS measures are displayed to the nearest one-tenth Diamond.

ADVaNCE MA model performance period means the 10-year period of time beginning on January 1, 2029, through December 31, 2038, as specified in § 516.2(b).

ADVaNCE MA Overall Diamond Rating means a rating on a scale of 1 to 5 Diamonds displayed in increments of one-tenth of a Diamond increment on Medicare Plan Finder.[161] This rating communicates the quality of the ADVaNCE MA model participant's parent organization (for the cohort within the Mandatory State) to beneficiaries choosing a plan in the relevant Mandatory State and cohort.

ADVaNCE MA Payment means changes to an ADVaNCE MA model participant's benchmarks and rebates as described in § 516.230.

Aligning Data and Value to Nurture Competition and Efficiency (ADVaNCE) in Medicare Advantage (MA) model means the CMS Innovation Center mandatory healthcare payment and delivery model test focused on the MA population in Mandatory States.

Bid refers to the bid submitted under section 1854(a)(1) of the Act.

Cohort means the classification of contracts into one of two groups based on whether they offer: (1) D-SNPs; or (2) General Enrollment Plans (HMO, PPO, PFFS, C-SNP).

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[161] Medicare Plan Finder is an online searchable tool located on the Medicare.gov website at https://www.medicare.gov/plan-compare that allows individuals to compare options for enrolling in MA or Part D plans.

CY means calendar year.

Guardrail has the same meaning as set forth in 42 CFR 422.162(a), but with the reference to Star Ratings replaces with a reference to Diamond Ratings.

Insufficient data means a situation in which an ADVaNCE MA model participant does not meet the minimum reporting requirements under § 516.215(d)(1).

Low enrollment means a designation that is assigned to an ADVaNCE MA model participant whose parent organization has fewer than 500 enrollees across all of its ADVaNCE MA contracts in a given cohort within a Mandatory State. An ADVaNCE MA model participant, who has a low enrollment designation, has insufficient data to receive an ADVaNCE MA Overall Score under § 516.215(d).

Low-income subsidy (LIS)-eligible individual has the same meaning as set forth in 42 CFR 423.34(b)(2).

MA and Part D Star Ratings assess plan quality in the MA and Part D Star Ratings system and the associated quality bonus payments, as described in 42 CFR 422.160 through 422.166 and 42 CFR 423.180 through 423.186, for contracts not subject to the requirements of the ADVaNCE MA model.

Mandatory State means a State within which CMS has required parent organizations offering MA plans in such a State to participate in the ADVaNCE MA model.

Mandatory supplemental benefits has the same meaning as set forth in 42 CFR 422.2.

Measurement period has the same meaning as set forth in 42 CFR 422.162.

Measure score has the same meaning as set forth in 42 CFR 422.162.

Model Test means the full period over which the ADVaNCE MA model is implemented, operated, and evaluated, consisting of three phases: the pre-implementation period, a 10-year performance period, and the post-implementation period.

New entrant means a parent organization that is new to the Mandatory State, meaning no prior MA or QBP participation in the Mandatory State for at least one performance year. A

parent organization can be a new entrant in either or both cohorts in a Mandatory State in a given year.

Non-missing zero measure score means a rescaled measure score of zero due to failure to adhere to reporting or data integrity requirements for a measure as required under § 516.200(a)(3).

Parent organization has the same meaning as set forth in 42 CFR 422.2.

Payment year means the calendar year for which CMS will provide ADVaNCE MA payments to ADVaNCE MA model participants as described in proposed § 516.200(c).

Performance year (PY) means the 12-month period beginning on January 1 and ending on December 31 during the ADVaNCE MA model test period as specified in § 516.2(b).

Quality Bonus Payment (QBP) system are the ratings for MA plans that determine CMS payments under section 1853(o) of the Act and increase beneficiary rebate retention allowances under section 1854(b) of the Act. QBP ratings are determined based on the Star Ratings calculated under the MA and Part D Star Ratings system.

Rebate refers to the beneficiary rebate described in section 1854(b)(1)(C) of the Act.

Rescaled measure score means the converted measure score with a rescaled point value between 0 and 100.

Traditional rounding rules has the same meaning as set forth in 42 CFR 422.162(a) and § 423.182(a).

Tukey outer fence outliers has the same meaning as set forth in 42 CFR 422.162(a).

We seek comment on these proposed definitions for the ADVaNCE MA model. We also seek comment on whether there are any definitions that should be added.

C. Statutory Authority and ADVaNCE MA Model Length

1. Statutory Authority

Section 1115A(a)(1) of the Act (42 U.S.C. 1315a) authorizes the CMS Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid,

and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs. Section 1115A(b) authorizes the Secretary to select and test payment and service delivery models subject to the requirements and considerations specified in that subsection. In addition, section 1115A(c) of the Act authorizes the Secretary to expand (including implementation on a nationwide basis), through rulemaking, the duration and scope of successful models if certain requirements are met–namely, reducing spending without reducing the quality of care or improving quality without increasing spending.

2. ADVaNCE MA Model Test

At § 516.2, we propose that the ADVaNCE MA model would operate across three periods that would comprise the model test: a pre-implementation period; a 10-year model performance period; and a post-implementation period, as detailed further in this section.

a. Pre-Implementation Period

We propose at § 516.2(a) to establish a pre-implementation period that encompasses the period beginning on June 8, 2027, the CY 2028 bid deadline, and ending December 31, 2028, during which pre-performance contracting and operational activities required for appropriate implementation of the ADVaNCE MA model would occur. We believe that the pre-implementation period is necessary to engage in preparation activities so that both CMS and ADVaNCE MA model participants are ready to begin the ADVaNCE MA model on the start date of the model performance period described in subparagraph VIII.C.2.b. below. Under the proposal, we would consider the shadow testing of the CMMI Inferred Risk Adjustment Model described in section VIII.E of this proposed rule to be an operational activity that would begin during the pre-implementation period, though we note that, as described in section VIII.C.2.a, this activity would continue beyond the pre-implementation period.

We seek comment on our proposal at § 516.2(a) to establish a pre-implementation period, on the proposed length of the pre-implementation period, and the proposed contracting and operational activities to be conducted during the pre-implementation period.

b. Model Performance Period

At § 516.2(b), we propose that the ADVaNCE MA model performance period would consist of 10 consecutive performance years, each aligned with the calendar year, beginning January 1, 2029, and ending December 31, 2038, unless the ADVaNCE MA model is terminated earlier either in accordance with 42 CFR 512.165 or to effectuate an expansion of the model in accordance with section 1115A(c) of the Act.

We considered employing a shorter ADVaNCE MA model performance period of five years. However, as discussed in sections VIII.F. and G. of this proposed rule, the ADVaNCE MA model would introduce new approaches to quality measurement and the associated payments, as well as supplemental benefits flexibilities, which, collectively, would constitute new efforts in MA and require substantial time to test, implement, and evaluate. For example, as described in section VIII.F of this proposed rule, the model's proposed -Diamond Ratings-system would replace the MA and Part D Star Ratings program's statutorily required approach for adjusting payments with a continuous payment scale. As proposed, there would be a three-year gap between when quality measurement data are collected and the point at which the outcomes would influence ADVaNCE MA model participant payments. For example, under the terms of the model, quality ratings based on the applicable measurement period data impacting the 2031 Diamond Ratings would not influence ADVaNCE MA payments until CY 2032. Consequently, a five-year ADVaNCE MA model performance period, CY 2029 through CY 2033, would result in CMS having only two years of payment data from the point at which an ADVaNCE MA model participant's payments were influenced by the Diamond Ratings system before the model would conclude. Further, we expect ADVaNCE MA model participants' quality of care in response to the model to improve over time as they gain more experience, which could impact

their bids and quality improvement practices in later years, potentially making results from the earlier years of the model less representative of future years. As such, we believe that a five-year model would have too short an implementation period to observe these changes, thereby limiting insights into the Diamond Ratings system's impacts on quality and payments. Furthermore, one of the goals of the proposed Diamond Ratings system is to promote local competition, which can take several years as it incentivizes organizations to enter new markets. A five-year model would allow there would only be two years of data to evaluate the effects of the ADVaNCE MA model's impact on MA market competition and the resultant effects on quality and costs, which we believe is not likely to be enough time for the competition to increase. Finally, MA data, such as encounter data, is typically not sufficient for analytics until up to two years after the completion of the service CY, meaning, we are unlikely to have sufficient data to accurately determine next steps for the model after only a five-year period. We believe this limited timeline would restrict our ability to make informed decisions about potential next steps for the model, such as nationwide expansion. Consequently, we believe that a five-year performance period ending in 2033 would provide insufficient evidence to evaluate the ADVaNCE MA model's proposed quality program's impact on quality of care, payment changes, and market competition.

We also considered interim performance-period lengths of six through nine years. Similar to the logic for a five-year performance period, given the lag between the measurement period and the associated payment, ADVaNCE MA model lengths of six or seven years also would not allow for enough payment data to accumulate to-properly evaluate the payment results before the conclusion of the ADVaNCE MA model. From there, recognizing that past mandatory models, such as the Comprehensive Care for Joint Replacement (CJR) model[38], were eight years in length, we further considered performance periods of eight and nine years. However, experience has shown that the greater the complexity of a model, the more likely it is that midstream changes are required, which then extend a model's performance period. For example, over the course of the CJR model, joint replacement surgeries went from being primarily inpatient

procedures to being primarily outpatient procedures. This fundamental shift in the clinical landscape required numerous midstream model changes and model extensions. Model extensions tend to be destabilizing for stakeholders, because the policy landscape is constantly shifting. Because the ADVaNCE MA model would create the Diamond Ratings system while simultaneously implementing changes to supplemental benefits, we believe that a longer performance period would ensure market stability in order to allow the expected outcomes of quality improvement and increased competition, goals that we believe will take time to materialize.

After consideration of these alternatives, we believe a 10-year ADVaNCE MA model performance period would provide ADVaNCE MA model participants with the time necessary to make operational and strategic investments to accommodate the model's requirements and would allow CMS to conduct a robust evaluation of the model's impacts on MA costs and quality, while giving sufficient time for ADVaNCE MA model participants to effectuate changes to competition and care delivery. We believe a 10-year performance period would increase the likelihood that these investments would have sufficient time to produce measurable effects and that CMS would have sufficient evidence to evaluate the model within the time constraints of CMS Innovation Center model test periods. If we believe we have gained sufficient evidence to make decisions about the model in fewer than 10 years, we could seek to end the model earlier pursuant to § 512.165, or, alternately, to expand the model in accordance with section 1115A(c) of the Act. We believe that preemptively choosing a shorter model performance period would increase the risk that there will not be sufficient time to see the full impact of the model.

We considered a model start date of January 1, 2030, or later, but we believe that our proposed start date affords sufficient preparation time for CMS and ADVaNCE MA model participants to implement and operationalize the necessary changes. We also believe that the potential positive impact of the proposed ADVaNCE MA model is significant enough to warrant beginning the test as soon as practicable. Furthermore, initiating the ADVaNCE MA model

performance period in CY 2029 would be sufficient to accommodate the Federal rulemaking process, allowing us to conduct thorough outreach to interested parties and gather critical feedback from commenters.

We seek comment on our proposal in § 516.2(b) to establish a 10-year model performance period, on the alternatives of five years through nine years, and potential alternate model lengths. We also seek comment on the proposed ADVaNCE MA model start date of January 1, 2029 for PY one, on the alternately considered start date of January 1, 2030, and the corresponding adjustment to dates of the ADVaNCE MA model performance period.

c. Post-implementation Period

We propose at § 516.2(c) to establish for the ADVaNCE MA model a post-implementation period consisting of the three consecutive payment years that would immediately follow the model performance period (*e.g.*, if the model performance period ends December 31, 2038, the post-implementation period would begin January 1, 2039, and end December 31, 2041). Further, we propose that the main purpose of the post-implementation period is for CMS to provide final payments associated with the model's Diamond Ratings system as described in section VIII.F of this proposed rule. As previously discussed in this section and further elaborated in section VIII.F.4. of this proposed rule, ADVaNCE MA model payments would begin in CY 2032 and continue for 10 years. We believe this proposal is appropriate to ensure that ADVaNCE MA model participants align their care delivery with the Diamond Ratings system's incentive structure throughout the entirety of the model's applicable performance period.

As described in greater detail in section VIII.F.1.a., CMS alternatively considered proposing a final measurement period for the ADVaNCE MA model applicable to the 2037 Diamond Ratings, which would have resulted in a shorter, seven-year period in which an ADVaNCE MA model participant's first and final ADVaNCE MA payments would occur (CY 2032 and CY 2038, respectively). This alternative would have no post-implementation period.

We considered this alternative as a means to accommodate the transition of ADVaNCE MA model participants back to the Star Ratings system and QBP system in CY 2039, following the conclusion of the model's performance period. However, we concluded that this consideration did not outweigh the importance of ADVaNCE MA model participants aligning their quality strategies and approaches with the Diamond Ratings system's incentive structure throughout the ADVaNCE MA model's entire applicable performance period, which we believe would strengthen the model's ability to generate reliable evaluation data by eliminating confounding factors that may arise from transitioning back to the Star Ratings system and QBP system during the model's performance period.

We seek comment on our proposal in § 516.2(c) for a post-implementation period of the three consecutive payment years that would immediately follow the model performance period to provide final payments associated with the model's Diamond Ratings System, as well as the alternative described that would lead to a seven-year overall payment period, as well as any additional approaches to the model's payment period that CMS should consider.

D. Mandatory Participation, ADVaNCE MA Model Participants, Geographic Areas and Contract Structure Requirements for Operations

1. Mandatory Participation

As discussed in section VIII.A.3 of this proposed rule, we believe that a mandatory model design is necessary to support a sound evaluation of the ADVaNCE MA model. We are proposing to establish at § 516.100(a) that participation in the ADVaNCE MA model would be mandatory for all MA organizations that operate one or more eligible plans within a Mandatory State) during the performance period. All eligible plans offered under a contract to Medicare beneficiaries residing in a service area (as defined at 42 CFR 422.2) within a Mandatory State would be required to participate; and the participation unit would be at the contract level. Under the proposal, all MA organizations that operate eligible plans during the ADVaNCE MA model's performance period would be required to participate in the model and offer eligible plans under

contracts that meet requirements proposed in section VIII.D.4.b of this proposed rule. Note that proposals to establish and describe eligible plans and Mandatory States are discussed in sections VIII.D.2 and 3, respectively, of this proposed rule, and that the contract structure requirements for the ADVaNCE MA model are discussed in detail in section VIII.D.4. In the sections that follow, we describe our rationale for proposing mandatory participation and the scope of MA organizations subject to that requirement.

We seek comment on our proposal and whether any modifications to the timing for model participation or ongoing participation requirements are warranted.

a. Rationale for Mandatory Participation

We considered making the ADVaNCE MA model voluntary. We believe that a mandatory model is necessary to ensure that a sufficient number of MA organizations participate in the ADVaNCE MA model, such that the model test is representative of the Nation and that CMS will be able to conduct a sound evaluation of the model's effects on cost and quality of care, in accordance with section 1115A(b)(4) of the Act.

CMS' past experience with models shows that potential model participants can be reluctant to participate voluntarily in any model in which their Medicare payments could be subject to change, and we do expect that this dynamic would be present with respect to the ADVaNCE MA model, specifically. Because payments under the Diamond Ratings system would be based on an MA organization's relative performance within its local market (see the discussion of Diamond Ratings system scoring methodology in section VIII.F.3 of this proposed rule), we believe that MA organizations that anticipate a competitive advantage under this new payment structure would be more likely to participate voluntarily than organizations that do not anticipate such an advantage. Under a voluntary design, this dynamic would be likely to produce a participant pool skewed toward organizations expecting favorable outcomes, rather than one representative of the national distribution of MA organizations. Additionally, we believe that voluntary participation in the model would make evaluations more challenging because, under a

voluntary participation scenario, different MA organizations within the same service area could operate under different quality payment structures: some organizations' payments would be predicated on the Diamond Ratings system of the ADVaNCE MA model, as described in section VIII.F.4, while others would continue to be in the standard MA and Part D Star Ratings and QBP system, which operates under a fundamentally different structure. Having MA organizations in the same market operate under different quality payment structures would complicate evaluation results. Because the ADVaNCE MA model would establish a new quality payment structure, CMS acknowledges that individual contracts may experience changes in payment based on the application of policies under the ADVaNCE MA model's Diamond Ratings system. The first payment under the Diamond Ratings system would not occur until 2032, which is the first time that we expect ADVaNCE MA model participants may experience increases or decreases in associated payments relative to their previous QBP. Because the Diamond Ratings system payments are based on relative performance within a market, and we cannot definitively predict how each ADVaNCE MA model participant within a market would perform in the model, we do not have specific estimates for any potential participant for their payment rates during the ADVaNCE MA model's performance period as this method of measurement is unique to the Diamond Ratings system and ADVaNCE MA model requirements. CMS will continue efforts to ensure MA organizations are able to provide uninterrupted, high-quality care to beneficiaries by considering and incorporating feedback received through comments to this proposed rule and by releasing additional guidance via Health Plan Management System (HPMS) memos prior to the ADVaNCE MA model start date to ensure ADVaNCE MA model participant readiness.

To facilitate the generalizability of model evaluation results, and as described in more detail in this section, we believe that mandating participation would minimize the risk of potential distortions in the model's effects on outcomes resulting from self-selection as described earlier in section VIII.A.3.

We seek comment on our proposal to make participation in the ADVaNCE MA model mandatory.

b. Scope of Mandatory Participation

There are two major elements to the proposed mandatory construct for the ADVaNCE MA model: eligible plan types and geographic areas. We discuss the eligible plan types for which mandatory participation would apply in section VIII.D.2 and the proposal for geographic areas in VIII.D.3. Under these proposals, all MA organizations offering eligible plans within the Mandatory States would be subject to ADVaNCE MA model requirements. Plans offered by MA organizations in States other than the Mandatory States would not be subject to ADVaNCE MA model requirements. To accommodate this scope, our proposals discussed in section VIII.D.2 would require MA organizations operating eligible plan types for which mandatory participation would apply to organize into contracts that meet the requirements described in section VIII.D.4 of this proposed rule. As noted in section VIII.D.1 above, at § 516.100(a), we propose to establish the participation unit at the contract level in accordance with § 516.150 and as discussed in section VIII.D.4 of this proposed rule. We considered establishing participation units at the level of MA plans rather than MA contracts. While we believe this alternative participation unit would have been simpler for MA organizations to implement and for CMS to include or exclude specific plan types from the model, operational considerations led us to ultimately propose MA contracts as the participation unit. Specifically, the current infrastructure of the MA program relies on several information systems to collect and calculate integral metrics for MA organizations at the contract level. For example, HPMS, which handles the data collection and reporting activities that MA and Part D plans must complete, organizes nearly all plan-level data by MA contract number. The MA and Part D Star Ratings and QBP system evaluates quality at the contract level, which shapes the benchmarks that plans within an MA contract bid against to set base capitated payment rates; CMS then adjusts these rates further through risk adjustment at the contract level. CMS also determines compliance, oversight, and

sanctions—including termination circumstances under 42 CFR 422.510 and MLR requirements under 42 CFR Part 422 Subpart X—at the contract level. Accordingly, an MA-based model that used a participation unit other than the MA contract would require far more extensive changes to several critical CMS systems than a model that continues to use the contract as its participation unit. Therefore, we are not proposing an alternative participation unit, to ensure the operational feasibility of the ADVaNCE MA model.

We seek comment on our proposal to use MA contracts as our unit of participation.

2. Plan Eligibility

At § 516.100(b)(1), we propose to identify an eligible plan as one that operates within a Mandatory State, is not ineligible under § 516.100(b)(2), and is one or more of the plan types for testing described in subsection VIII.D.2.a., below. We believe this broad approach to inclusion would create a representative testing environment that reflects the MA landscape and enables CMS to better assess the ADVaNCE MA model's reforms across different plan structures.

We considered defining eligible and ineligible plans for the ADVaNCE MA model by service area. However, we believe this approach is unnecessary. As discussed in section VIII.D.4 of this proposed rule, MA organizations that participate in the model would be required to organize eligible plan types under a contract structure specific to the ADVaNCE MA model that limits each plan’s service areas to a single Mandatory State.

We wish to clarify here that we are not proposing to test any PACE organizations under the ADVaNCE MA model. PACE is separate from the MA program and operates under separate authorities (section 1894 of the Act for Medicare and section 1934 of the Act for Medicaid) that are distinct from MA authority.

a. Eligible Plan Types

We propose at § 516.100(b)(1) that an eligible plan would be one that operates within a Mandatory State, would not be ineligible under § 516.100(b)(2), and is one or more of the following plan types (which are listed in clauses (i) through (v), respectively): (1) Health

Maintenance Organizations (HMOs) that are not ineligible under § 516.100(b)(2), (2) Local Preferred Provider Organizations (PPOs) that are not ineligible under § 516.100(b)(2), (3) Chronic Condition Special Needs Plans (C-SNPs); (4) Private Fee-for-Service (PFFS) plans; and (5) D-SNPs subject to § 516.100(c) (discussed in section VIII.D.2.a.(3) below). We note that we discuss proposed ineligible plans in section VIII.D.2.b. We discuss the interactive effects of our proposed eligibility and ineligibility provisions in each applicable plan type's discussions. To begin, we describe our reasoning for each plan type's eligibility below.

(1) Local CCP Plans: Non-SNP and non-Employer Group

As described above, we propose at § 516.100(b)(1)(i) and § 516.100(b)(1)(ii) to include as eligible plan types HMOs and Local PPOs that would not be ineligible under § 516.100(b)(2) respectively. Under our proposal, these plan types refer to MA HMO and local PPO plans as defined under 42 CFR 422.4. Further, as detailed in section VIII.D.2.b, under our proposal, even if a plan is one of these two types, it would be ineligible if it is an I-SNP, EGWP, or a D-SNP that opted out pursuant to § 516.100(c).

In 2026, approximately 99 percent of all Medicare beneficiaries live in a county where HMO and Local PPO plans are available, not including plans with restricted enrollment (e.g., SNPs and EGWPs).[162] Because of their collective prevalence, we believe that including these plan types is essential to understanding the ADVaNCE MA model's effects on the MA market as their standardized operational structures — including network management, care coordination, and quality improvement activities — provide a consistent foundation for implementing the model's requirements at scale across a large and diverse beneficiary population.

We solicit comments on the inclusion in the ADVaNCE MA model of HMO and Local PPO plans that are not I-SNPs, EGWPs, or D-SNPs that opted out pursuant to § 516.100(c).

(2) C-SNPs

[162] Medicare Payment Advisory Commission, *A Data Book: Health Care Spending and the Medicare Program* (July 2026), 134, https://www.medpac.gov/wp-content/uploads/2026/07/July2026_MedPAC_DataBook_Sec9_SEC.pdf.

As described above, we propose at § 516.100(b)(1)(iii) to include C-SNPs as an eligible plan type. Under the proposal, all C-SNPs that operate within the Mandatory States would be included in the model. Under 42 CFR 422.4(a)(1)(iv)(A), C-SNPs may focus on one severe or disabling chronic condition, as defined in 42 CFR 422.2, or on a grouping of severe or disabling chronic conditions. Upon approval, an MA organization may offer a C-SNP that focuses on multiple commonly co-morbid and clinically linked conditions, which are specified in subclauses *(1)* through *(8)* of 42 CFR 422.4(a)(1)(iv)(B). These plans provide specialized care management and clinical programs tailored to the needs of enrollees with these conditions.

One of the strategic pillars of the CMS Innovation Center is promoting evidence-based prevention.[163] Research has shown that targeted interventions for MA enrollees living with chronic conditions reduce hospitalizations, emergency department visits, and risk of mortality.[164,165] As of February 2026, the number of C-SNPs had increased by 46 percent since February 2025 and enrolled about 5 percent of all MA enrollees.[166] We believe including C-SNPs in the ADVaNCE MA model would allow us to evaluate: (1) the impact on operations of C-SNPs serving enrollees with specific severe or disabling chronic conditions; (2) how disease-specific risk factors interact with the ADVaNCE MA model's payment methodology; and (3) how outcomes would compare between enrollees who are living with chronic conditions and those who are not.

We solicit comments on the inclusion of C-SNPs in the ADVaNCE MA model.

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[163] Centers for Medicare & Medicaid Innovation Center, "CMS Innovation Center 2025 Strategy to Make America Healthy Again," Strategic Direction, Centers for Medicare & Medicaid Services, last modified March 2026, https://www.cms.gov/priorities/innovation/about/strategic-direction.

[164] Better Medicare Alliance, 2022 State of Medicare Advantage Report (Washington, DC: Better Medicare Alliance, 2022), 23, https://bettermedicarealliance.org/wp-content/uploads/2022/11/BMA-State-of-MA-2022.pdf. The report notes beneficiaries with major complex chronic conditions in Medicare Advantage – a demographic that includes many C-SNP beneficiaries – saw a 48 percent lower rate of avoidable hospitalizations for any reason and a 12 percent lower rate of hospital readmissions than similar beneficiaries in OM Medicare.

[165] Bryan N. Becker et al., "Association of Chronic Condition Special Needs Plan With Hospitalization and Mortality Among Patients With End-Stage Kidney Disease," JAMA Network Open 3, no. 11 (2020): e2023663, https://doi.org/10.1001/jamanetworkopen.2020.23663. This study showed lower hospitalization risks and mortality risks among End Stage Renal Disease patients enrolled in C-SNPs in comparison to those not enrolled in C-CNPs.

[166] Medicare Payment Advisory Commission, *A Data Book: Health Care Spending and the Medicare Program* (July 2026), 134, https://www.medpac.gov/wp-content/uploads/2026/07/July2026_MedPAC_DataBook_Sec9_SEC.pdf.

(3) D-SNPs

We propose at § 516.100(b)(1)(v) to include D-SNPs as eligible plan types. Under our proposal, all D-SNPs that operate within the Mandatory States would be included in the ADVaNCE MA model, unless, as discussed in section VIII.D.2.c., the State Medicaid Agency opts-out—that is, elects to exclude all D-SNPs operating in their State from participation in the ADVaNCE MA model. Because the State Medicaid Agency opt-out proposal is discussed in detail in section VIII.D.2.c. of this proposed rule, in this section we focus on the proposed inclusion of D-SNPs as eligible plan types.

D-SNPs are categorized into three integration types: Fully Integrated Dual-Eligible (FIDE) SNPs, Highly Integrated Dual-Eligible (HIDE) SNPs, and Coordination-Only (CO) D-SNPs. FIDE SNPs and HIDE SNPs are defined in 42 CFR 422.2, while CMS uses the term "Coordination-Only D-SNP" to refer to D-SNPs that are not FIDE SNPs or HIDE SNPs and that instead meet the additional contract requirement at § 422.107(d)(1), except as provided in 42 CFR 422.107(d)(2). As defined in 42 CFR 422.561, applicable integrated plans (AIPs) are either (1) a FIDE SNPs or HIDE SNPs with exclusively aligned enrollment, as defined in 42 CFR 422.2, that is linked to a Medicaid managed care plan under common ownership to cover Medicaid services or (2) a CO D-SNP that limits enrollment to individuals already enrolled in Medicaid managed care organizations, and requires a capitated contract between the MA organization (or related entities) and either a Medicaid agency or Medicaid managed care organization that must cover the Medicaid services for primary care and acute care as well as at least one of the following: (a) home health services; (b) medical supplies, equipment, and appliances; and/or (c) nursing facility services.

Given the diversity of D-SNP integration levels and their collective role in serving the majority of SNP enrollees, including all D-SNP types as eligible plans offers the most robust opportunity for evaluation under the ADVaNCE MA model while preserving State Medicaid Agency flexibility. Given the ADVaNCE MA model's proposed changes to quality rating

measurement described in section VIII.F of this proposed rule, the inclusion of all D-SNPs, regardless of integration levels, enhances the ability of dually eligible beneficiaries to evaluate and select D-SNPs based on quality ratings that reflect their needs.

We considered two alternatives to our proposal to make D-SNPs of all integration levels eligible plan types for the ADVaNCE MA model. First, we considered proposing the exclusion of all D-SNPs because of the complex coordination requirements between Medicare and Medicaid services and varying levels of integration across different D-SNP configurations, which we recognized could complicate the implementation of the ADVaNCE MA model. Second, we considered proposing that all non-AIP CO D-SNPs participate in the ADVaNCE MA model because they historically hold the highest share of D-SNP enrollees and offer the minimum required level of integration. Though we recognize that more highly integrated D-SNP types, such as FIDE SNPs and HIDE SNPs, must meet extensive Medicare-Medicaid coordination, enrollment, and benefit coverage requirements, we considered that non-AIP CO D-SNPs could adapt to the ADVaNCE MA model's temporary changes while still providing meaningful data on their impact. We rejected these first two alternatives as we believe that broader participation of D-SNPs in the ADVaNCE MA model would strengthen the model's evaluation by increasing sample sizes, improving demographic heterogeneity, and producing more statistically robust and generalizable findings. Further, including D-SNPs of all integration levels ensures that all D-SNPs in a Mandatory State that do not opt out—as discussed in section VIII.D.2.c—operate under a cohesive set of rules. While dually eligible beneficiaries enrolled in C-SNPs and general MA plans would continue to have access to the model's benefits, CMS believes it is important that the model's potential benefits extend to dually eligible beneficiaries across all D-SNP integration levels. Broad inclusion of D-SNPs also avoids uneven incentives across the market that may distort D-SNP behavior and undermine the integrity of the ADVaNCE MA model's test conditions.

We solicit comments on the inclusion of D-SNPs of all integration levels as eligible plan types in the ADVaNCE MA model.

(4) MA PFFS Plans

We propose at § 516.100(b)(1)(iv) to include PFFS as eligible plan types. Under our proposal, all PFFS plans that operate within the Mandatory States would be included in the ADVaNCE MA model. We propose inclusion of PFFS plans as they share important operational characteristics with Local PPO plans, such as offering enrollees flexibility in provider selection without requiring referrals from primary care providers and offering enrollees flexibility in out-of-network provider selection. Like Local PPO plans, PFFS plans also submit bids against county-level benchmarks and receive capitated per-member per-month payments from CMS, making their payment structure broadly compatible with the ADVaNCE MA model design. We believe that because PFFS plans are operationally and financially similar to other eligible plan types proposed for inclusion, their inclusion is feasible without requiring substantial modifications to the model's design. Broadly, we believe that by including plan types in the ADVaNCE MA model where it is feasible to do so, we strengthen the model's evaluation by increasing sample sizes and capturing results from the model's application to a variety of plan types, ultimately improving the generalizability of findings across eligible plan types. Specifically, the inclusion of PFFS plans allows CMS to evaluate the impacts of the ADVaNCE MA model on an MA plan type subject to varying network requirements, as described under 42 CFR 422.114(a)(3), and a prohibition on the use of prior authorization under 42 CFR 422.138(a).

We considered excluding PFFS plans from the ADVaNCE MA model because they may lack provider networks and have a different approach to care coordination compared to other MA plan types. However, we determined that these differences do not represent a barrier to participation and that inclusion of PFFS plans strengthens the model's evaluation as described above. Accordingly, we are not proposing the exclusion of PFFS plans.

We solicit comments on inclusion of PFFS plans as eligible plan types in the ADVaNCE MA model.

b. Ineligible Plan Types

We propose at § 516.100(b)(2) that an ineligible plan is one of the following plan types (listed at clauses (i) through (iv), respectively): (1) Institutional SNPs (I-SNPs); (2) Medical Savings Accounts (MSAs); (3) Regional Preferred Provider Organization (RPPOs); and (4) EGWPs. In each case, we believe that including these plan types would conflict with ADVaNCE MA model-specific policies, as described in the following sections.

(1) I-SNPs

We propose in § 516.100(b)(2)(i) that I-SNPs are ineligible for the ADVaNCE MA model. I-SNPs are MA plans that restrict enrollment to MA-eligible individuals who meet the definition of institutionalized or institutionalized-equivalent (42 CFR 422.2), a population with particularly complex care needs that is highly sensitive to changes in plan benefit structures. We believe that including I-SNPs in the ADVaNCE MA model would introduce implementation and evaluation complexity that differs materially from the plan types otherwise proposed for inclusion for two primary reasons. First, I-SNP enrollees are among the highest-need beneficiaries in the MA program, and we believe that subjecting this population to the operational and benefit structure changes associated with ADVaNCE MA model participation could risk unnecessary disruptions to the specialized care and benefits they currently receive. While we recognize that a proportion of enrollees in other SNP types may also have high acuity needs or reside in skilled nursing facilities, I-SNPs are uniquely defined by and designed around the institutionalized population, making the potential risks of disruption more acute and uniform across their enrolled populations. Second, I-SNPs represent a relatively small share of total MA enrollment, and as a result, their inclusion would contribute minimally to the model's overall sample size and would not meaningfully impact the model's ability to generate generalizable

findings. Accordingly, we propose to exclude all I-SNP subtypes from the ADVaNCE MA model.

We solicit comments on our proposal to make I-SNPs ineligible for the ADVaNCE MA model.

(2) MSA Plans

We propose at § 516.100(b)(2)(ii) that MSA plans are ineligible for the ADVaNCE MA model. MSA plans have a fundamentally different payment and benefit structure compared to other MA plan types, such as HMOs and Local PPO plans, which we believe imposes the risk of skewing model evaluations. Specifically, unlike eligible plan types proposed for inclusion in the model, MSA plans do not directly submit bids against county-level benchmarks and are not paid based on a comparison of plan bids against county level benchmarks. Because the ADVaNCE MA model's payment approach is designed around the bid-to-benchmark payment structure common to other MA plan types, incorporating MSA plans would require substantial modifications to the ADVaNCE MA model's payment methodology and risk skewing model evaluations by introducing a structurally distinct comparator. Further, MSA plans generally lack provider networks that could be leveraged to improve quality through care coordination, which is the underlying foundation of the Diamond Ratings system, discussed in section VIII.F of this proposed rule. Overall, we believe excluding MSA plans would ensure that the ADVaNCE MA model could be implemented consistently across participating plan types without requiring substantial modifications to the ADVaNCE MA model's proposed payment approach to accommodate fundamentally different payment structures.

We solicit comments on our proposal to make MSA plans ineligible for the ADVaNCE MA model.

(3) RPPOs

We propose in § 516.100(b)(2)(iii) that RPPO plans are ineligible for the ADVaNCE MA model. We recognize that RPPOs use a different payment methodology than the majority of MA

plans. Unlike most MA plans, whose benchmarks are based on county rates, the benchmark for an RPPO plan is determined using a blend of the statutory regional benchmark and the weighted average of RPPO plan bids within the region which would create an uneven payment structure across plan types in the context of the ADVaNCE MA model. Excluding RPPO plans, as proposed, would allow for more consistent implementation across participating plan types while avoiding unnecessary complications associated with regional plan structures.

We solicit comments on our proposal to make RPPO plans ineligible for the ADVaNCE MA model.

(4) EGWPs

We propose in § 516.100(b)(2)(iv) that EGWPs are ineligible for the ADVaNCE MA model. EGWPs have a distinct regulatory and contractual framework (notably with respect to bidding requirements and enrollment mechanisms) and non-representative enrollee population relative to the MA plan types that we are proposing to be eligible for the ADVaNCE MA model. The bidding requirements for EGWPs differ from the standard MA bid submission process used by the other MA plan types we propose as eligible and would require consideration of additional payment policies unique to this plan type. Including EGWPs may also add complexity in navigating contracts between CMS, MA organizations, and employers or unions when implementing mandatory requirements for the ADVaNCE MA model. Beyond these complexities, EGWP enrollment processes and timelines observe unique flexibilities that are not available to individual MA plans, which we believe would limit the generalizability of the model's findings. Accordingly, we propose to exclude EGWPs from the ADVaNCE MA model.

We solicit comments on our proposal to make EGWPs ineligible for the ADVaNCE MA model.

c. Provisions for D-SNP Mandatory State Opt-Out

In § 516.100(c), CMS is proposing that State Medicaid Agencies can opt out all D-SNPs operating in a Mandatory State from ADVaNCE MA model participation. All other eligible plan

types with service areas in the Mandatory State would be required to participate in the ADVaNCE MA model.

CMS believes that D-SNPs represent a critical population for testing the ADVaNCE MA model parameters and that excluding all D-SNPs would materially limit the ADVaNCE MA model's ability to have generalizable findings, to the extent reasonable, for the population of dually eligible beneficiaries enrolled in these plans.

However, CMS recognizes that State Medicaid Agencies have significant and long-standing interests in D-SNPs operating in their States. D-SNPs are subject to State Medicaid Agency Contracts (SMACs) under § 422.107, which establish State-specific requirements for Medicaid managed care integration, care coordination, and benefit alignment. Changes to the operational and financial structure of D-SNPs resulting from ADVaNCE MA model participation could affect States' ability to fulfill their Medicaid managed care program obligations and coordination responsibilities under those contracts. For instance, State Medicaid Agencies that directly contract with D-SNPs to provide Medicaid managed care benefits may need to consider the implications of participation in this model where the SMAC is also the Medicaid managed care contract required to meet all statutory and regulatory obligations under Title XIX of the Act and 42 CFR Part 438. Therefore, CMS believes it is appropriate to provide States with a formal mechanism to opt-out all D-SNPs operating in the State from the ADVaNCE MA model.

Accordingly, CMS proposes in § 516.100(c)(1) that State Medicaid Directors have the option to exclude all D-SNPs from the mandatory participation requirements in their State for the entirety of the ADVaNCE MA model's performance period, which would otherwise begin in CY 2029, by sending a written opt-out notification to CMS via email at ADVaNCEMA@cms.hhs.gov. Additionally, considering that integration levels are permitted to change at any point during a contract year as warranted by amendments to a SMAC, we propose

in § 516.100(c)(2) that if a State Medicaid Director decides to submit an opt-out notification, this notification must apply to all D-SNPs operating in their State for the entirety of the model.[167]

To be accepted such that all D-SNPs are excluded from mandatory participation, an opt-out notification would be required to meet the criteria proposed at § 516.100(c)(3) and: (1) describe the State's specific concerns regarding D-SNP inclusion and the potential impact of ADVaNCE MA model participation on the State's Medicaid program obligations and coordination arrangements; (2) be submitted by the State Medicaid Director or a designee with authority to bind the State Medicaid Agency; and (3) be submitted in writing via email to ADVaNCEMA@cms.hhs.gov between June 8, 2027, or the anticipated effective date of the CY 2028 Medicare Advantage and Part D final rule (that is, 60 days after such a final rule is displayed in the **Federal Register**), and October 1, 2027 with the subject line "[State Name] D-SNP Opt-Out Notification." At § 516.100(c)(4), we propose that CMS will review and accept opt-out notifications submitted in accordance with the process described in proposed § 516.100(c)(3) and announce on the ADVaNCE MA model website which States have chosen to opt out their D-SNPs in October 2027.

As proposed in § 516.100(c)(5), D-SNPs operating in Mandatory States for which an opt-out notification has been accepted by CMS must be treated as ineligible plans under the model's proposed contract structure requirements at § 516.150. Moreover, at § 516.100(c)(6), we propose that an opt-out notification meeting the proposed requirements under § 516.100(c)(3) applies to all D-SNPs operating in the Mandatory State.

D-SNPs would be subject to mandatory participation requirements under § 516.100(a), considered as eligible plans under § 516.100(b)(1)(v), and subject to the contract restructuring requirements described in section VIII.D.4. of this proposed rule in any Mandatory State where the State Medicaid Director either did not submit a timely opt-out notification or submitted a

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[167] Centers for Medicare & Medicaid Services, Medicare Managed Care Manual, Chapter 16b, § 20.2.2.2.1, "Changes in Integration Status" (Rev. 131, issued Nov. 22, 2024), available at https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c16b.pdf.

notification that CMS did not accept for failure to meet the requirements of § 516.100(c)(3). We note that in accordance with § 516.100(c)(3)(i), CMS would not accept any opt-out notifications received prior to June 8, 2027. We believe this scoping provision is necessary to ensure that the opt-out mechanism operates in a manner that does not shift a given State's D-SNP landscape unevenly between plans with varying levels of integration. In the event that a State Medicaid director submits an opt-out request before such effective date, CMS would not accept such submission and notify the State Medicaid director that they must submit such an opt-out notification during the appropriate period of time as described in § 516.100(c)(3)(ii)(C).

CMS encourages State Medicaid Directors to engage with CMS prior to submitting an opt-out notification if a State has concerns about participation or the potential impact of D-SNP inclusion on the State's Medicaid program. CMS will also make staff available for consultations prior to the October 1, 2027 deadline for submitting an opt-out notification. CMS will make every effort to meet with all States that request such engagement, but request that States submit requests early to ensure there is sufficient time to address all questions. States should submit an email to the aforementioned mailbox (ADVaNCEMA@cms.hhs.gov) with the subject line "[State Name] Consultation Request" to request engagement with CMS. CMS will look to schedule engagement based on the order in which requests are received, with exact timing being driven principally by availability of key staff. CMS will also offer a webinar to States during the pre-implementation period to discuss participation by D-SNPs in the ADVaNCE MA model. However, consistent with our proposal at § 516.100(c)(6), neither the submission of a comment on this proposed rule nor a prior meeting with CMS would be a precondition for submitting an opt-out notification, and the absence of either would not affect CMS's consideration of a timely opt-out notification.Finally, the submission of a comment to this proposed rule or engagement with CMS does not replace the opt-out notification, CMS must receive and accept a timely opt-out notification in order for D-SNPs to be opted out of the model.

We recognize that Medicaid managed care procurement cycle or Medicaid managed care plan readiness reviews represent two processes that may span multiple years. The timeline associated with these processes may complicate a State Medicaid Director's decision to participate in the ADVaNCE MA model, even when the State would otherwise opt-in. To give State Medicaid Directors flexibility when these processes conflict with their intent to participate, we propose a process at § 516.100(c)(7)(i) that would provide a Mandatory State's Medicaid Director the opportunity to delay D-SNPs' participation by up to two years beginning with the ADVaNCE MA model's first performance year by submitting a written email request to CMS. Accordingly, this proposal would allow the Medicaid Director of a Mandatory State to request a delay in participation until as late as the ADVaNCE MA model's third performance year.

At § 516.100(c)(7)(ii), we propose that requests for delayed participation would be required to (1) specify the performance year, within two years of the ADVaNCE MA model's first performance year, in which the State Medicaid Agency would initiate participation of its D-SNPs, (2) justify the request as necessary due to either an ongoing Medicaid managed care procurement cycle or Medicaid managed care plan readiness review, and (3) be submitted in writing via email to ADVaNCEMA@cms.hhs.gov between June 8, 2027 and October 1, 2027 with the subject line "[State Name] D-SNP Opt-Out Notification."

Regarding CMS determinations, we propose at § 516.100(c)(7)(iii)(A) that CMS would accept any State Medicaid Director's request for delayed participation that meets the requirements described above. State Medicaid Directors with approved requests for delayed participation would no longer be able to submit an opt-out notification as proposed at § 516.100(c)(3). Additionally, Mandatory States with accepted requests for delayed participation would be listed on the ADVaNCE MA model website in October 2027. Conversely, as proposed at § 516.100(c)(7)(iii)(B), CMS would reject a State Medicaid Director's request for delayed participation that fails to meet the proposed requirements described above and would provide them the opportunity to submit an opt-out notification in accordance with § 516.100(c)(3) if they

wish to exclude D-SNPs in their State from participation for the entirety of the ADVaNCE MA model's performance period. Under this proposal, any State Medicaid Director that intends to submit an opt-out notification following the rejection of a request for delayed participation would be required to do so prior to the October 1, 2027 deadline proposed at § 516.100(c)(3)(ii)(C).

As discussed with opt-out notifications, CMS will make staff available for consultation prior to the October 1, 2027 deadline for submitting requests for delayed participation. State Medicaid Directors are encouraged to engage with CMS and request consultations by emailing ADVaNCEMA@cms.hhs.gov with the subject line "[State Name] Consultation Request." Further, we encourage State Medicaid Directors who wish to request delayed participation to do so as early as possible. This gives State Medicaid Directors whose requests for delayed participation are rejected enough time to prepare and submit an opt-out notification before the October 1, 2027 deadline, if they wish to do so.

We considered three alternatives to our proposed policy at § 516.100(c) to provide the option to State Medicaid Directors to exclude all eligible D-SNPs, as defined at proposed at § 516.100(b)(1)(v), in their State from mandatory participation in the ADVaNCE MA model First, we considered proposing that State Medicaid Directors in Mandatory States have discretion to submit opt-out notifications for a portion of their D-SNPs based on factors such as integration level or AIP designation. Second, we considered an alternative under which State Medicaid Directors in Mandatory States could submit opt-out notifications only for D-SNPs with higher integration levels, such as FIDE and/or HIDE SNPs. We rejected both alternatives due to operational and administrative concerns that would arise from subjecting D-SNPs with varying integration levels or AIP designations within the same Mandatory State to different rules based on their inclusion in the ADVaNCE MA model. Additionally, these alternatives were rejected due to additional complexities that could result from the fact that integration levels are permitted

to change at any point during a contract year as warranted by amendments to a SMAC.[168] The third and final alternative we contemplated proposing was to mandate participation for all D-SNPs, regardless of integration requirements, without the ability to opt out. However, we ultimately decided to allow for the State-level opt-out, proposed at § 516.100(c), to ensure that Mandatory States have freedom in administering their Medicaid program.

Additionally, we considered two alternatives to our proposals at § 516.100(c)(7) on delayed participation requests. First, we considered limiting State Medicaid Directors to a one-year delay in D-SNP participation, beginning with the model's first performance year. However, the acceptable processes for justifying a delayed participation request under § 516.100(c)(7)(ii)(B), that is, ongoing Medicaid managed care procurement cycles or plan readiness reviews, may span up to two years. Therefore, we decided to allow State Medicaid Directors to request up to a two-year delay, beginning with the model's first performance year, so State Medicaid Agencies would have enough time to complete these processes before transitioning to the ADVaNCE MA model. Second, among State Medicaid Agencies with accepted delayed participation requests, we considered a proposal that would allow State Medicaid Directors to submit an opt-out notification at any point between CMS' acceptance of a delayed participation request and October 1 of the year preceding the performance year in which the State Medicaid Agency's delayed participation would begin. However, we rejected this approach to ensure consistent application of the opt-out notification process proposed at § 516.100(c)(3) across all Mandatory States' Medicaid Agencies.

CMS believes the process proposed at § 516.100(c) appropriately balances the ADVaNCE MA model's need for broad D-SNP participation, which is essential for generating meaningful and generalizable findings for dually eligible beneficiaries, while preserving

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[168] Centers for Medicare & Medicaid Services, Medicare Managed Care Manual, Chapter 16b, § 20.2.2.2.1, "Changes in Integration Status" (Rev. 131, issued Nov. 22, 2024), available at https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c16b.pdf.

autonomy for States to engage in efforts that are best suited to support their care delivery and Medicaid integration initiatives.

We seek comment on the participating plan types and the excluded plan types. We specifically seek comment on the proposed D-SNP inclusion policy, including scope and timing, the State opt-out mechanism, and alternatives considered. We are interested in comments on whether D-SNP participation should be mandatory for all D-SNPs, regardless of integration level, or only AIP D-SNPs, whether the proposed requirements for opt-out in § 516.100(c)(3) are appropriate, and whether other specific opt-out criteria should be considered. We also seek comment regarding the alternative proposals considered for delayed participation requests. Specifically, we seek comment on whether State Medicaid Agencies should only be able to request delayed participation of up to one-year beginning with the model's first performance period. Further, we seek comment on whether State Medicaid Agencies should have the opportunity to submit opt-out notifications between the date of receiving an approved request for delayed participation and October 1 of the year preceding the performance year in which the State Medicaid Agency's delayed participation would begin.

3. Geographic Areas

We propose to describe at § 516.100(e) the geographic areas that would be included in the ADVaNCE MA model. Specifically, as discussed further in section VIII.D.3.b below, we propose to use States, including the District of Columbia (herein collectively referred to as "States"), as the selected geographic areas that determine mandatory participation in the ADVaNCE MA model. Under this proposal, all MA organizations that meet the participation requirements discussed in section VIII.D.2.a. of this proposed rule and operate within a Mandatory State would be subject to the ADVaNCE MA model, consistent with the contract-level participation framework discussed in section VIII.D.4. We further propose to exclude all U.S. Territories from eligibility as discussed in section VIII.D.3.c below, as well as any State that, based on the Monthly Enrollment by Contract/Plan/State/County data, MA State/County

Penetration, and Special Needs Plan (SNP) Data made publicly available for the timeframe described, had fewer than 1,000 beneficiaries enrolled in eligible plans. For Alaska and Connecticut, the applicable timeframe is July 2024. For all other States, the applicable timeframe is March 2026. The reason for these timeframes is discussed in section VIII.D.3.c relating to the exclusions and is explained more broadly in section VIII.D.3.d.

We would use a three-step process to determine the specific Mandatory States that would participate in the model, as described in more detail in this section. First, as described in section VIII.D.3.c of proposed rule, we propose to exclude States that do not meet our geographic inclusion criteria. Second, as described in section VIII.D.3.d. of this proposed rule, we propose to classify States into groups on the basis of their similarity across composite variables. Third, as described in section VIII.D.3.e. of this proposed rule, we propose to randomly select States from within each group.

a. Alternatives Considered

In developing the proposed ADVaNCE MA model, we considered several alternative approaches to using entire States for defining the geographic and organizational units that would be used for reportability of Diamond Ratings scores (see section VIII.F of this proposed rule). These alternatives included: (1) retaining the use of Original Contract Service Areas without modification; (2) using Office of Management and Budget (OMB)-defined Combined Statistical Areas (CSAs), or combinations of multiple CSAs, as the geographic unit; and (3) other organizational grouping configurations. After careful analysis, we determined, as discussed below, that none of these alternatives adequately achieved the policy objectives of the ADVaNCE MA model and, accordingly, we are not pursuing them.

(1) Original Contract Service Areas

We considered proposing existing MA contract service areas, that is, the geographic boundaries already established under each MA contract with CMS, as the sole basis for defining the geographic unit of participation and reportability. Under this approach, MA organizations

would have been evaluated for reportability solely within the boundaries of their existing contract service areas, as those areas are defined at the time of bid submission.

We believe that using existing contract service areas would inhibit the goals of the model around competition based on quality. Relying solely on existing contract service areas without modification would be inconsistent with our goal of testing the ADVaNCE MA model's impact on program expenditures and quality within a regional market that was applicable to a beneficiary's care experience. Additionally, utilizing the original contract service areas can lead to comparison of possibly incontiguous areas of the county, making the presentation of quality information to potential or current MA enrollees confusing. Though Star Ratings utilizes this approach, the use of a set geographic area was paramount to the Diamond Ratings program to promote local competition and geographic region easily understood by beneficiaries.

We also considered whether contract service areas could be combined on an ad hoc or manual basis, for example, by grouping geographically proximate or administratively related service areas without the application of a systematic, replicable algorithm. We determined that this approach would introduce inconsistency, lack transparency, and be difficult to administer uniformly for similarly situated MA organizations at scale across the full population of MA organizations participating in the ADVaNCE MA model. We believe that such potential inconsistency and lack of transparency could undermine the models' goal of enhancing competition.

(2) Combined Statistical Areas

We also considered the use of OMB-defined CSAs, which are broad geographic units that aggregate adjacent Core-Based Statistical Areas (CBSAs) based on economic and commuting ties, as the geographic unit for reportability determinations under the ADVaNCE MA model. We further considered whether combinations of multiple CSAs could be constructed to serve as adequate reportability units for the purposes of the Diamond Ratings system, with sufficient enrollment size. While the level of granularity, especially for the Diamond Ratings system, is

desirable to CMS for its additional level of geographic detail, after careful analysis, we determined that neither the OMB CSA approach nor the multiple-CSA approach was appropriate for the ADVaNCE MA model for the reasons set forth below.

OMB-defined CSAs are delineated based on economic and social integration among adjacent metropolitan and micropolitan statistical areas, as reflected in commuting patterns and other indicators of functional interdependence.[169] While this framework serves important purposes in Federal statistical and administrative programs, it was not designed to reflect the geographic structure of MA contracting. MA contracts are organized at the county level and are established through county-level elections that reflect market strategy, network adequacy, and operational capacity, not the economic integration criteria that underlies OMB's CSA delineations.[170] Additionally, CBSAs and therefore CSAs can cross state lines. Because the ADVaNCE MA model, as proposed, would include D-SNPs, such potential spanning of State lines would introduce the complication that within the mandatory geographic unit there could be inconsistent State-level policies for dually eligible beneficiaries. Therefore, we believe that CSAs would complicate and impede aspects of the ADVaNCE MA model.

OMB-defined CSAs also do not provide comprehensive coverage of the United States. As of the most recent OMB delineations, a substantial portion of the U.S. population and a corresponding share of MA beneficiaries reside in counties that are not included within any CSA, including counties that are part of standalone Metropolitan Statistical Areas, Micropolitan Statistical Areas, or that fall outside all OMB-defined metropolitan and micropolitan delineations entirely.[171] Because MA enrollment can occur nationally, in non-CSA counties, a reportability

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[169] Office of Management and Budget, OMB Bulletin No. 23-01: Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas (July 2023), https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.

[170] Centers for Medicare & Medicaid Services, "Medicare Advantage/Part D Contract and Enrollment Data," Data and Research, last modified June 2026, https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data.

[171] Office of Management and Budget, OMB Bulletin No. 23-01: Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas (July 2023), https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.

framework anchored to CSA boundaries would systematically exclude or disadvantage MA organizations with significant enrollment in non-CSA counties. This would create unfair differences in treatment among similarly situated organizations and undermine the ADVaNCE MA model's goal of broad, representative participation across the national MA market. Additional detail regarding the process to create a nationally representative set of Mandatory States can be found in section VIII.D.3.d. of this proposed rule (Stratification Methodology).

We further considered whether the limitations of individual CSAs could be addressed by constructing reportability from combinations of multiple CSAs (for example, by aggregating adjacent or regionally proximate CSAs to achieve enrollment denominators sufficient for quality reporting under the Diamond Ratings system). We rejected this approach for several reasons, as described in this section.

First, there is no established Federal framework for systematically combining OMB-defined CSAs into larger geographic units for administrative or programmatic purposes. OMB's statistical area delineations are intended to reflect functional economic relationships among adjacent communities; combining multiple CSAs into larger composite units would depart from the underlying conceptual basis of the OMB framework and produce geographic units that lack a coherent administrative or analytical rationale.

Second, the construction of multiple CSA combinations would require significant discretion in determining which CSAs to aggregate and on what basis. Whether combinations were defined by geographic contiguity, enrollment size, market concentration, or other criteria, the resulting units would be difficult to define transparently and apply consistently. This discretionary complexity was part of the reason this option was considered and not proposed. Even if we were able to determine a reasonable method for constructing multi-CSA units, such an approach would not capture the non-CSA areas and therefore would not solve the above-described problems stemming from that exclusion.

(3) Other Organizational Configurations

We considered alternative organizational configurations, including approaches that would have applied uniform national or regional thresholds without regard to contract service area boundaries, or that would have grouped MA organizations across cohort designations. These alternatives were considered but not proposed for the following reasons.

First, our analysis indicates that the impact of any grouping methodology would not be uniform across parent organizations. Smaller parent organizations or those in the lower enrollment quartiles experienced negligible changes in reportability regardless of the grouping approach applied. This reflects the structural reality that smaller parent organizations may either have widely dispersed enrollment that is insufficient to meet reportability thresholds within any given service area or have enrollment that is so geographically concentrated that reportability is determined primarily by whether their service area falls within a specific geographic area. Alternative configurations applying uniform thresholds would not have resolved these underlying structural challenges and would have introduced additional administrative complexity without commensurate benefit.

Second, approaches that ignored contract service area boundaries would have obscured meaningful geographic variation in MA market structure and enrollment patterns, undermining the goal of geographic integrity of quality measurement and further complicating the ADVaNCE MA model's evaluation design. Additionally, ignoring contract service area boundaries would have complicated payments between CMS and MA organizations, which are completed at the contract level, including payments under the Diamond Ratings system. While we acknowledge there would be mandated alterations to contracts to abide by the service area requirements within Mandatory States, we believe this approach allows us to keep operations as similar as possible to payments absent the model.

Third, configurations that grouped parent organizations in a way that did not allow for cohort designations were rejected because these cohorts reflect meaningful clinical and organizational distinctions among MA contracts. We believe that collapsing these distinctions

solely to achieve reportability thresholds would compromise the comparability of quality measures across similarly situated plans and reduce the analytical validity of ADVaNCE MA performance assessments.

We seek comment on whether CSAs, CBSAs, or some other geographic unit would be better suited for the ADVaNCE MA model than using entire States.

b. Rationale for States as the Geographic Unit

As described above, we are proposing to designate entire States as the mandatory geographic unit of participation for the ADVaNCE MA model. We believe States are the most appropriate geographic unit for the ADVaNCE MA model for the following reasons:

● Representative breadth: CMS officially recognizes five types of counties for purposes of MA network adequacy: Large Metropolitan, Metropolitan, Micropolitan, Rural, and Counties with Extreme Access Considerations.[172] Each county type has unique characteristics and other MA attributes. States naturally incorporate all five county types, making them ideal for capturing the full range of MA market dynamics and ensuring the ADVaNCE MA model's findings are generalizable to the different county types for potential nationwide adoption in the future. In particular, if this model is expanded, including potentially being implemented on a nationwide basis, pursuant to section 1115A(c) of the Act, we believe that a geographic unit that encompasses the full variety of county types would best serve such an expansion in the context of MA because MA employs county specific policies, like contract service areas.[173]

● Operational alignment with contract-level participation: In section VIII.D.4. of this proposed rule, we discuss our proposals for ADVaNCE MA model contract restructuring. When the geographic unit is defined at the State level as we are proposing, that contract restructuring can be implemented cleanly along State lines, ensuring that the contracts that result from the proposed restructuring as described in that section are either wholly within or wholly outside a

[172] 42 CFR 422.116, https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-C/section-422.116.
[173] 42 CFR 422.2, https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-A/section-422.2.

Mandatory State. We believe that this approach is more straightforward to implement and administer than geographic units that would require intra-State contract splitting or county-level carve-outs.

● Mitigation of adverse selection and market avoidance: We believe that statewide implementation would make it harder for potentially eligible MA organizations to avoid ADVaNCE MA model participation because they would not be able to do so without materially exiting an entire State market. Under a CSA-based approach, MA organizations could potentially adjust service areas or product offerings at a more localized level to avoid selected geographies while continuing to operate elsewhere in the same State. We believe that statewide participation would reduce opportunities for that type of geographic avoidance and would apply the ADVaNCE MA model more uniformly across similarly situated organizations within the selected State.

● Rural access and guardrails: We believe that statewide participation would allow high-performing MA organizations operating in rural areas to benefit from the Diamond Ratings system (described in section VIII.F of this proposed rule) rather than excluding rural counties or creating uneven treatment within a State, as would be a consequence of CSA delineation. We believe that this approach would be consistent with CMS's commitment to rural MA beneficiaries by ensuring that they are not systematically excluded from the benefits of ADVaNCE MA model participation.

● Simplicity and stability of State definitions: States are the simplest geographic unit to define for purposes of the ADVaNCE MA model scope. Unlike CBSAs and CSAs, which are subject to periodic OMB delineation updates, including annual adjustments and a mid-decade boundary adjustment, State boundaries are stable and do not require ongoing administrative adjustment.[174] We expect that stability in State boundaries would reduce operational burden for

[174] Office of Management and Budget, *2020 Standards for Delineating Core Based Statistical Areas*, 86 FR 37770, 37777 (July 16, 2021).

CMS and ADVaNCE MA model participants over the course of the ADVaNCE MA model, particularly in light of our proposal in section VIII.C.2 to implement the model over a 10-year performance period. States also are a concept that beneficiaries are familiar with, which will be important for the model, for example, because the Diamond Ratings system would appear differently from the Stars Ratings system in Medicare Plan Finder (as discussed further in section VIII.F.3 of the proposed rule). Having the ADVaNCE MA model's geographic area be defined as Mandatory States also simplifies the dual eligibility criteria necessary to operationalize the D-SNP cohort as described in section VIII.D.4.

CMS seeks comment on our proposal at § 516.100(e)(1) to use States as the geographic unit for the ADVaNCE MA model.

c. Scope of Geographic Exclusions

As described above, the first step in our determination of Mandatory States is to apply proposed exclusions. We are proposing to establish in § 516.100(e)(1)(ii) that two categories of geographic areas are excluded from eligibility for selection as Mandatory States. First, we propose at § 516.100(e)(1)(ii)(A) to exclude all U.S. Territories, and second, we propose at § 516.100(e)(1)(ii)(B) to exclude any State that, based on the Monthly Enrollment by Contract/Plan/State/County data, MA State/County Penetration data, and Special Needs Plan (SNP) data made publicly available for the timeframe described, had fewer than 1,000 beneficiaries enrolled in eligible plans as described under § 516.100(b).[175] For Alaska and Connecticut, the applicable timeframe is July 2024. For all other States, the applicable timeframe is March 2026. The first proposed exclusion criterion applies to all U.S. Territories, including Puerto Rico, because U.S. Territories have a unique statutory and regulatory framework for Medicare and Medicaid financing, which would create significant challenges for the cost-savings estimation methodology central to the ADVaNCE MA model. Unlike the States, U.S. Territories

[175] For Alaska and Connecticut, the most recent year of data available at the time that data were pulled was 2024. The July 2024 data served as the mid-year data point in these cases.

are not eligible for the Part D LIS under section 1860D–14(a)(3)(F) of the Act and 42 CFR 423.907(a)(1). However, as discussed in section VIII.G.2 of this proposed rule, we consider LIS-targeting of supplemental benefits, as proposed at § 516.300, and any costs and quality improvements associated with them, to be an essential part of the ADVaNCE MA model. Because of the inability of U.S. Territories to participate in the LIS-targeting of supplemental benefits component of the model, the cost comparisons between U.S. Territories and States would be less meaningful, and, we believe, would substantially diminish the scope of the LIS-related policy tested in a way that would be unique to U.S. Territories, because participants located in U.S. Territories would not be able to offer and enrollees would not be able to receive the LIS-targeted supplemental benefits. Furthermore, U.S. Territories receive funding through the Enhanced Allotment Plan under section 1935(e) of the Act—a U.S. Territory-specific funding mechanism whose inclusion we believe would complicate the development of a unified cost-savings estimate. Additionally, U.S. Territories are not required to establish Medicare Savings Programs under section 1905(p)(4)(A) of the Act, and no U.S. Territory employs a Medicare Savings Program.[176] For these reasons, we propose to exclude U.S. Territories. As such, under the proposal, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands would be ineligible for participation.

Second, to enhance the likelihood of Mandatory States having sufficient MA market participation to generate comprehensive evaluable data, we propose to exclude States that, based on the Monthly Enrollment by Contract/Plan/State/County data, MA State/County Penetration, and Special Needs Plan (SNP) Data made publicly available for the timeframe described, had fewer than 1,000 beneficiaries enrolled in eligible plans described under § 516.100(b). For Alaska and Connecticut, the applicable timeframe is July 2024. For all other States, the

[176] Centers for Medicare & Medicaid Services, "Medicaid Program; Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment, and Renewal Processes" final rule (89 FR 22780) (April 2, 2024), https://www.federalregister.gov/documents/2024/04/02/2024-06566/medicaid-program-streamlining-the-medicaid-childrens-health-insurance-program-and-basic-health.

applicable timeframe is March 2026. We used the most recent data available at the time we were considering geographic exclusions in our proposed Mandatory States.[177]Estimates of means and rates can be skewed by outliers, and this risk of skewed results is large when there are fewer enrollees. As such, a very small number of enrollees with extreme values within a single State could distort the results for that State to a greater extent than those same outliers affect results in a State with many enrollees. We expect that excluding States with extremely small numbers of enrollees would not change the overall generalizability of model evaluation findings and would reduce the risk of skewed model test results. We believe that introducing a State-level minimum number of beneficiaries enrolled in eligible plans would decrease the likelihood of this data quality issue occurring for every MA parent organization cohort in a State and by extension the risk of leaving the model evaluation without any usable measures for a State. Applying this exclusion as proposed would result in only Alaska additionally being ineligible for participation.

For the reasons described above, we would exclude every U.S. Territory as well as Alaska from participation eligibility under the proposed geographic exclusion criteria. CMS has determined that establishing additional geographic exclusion criteria would be inconsistent with the goals of the ADVaNCE MA model and the statutory authority under section 1115A of the Act. We considered whether to establish broader geographic exclusion criteria that would exempt certain States or jurisdictions from the Mandatory State designation process. After careful consideration, we determined that no such geographic exclusion criteria were warranted beyond the U.S. Territory exclusion and the minimum enrollment exclusion described earlier. We believe that universal applicability of the stratified random sampling process across all eligible States is necessary to achieve the policy objectives of this rule, to ensure consistency in ADVaNCE MA model administration, and to prevent adverse selection that could undermine the integrity and generalizability of the ADVaNCE MA model test.

[177] For Alaska and Connecticut, the most recent year of data available at the time that data were pulled was 2024. The July 2024 data served as the mid-year data point in these cases.

We seek comment on our proposal at § 516.100(e)(1)(ii) to exclude from eligibility for selection as Mandatory States all U.S. Territories and any State that, based on the Monthly Enrollment by Contract/Plan/State/County data made publicly available for March 2026, had fewer than 1,000 beneficiaries enrolled in eligible plans described under § 516.100(b).

d. Stratification Methodology

We propose at § 516.100(e)(1)(i) to identify Mandatory States, including the District of Columbia, for the ADVaNCE MA model through a stratified random sampling methodology. Our goal with stratification is to select, in a fair way, a small set of States that reflect the heterogeneity of the Nation on characteristics that CMS considers relevant to the ADVaNCE MA model. Individual States may have unique or similar profiles with respect to the combinations of these characteristics. We believe that such characteristics consist of market competitiveness, size of the MA market, MA market structure, and market geographic homogeneity. We believe that stratifying States based on the profiles generated by the below-described process support the production of a nationally representative sample and longer-term use of the model.[178] Further, pursuant to section 1115A(b)(4) of the Act, the proposed stratification of States would support CMS's ability to evaluate the quality of care furnished under the model and changes in program spending due to the model.

CMS determined from power calculations for the proposed evaluation, discussed in section VIII.D.3.e, that 12 States would be a sufficient sample size to test the model. Below and in the following section VIII.D.3.e, we propose a method to determine, in a fair and impartial manner, the 12 States to be selected as Mandatory States, using random selection while obtaining a nationally representative sample.

Our analysis allows for selecting multiple measures from the State characteristics for stratification described below, rather than stratifying on only one or a narrow subset of measures

[178] These characteristics are used to stratify States for purposes of the State selection methodology and are distinct from the outcomes CMS will assess in evaluating the effects of the model.

within a characteristic or a subset of characteristic— because profiles of States are multidimensional. We considered an alternative approach of stratifying States upon a subset of the proposed measures. However, we believe that a profile accounting for the multiple, relevant measures of characteristics described below would better reflect similarities and differences among State MA markets leading to a representative sample. We used a similar stratification approach as the Home Health Value Based Purchasing Model which incorporated several characteristics into the stratification process to group States before randomly selecting Mandatory States.[179] State MA markets may have more or different characteristics relevant to the model than State home health markets and thus we determined it was appropriate to include all the measures described later in the section to construct State profiles for the ADVaNCE MA model stratified random sample.

We propose applying a principal components analysis (PCA) to reduce the set of potentially interrelated measures to a smaller set of composite variables, which we would use to define the groups from which States would be selected. PCA is a widely used method in data science and machine learning that uses weighted combinations of related measures to construct a smaller number of composite variables that retain the most important multidimensional patterns present in the underlying data.[180] In other words, the PCA process includes information from all the proposed State characteristics and the underlying measures related to the ADVaNCE MA model by creating a smaller number of composite variables in place of many individual characteristics and measures. One composite variable can capture the biggest patterns in the data, and a second variable can capture other important, independent ways in which States differ.

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[179] Medicare and Medicaid Programs; CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements, 80 FR 68618, 68661–68662 (Nov. 5, 2015) (codified at 42 CFR part 484) ("We proposed to group states by each state's geographic proximity to one another accounting for key evaluation characteristics (that is, proportionality of service utilization, proportionality of organizations with similar tax-exempt status and HHA size, and proportionality of beneficiaries that are dually-eligible for Medicare and Medicaid)").

[180] Ian T. Jolliffe and Jorge Cadima, "Principal Component Analysis: A Review and Recent Developments," Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences 374, no. 2065 (2016): 20150202, http://dx.doi.org/10.1098/rsta.2015.0202

We propose using two composite variables, drawn from measures representing State market characteristics, to construct groups of States. The extent to which any individual characteristic or measure representing a characteristic contributes to a composite variable is determined by how strongly it correlates with that component's underlying pattern of variation. Two PCA-derived composite variables captured more variation across States than any two individual measures from the original set, which we believe supports the use of PCA over simpler two-measure stratification.

We used the statistical software Stata and the function “pca” to carry out the PCA process to create the two composite variables. Through this process we examined 13 potential composite variables, but ultimately determined that for purposes of the ADVaNCE MA model, two was an appropriate number. In determining the number of composite variables to retain, we considered the Kaiser-Guttman Rule, under which a composite variable is retained only if its eigenvalue exceeds one.[181] Our first two composite variables had eigenvalues of 6.26 and 1.72; the third had an eigenvalue of 1.05. Because the Kaiser-Guttman Rule alone can lead to over-extraction,[182] we did not rely on it exclusively. We confirmed a two-variable solution using Cattell's Scree Test, Horn's Parallel Analysis, and accepted cumulative variance thresholds for the social sciences (our cumulative variance with two composite variables was 0.61).[183] Because the third composite

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[181] Henry F. Kaiser, "The Application of Electronic Computers to Factor Analysis," *Educational and Psychological Measurement* 20, no. 1 (1960): 141–151, cited in William R. Zwick and Wayne F. Velicer, "Comparison of Five Rules for Determining the Number of Components to Retain," *Psychological Bulletin* 99, no. 3 (1986): 432–442, https://doi.org/10.1037/0033-2909.99.3.432

[182] William R. Zwick and Wayne F. Velicer, "Comparison of Five Rules for Determining the Number of Components to Retain," *Psychological Bulletin* 99, no. 3 (1986): 432–442, https://doi.org/10.1037/0033-2909.99.3.432

[183] William R. Zwick and Wayne F. Velicer, "Comparison of Five Rules for Determining the Number of Components to Retain," Psychological Bulletin 99, no. 3 (1986): 432–442, https://doi.org/10.1037/0033-2909.99.3.432 (discussing Raymond B. Cattell, "The Scree Test for the Number of Factors," Multivariate Behavioral Research 1, no. 2 (1966): 245–276, https://doi.org/10.1207/s15327906mbr0102_10, and John L. Horn, "A Rationale and Test for the Number of Factors in Factor Analysis," Psychometrika 30, no. 2 (1965): 179–185, https://doi.org/10.1007/BF02289447); James C. Hayton, David G. Allen, and Vida Scarpello, "Factor Retention Decisions in Exploratory Factor Analysis: A Tutorial on Parallel Analysis," Organizational Research Methods 7, no. 2 (2004): 191–205, https://doi.org/10.1177/1094428104263675 (discussing Louis W. Glorfeld, "An Improvement on Horn's Parallel Analysis Methodology for Selecting the Correct Number of Factors to Retain," Educational and Psychological Measurement 55, no. 3 (1995): 377–393, https://doi.org/10.1177/0013164495055003002); Joseph F. Hair, Jr. et al., Multivariate Data Analysis, 8th ed. (Boston: Cengage Learning, 2019).

variable's eigenvalue was only marginally above one and each supplemental method supported a two-variable solution, we retained two composite variables.

We included the proposed characteristics, as represented by their underlying measures, based on both their theoretical relevance to how markets might behave under the ADVaNCE MA model and the extent to which the combinations best explained variation across States.

Under this methodology, the characteristics described below would be used to construct the two composite variables that would determine the final groups.

● Market Competition: One of the goals of the ADVaNCE MA model is to enhance competition between plans in health care markets as a mechanism to improve quality. Competition can occur between MA and OM and between plans within the MA market. Because the proposed Diamond Ratings system discussed in section XIII.F would use parent organization level cohorts, we focus on competition between parent organizations. The level of competition within MA varies across States. The impact of the ADVaNCE MA model may differ depending upon the level of competition that exists prior to implementation of the ADVaNCE MA model. We believe that including States with varying levels of competition prior to the ADVaNCE MA model is important to enable the production of results that will generalize nationally.

● The Size of the MA Market: The market capture opportunity in a State, in terms of potential enrollee volume, might impact the response to the ADVaNCE MA model. We measure the size of the MA market in terms of the number of enrollees in D-SNPs and in other eligible plan types as well as market penetration of MA among all Medicare enrollees. A larger Medicare population reflects a larger market and a greater market capture opportunity. A State with higher MA penetration also reflects a larger market. Including States of varying MA market sizes would support the production of results that are generalizable nationally.

● Market Structure: The extent to which the ADVaNCE MA model would alter the State's MA market structure may impact the response to the ADVaNCE MA model. We would

assess market structure based on the number of MA contracts by contract characteristics relevant to the model, as well as the existence of Medicaid managed care programs for full benefit dual eligible enrollees, as these programs can intersect with D-SNP contracts. The extent to which a State's MA contracts between CMS and MA organizations would need to be split, as described in section VIII.D.4 of this proposed rule, to comply with the ADVaNCE MA model is an example of an alteration to a State's MA market structure that can differ across States. While stratification based on competition can encompass the number of parent organizations within a State, stratification based on market structure enables additional inclusion of the traits of the contracts these entities oversee. Including States with varying levels of exposure to multi-State contracts and intersection with Medicaid managed care would support the production of results that are generalizable nationally.

● Market Urban/Rural Homogeneity: Rural and urban markets within a State can differ and may have differential impacts across numerous domains including network adequacy requirements (42 CFR 422.116), market competition, and plan designs. The effects of the ADVaNCE MA model on States are likely to vary systematically by patterns of homogeneity related to rurality or urbanicity. We would measure geographic heterogeneity based on the percentage of MA enrollees within a State residing in rural counties. Including States across the range of patterns of rurality is important to enable the production of results that will generalize nationally.

We used 13 measures to represent the characteristics described above. We chose these measures based on their relevance to the ADVaNCE MA model and availability to CMS as of April 2026, the time at which CMS needed to begin making decisions about the stratification process. Specifically, we used publicly available Monthly Enrollment by Contract/Plan/State/County data, MA Contract Service Area by State/County data, MA State/County Penetration data, and Special Needs Plan (SNP) data to construct the below described measures for enrollment, Herfindahl-Hirschman Index (HHI), market share, number of parent organizations,

numbers of contracts, and MA penetration. For Alaska and Connecticut, the applicable timeframe was July 2024, the midpoint of the most recent year for which the MA penetration data were available for these States, for the enrollment, HHI, market share, number of parent organizations, and MA penetration measures. For the number of contract measures and all other States, the applicable timeframe was March 2026. We used internal analyses to construct the below described measure for Medicaid managed care programs for full benefit dual enrollees. We used the 2024 Master Beneficiary Summary File and 2020 Rural-Urban Commuting Area Codes (RUCA) codes to construct the below described measure regarding rurality. Because the characteristics and individual measures are highly related, individual measures may fit into more than one of the four characteristics.

We chose to use two HHI measures, as measured by the number of MA enrollees per parent organization. We incorporate an HHI measure for all MA enrollees in eligible plans (measure one) as well as a measure for D-SNP enrollees (measure two), because the proposed Diamond Ratings system discussed in section VIII.F would look at a separate D-SNP cohort, and we recognize that a market's D-SNP concentration may differ from its market concentration for its General Enrollment population. HHI is a common measure for market concentration used in MA literature.[184]

We also chose to include the percent market share of the largest parent organizations, in terms of MA enrollees (measure three), to further capture the extent of market dominance among the largest actors. Analysis from KFF suggests that a small number of actors tend to dominate markets.[185] Additionally, we included the number of parent organizations with at least 600 enrollees (measure four) to capture the number of entities that would compete under the

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[184] See, e.g., Joseph G. P. Hnath, J. Michael McWilliams, and Michael E. Chernew, "Medicare Advantage: National Carriers Expand Market Share While Regional Carriers Without Affiliation Decline, 2012–23," Health Affairs 43, no. 12 (2024): 1647–1654, https://doi.org/10.1377/hlthaff.2024.00577; and Bowen Garrett and John Holahan, "Reduced Medicare Advantage Insurer Concentration Associated with Small Improvements in Market Outcomes, 2013–23," Health Affairs 44, no. 10 (2025): 1244–1249, https://doi.org/10.1377/hlthaff.2025.00119.

[185] Nicole Zhu, Jeannie Fuglesten Biniek, Nolan Sroczynski, and Tricia Neuman, "Most Medicare Advantage Markets Are Dominated by One or Two Insurers," KFF, July 14, 2025, https://www.kff.org/medicare/most-medicare-advantage-markets-are-dominated-by-one-or-two-insurers/.

proposed Diamond Ratings system and, due to meeting minimum enrollment thresholds discussed in section VIII.I.2.b of this proposed rule, be required to report on the full range of measures under the proposed Diamond Ratings system.

We also included the number of MA enrollees in all eligible plans (measure five) and in D-SNPs (measure six) within a State market, as well as the MA penetration rates (measure seven) as defined by the number of MA enrollees divided by the total number of Medicare beneficiaries in a State market. We believe that these three measures together provide adequate information on the number of beneficiaries that a parent organization could enroll, impacting anticipated associated costs and profits under the ADVaNCE MA model.

Because the ADVaNCE MA model would change contract requirements, as described in section XIII.D.4, and we believe that the way a State market responds under the ADVaNCE MA model may differ depending on the pre-existing contractual landscape, including the degree of disruption to the contract status quo from prior to the ADVaNCE MA model's implementation, we also chose to incorporate four measures specific to MA contracts. The number of multi-State contracts within a State market (measure eight) captures the number of contracts that participants would need to split along State lines in a Mandatory State. The number of D-SNP-only multi-State contracts (measure nine) provides additional detail as to the number of contracts that would only need to be split along State lines and not by D-SNP inclusion. The number of single-State contracts (measure ten) captures the number of contracts that MA organizations would not need to split along State lines. The number of single-State D-SNP-only contracts (measure 11) captures the number of contracts that MA organizations would not need to split along State lines nor by D-SNP inclusion.

We also included a binary measure as to whether States had a Medicaid managed care program for full benefit dual enrollees (measure 12). Reliance on Medicaid managed care could further complicate needed contractual changes under the model as there could be differing numbers of Medicare Contracting Organizations involved, and States could be in different stages

of their Medicaid managed care procurement processes. For these reasons, we believe that the presence of a Medicaid managed care program for full benefit dual-enrollees could influence State decisions around opting out D-SNPs from the ADVaNCE MA model or lead to a different trajectory for the ADVaNCE MA model, as there are additional stakeholders in this scenario.

Lastly, we included the percentage of MA enrollees residing in rural zip codes (measure 13), defining rural as categories seven, eight, nine, or 10 in the 2020 RUCA Codes.[186] We included this measure for the reasons described above under the geographic heterogeneity characteristic.

The number of groups and number of States within each group would be dependent upon the similarities and differences in the profiles of States produced under this analysis of composite variables, based on the above-described measures and characteristics, when trying to capture meaningful patterns of differences between States. Where more States are clustered together due to having similar profiles based upon the composite variable values, a group would be larger in size (consisting of more total States). The purpose of grouping similar States together is to facilitate creating a small set of Mandatory States that represent the Nation as a whole. If, for example, 40 States were similar with respect to the characteristics that we determined are relevant to the model, but the other 10 States were unique with respect to those same characteristics, creating two more groups of five states each would adequately differentiate those states from each other, the result would be one group of 40 States and two additional groups of five States each. If six States were an adequate sample to test the model, we would select two States from the group of 40 and two from each group of five, resulting in six total States selected as Mandatory States. The first group would have a two-in-40, or 5 percent, chance of selection into the model as Mandatory States, while the States in the other two groups would have a two-

[186] U.S. Department of Agriculture, Economic Research Service, "Rural-Urban Commuting Area Codes: Documentation," last updated March 18, 2026, https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes/documentation. While we recognize that codes 4-10 can constitute rural areas under HRSA's recommendation, we are primarily interested in non-micropolitan areas.

in-five, or 40 percent chance, due to the relative sizes of the groups. The chances of being selected into the ADVaNCE MA model as a Mandatory State depends upon the number of States in each group based upon the PCA stratification.

As we discuss in more detail below, we determined that using seven groups enabled sufficient differentiation between groups of similar States. The two PCA-derived composite variables resulted in clusters of States in which the composite variables each comprised an axis, and we examined how the States clustered to determine the groupings. Specifically, PCA enabled groupings based on the clusters.

In deciding the appropriate number of groups of States, we incorporated both statistical and policy-based considerations. As a policy matter, we sought to advance our goals of fairness of selection among eligible States and national representativeness of the Mandatory States. As a statistical matter, we sought to create groups that would facilitate precise estimates and a sufficient sample size to support evaluation of the ADVaNCE MA model. First, we wanted to avoid creating a group with only one State, in which that State would have a 100 percent chance of selection, and to make the likelihood of selection as similar as possible across States while still pursuing national representativeness. We, therefore, preferred groups of a similar size in terms of the number of States, while still accommodating the possibility that some States had less common market characteristics and should be grouped together on that basis. Second, we wanted to avoid too few groups that would combine a greater number of States into the same group and increase the risk of dissimilarities within grouped States that could reduce representativeness, as measured by their composite variable values. Dissimilar observations within a group could reduce the precision of statistical estimates, relative to an internally homogeneous group.[187] Such dissimilarity could require a larger sample size to reach adequate statistical power to detect model effects. Third, we wanted to avoid having too many groups, which would separate similar

[187] William G. Cochran, *Sampling Techniques*, 3rd ed. (New York: John Wiley & Sons, 1977), 89–90 (noting that dividing a heterogeneous population into internally homogeneous strata allows for precise stratum-level estimates from small samples that combine into a precise overall population estimate).

States into different groups unnecessarily. Standard statistical practice dictates using the minimum number of groups necessary to achieve meaningful internal homogeneity.[188]

Within the statistical software Stata, we used the function 'cluster kmeans [two composite variable names], k([number of groups]) start(segments)' to assign States to groups. K-means clustering is a method commonly used in quantitative analysis and applied statistics that allows us to group States by minimizing the Euclidean distances between each State and its assigned cluster centroid, based on the two continuous composite variables that we derived through the process described earlier in this section.[189] We reviewed empirical clustering outputs across the two composite variables to identify the minimum number of groups necessary to achieve internal homogeneity, which, based on the analysis described in the preceding paragraph, we determined to be seven. Once the number of groups was set, this function impartially assigned each State to a group based on its composite variable values, without further discretion on our part, minimizing the risk that groupings reflect arbitrary or biased manual selection. One resulting group contains four States. We reviewed this group specifically and determined that its members are substantively similar based on the characteristics we deemed important in generating a nationally representative sample and differed substantively from the other States, supporting our use of this group despite its smaller size relative to the other groups.

This operationalization and prioritization resulted in our selecting seven State groups:

- Group One: DC, MT, ND, NH, SD, VT, WY
- Group Two: AR, ID, KS, ME, NE, OK, RI, WV
- Group Three: IA, KY, MD, MO, MS, NV, UT
- Group Four: AL, CO, CT, DE, HI, LA, NM
- Group Five: GA, IL, IN, MN, NC, NJ, SC, TN, VA, WA, WI
- Group Six: AZ, MA, MI, OH, OR, PA

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[188] See, e.g., William G. Cochran, *Sampling Techniques*, 3rd ed. (New York: John Wiley & Sons, 1977), 132–134
[189] Brian S. Everitt et al., Cluster Analysis, 5th ed. (Chichester, West Sussex: John Wiley & Sons, 2011), 114–15, 123.

- Group Seven: CA, FL, NY, TX

These groupings are determined mathematically based on composite variable values that are correlated with the underlying characteristics we used in the PCA process. In looking at average values per measure within groups, higher group numbers tend to be associated with higher numbers of MA enrollees, parent organizations with at least 600 enrollees, and single State contracts. Higher group numbers also tend to be associated with lower HHI values and percentages of MA enrollees residing in rural counties. To a lesser extent, high group numbers are also associated with higher MA penetration rates, though the primary difference is lower penetration in Group One relative to the other groups. Additionally, higher group numbers tend to be associated with lower percent market share of the three largest parent organizations, though the differences are larger between Groups One and Two and between Five and Six relative to the differences between other groups. We believe that using PCA enables groups to capture a more sophisticated understanding of what a market is like than grouping States on two variables. For example, multi-State D-SNP only contracts tend to be concentrated in Groups Two and Three, while D-SNP only contracts limited to single States are most concentrated in Groups Six and Seven. The number of multi-State contracts, not limited to D-SNP only contracts, tended to be higher in Groups Three, Five, and Six relative to Groups One, Two, Four, and Seven.

We seek comment on our proposed approach to stratifying States for ADVaNCE MA model participant selection, including whether the measures and characteristics described above are appropriate and whether CMS should consider additional, fewer, or different measures and characteristics.

e. Random Selection of States from Groups

We carefully considered many selection methodologies, including selecting States on a non-random basis to be Mandatory States. Ultimately, our proposal in § 516.100(e)(1) would employ stratified random sampling to select Mandatory States. Under the proposal, we would use a selection methodology based on a randomized sampling of States within each of the groups

constructed using the methodology described earlier in section VIII.D.3.e of this proposed rule. As we discussed above in section VIII.D.3.d, we determined that using seven groups enabled sufficient differentiation between groups of similar States.

We conducted simulations of the proposed randomization-within-groups strategy to ensure that our approach can produce unbiased samples of States, ensure that no State was excluded unintentionally, confirm no State appeared more than once across groups, and verify no single State's characteristics disproportionately influenced any group. If the proposed methodology is finalized, the random selection process would be run once to determine the list of Mandatory States. We will include the finalized methodology and the list of Mandatory States in the final rule. We determined that a randomized selection of States could be accomplished using the function "sample" within the statistical software Stata, an industry standard and scientifically valid computer algorithm and software widely used among researchers. The simulations of the randomized selection of States were run on each of the previously described groupings using exactly the same process, and, therefore, reflect a commonly accepted method of randomized sampling. The proposed computer algorithm omits any human interaction once it runs.

We conducted power analyses to identify detectable changes in quality measures tracked under the Diamond Ratings system, comparing a potential group of parent organization cohorts in 12 potential Mandatory States and a potential group of parent organization cohorts in 38 potential eligible but not selected States, using a Type I error of 0.05, Type II error of 0.2 (implying a power of 0.8), and a one-sided test in which we anticipate quality measures will improve under the ADVaNCE MA model. The analysis shows that, if 12 eligible States are selected for the ADVaNCE MA model, as proposed, we would be able to detect between a 2.84 and a 3.48 annual percent increase in mean Diamond score, all else being equal. This increase in mean Diamond score is within the range that CMS expects to achieve. The range in potential detectable scores is due to varying the assumption of the number of years of data available for the years immediately preceding the model performance period. We tested the possibility of

using between one and three years of such data. Across all iterations, we consistently assumed that the covariance between any pair of annual scores remains constant across years.

In consideration of sampling efficiency and maintaining generalizability while being cognizant of the ADVaNCE MA model 's footprint, we would select the minimum number of States that we believe is necessary to achieve adequate statistical power to detect ADVaNCE MA model effects representative of the national MA landscape. From the seven groups we constructed under the methodology described above in section D.3.d of this proposed rule, we propose to select one to two States per group, with two States chosen from Groups one through five and one State chosen from Groups six and seven, the smallest groups. Through this selection process, we would select a total of 12 (24.0 percent) eligible States across which the ADVaNCE MA model would be implemented. A State's probability of being selected as a Mandatory State to participate in the ADVaNCE MA model would depend on the group it falls in and would range from 16.7 percent to 28.6 percent:

- Groups One, Three, and Four: 28.6 percent selection probability
- Groups Two and Seven: 25.0 percent selection probability
- Group Five: 18.2 percent selection probability
- Group Six: 16.7 percent selection probability

If our methodology is finalized as proposed, all MA organizations that have contracts with eligible plans in the selected Mandatory States would be required to participate in the ADVaNCE MA model. However, State Medicaid Agencies may elect to opt-out D-SNPs from the ADVaNCE MA model as described in section VIII.D.2.c of this proposed rule. The opt-out process would not occur until after the Mandatory State selection process, and CMS cannot operationalize a prediction of the likelihood of any State opting out D-SNPs prior to selection of the Mandatory States. Therefore, the possibility of D-SNPs not participating in the model was not incorporated into the Mandatory State selection process. Eligible plans in the General Enrollment Cohort in Mandatory States would still participate in the model, regardless of

whether any individual Mandatory State's D-SNPs would be excluded, so the list of Mandatory States would not change due to a State's decision to opt-out its D-SNPs.

In § 516.100(e)(1), we are proposing the States be selected utilizing this proposed stratified random sampling methodology. Thus, all MA organizations in Mandatory States with contracts containing eligible plans would be required to participate in the ADVaNCE MA model with the exception of opted out D-SNPs.

We seek comment on our proposed approach to selecting ADVaNCE MA model Mandatory States, including the proposed stratified randomization approach and selection percentages.

f. Stability and Publication of the Mandatory State List

We propose at § 516.100(e)(2) that the list of Mandatory States would remain fixed and would not be revised or updated across performance years of the ADVaNCE MA model except as may be required under applicable State or Federal law, including the authority of the Secretary to expand models under section 1115A(c) of the Act. We believe that a stable, fixed geographic scope is essential to the integrity of the ADVaNCE MA model's evaluation design and to providing MA organizations, State Medicaid Agencies, and other affected parties with the regulatory certainty needed to make long-term operational and investment decisions.

Maintaining a fixed Mandatory State list is important to the integrity of the ADVaNCE MA model evaluation. Because the ADVaNCE MA model spans 10 performance years, a stable set of participating States ensures that changes in MA organization participation reflect ADVaNCE MA model dynamics rather than geographic variation introduced by mid-ADVaNCE MA model revisions. Altering the Mandatory State list after implementation would compromise the comparability of outcomes across performance years, making it difficult to accurately detect and attribute changes to the ADVaNCE MA model itself.

Accordingly, we propose that no mechanism will exist for adding or removing States from the mandatory participation list after the final rule is published, except as may be required

under applicable State or Federal law. We note that section 1115A(b)(3)(B) of the Act does provide that the Secretary has the statutory authority to modify the design and implementation of the model, which may include the list of Mandatory States, if certain statutory requirements are not met.

We propose that the final list of Mandatory States would be published in the Federal Register as part of the final rule establishing the ADVaNCE MA model. We propose that, once the Mandatory States are finalized, all MA organizations meeting the ADVaNCE MA model participant criteria, discussed earlier in section VIII.D.2.a, and operating in a Mandatory State as of January 1, 2029, would be required to participate in the ADVaNCE MA model.

We seek comment on this approach, including whether any circumstances should permit modification of the Mandatory State list after finalization.

4. Contract Structure Requirements for Operations

a. General Requirements and Need for Contract-Level Restructuring

Consistent with the proposal at § 516.100(a) and described in section VIII.D.1 that mandatory participation applies at the unit of an MA contract, we propose MA contract requirements at § 516.150 that would apply to all ADVaNCE MA model participants. As such, we propose at § 516.150(a) that ADVaNCE MA model's contract requirements would apply to any MA organization that plans to have a contract under 42 CFR 422.504 in a given contract year during the ADVaNCE MA model's performance period described in § 516.2(b) (discussed in section VIII.C.2.b of this proposed rule) that includes one or more eligible plans, described in § 516.100(b) (discussed in section VIII.D.2 of this proposed rule) that operate in a Mandatory State as defined under § 516.5 and discussed in section VIII.D.3 of this proposed rule. Under the proposal, MA organizations with eligible plans in the model would need to consider the ADVaNCE MA model's policies when preparing their MA contract applications, Change of Ownership requests, and CY 2029 bid submissions. The work that would be required during the ADVaNCE MA model's pre-implementation period (discussed in section VIII.C.2.a of this

proposed rule) would support implementation for all MA organizations that operate eligible plans, as defined under § 516.100(b), for both the General Enrollment Cohort and the D-SNP cohort, within the Mandatory States identified using the criteria specified in § 516.150.

The relationship between an MA organization and CMS is established and governed by a contract executed pursuant to section 1857 of the Act and 42 CFR 422.504. Each MA contract is assigned to a single legal entity and is identified by a unique contract identifier, or number. Under the current framework, a single MA contract may encompass multiple plan offerings of varying attributes, such as SNP and employer group plans, under the same MA plan type, as defined at 42 CFR 422.4. Further, both the contract itself and the plans offered thereunder may operate across service areas that span more than one State. Consequently, an existing MA contract may include plans whose service areas extend both within and outside of a Mandatory State.

We believe that this multi-State contract structure would be incompatible with the administration of the ADVaNCE MA model, as the model's payment, quality, and Medicaid coordination requirements would necessitate a State-specific contract framework, for the reasons discussed below. First, the ADVaNCE MA model would require State-specific data reporting and payment methodologies. Because these methodologies would be applied at the contract level, a contract with plans that span both Mandatory States and non-Mandatory States could not be cleanly subject to ADVaNCE MA model requirements without creating ambiguity in how those requirements would apply to the non-mandatory portions of the contract. Second, we must be able to distinguish ADVaNCE MA model contracts from non-ADVaNCE MA contracts for purposes of monitoring, evaluation, and payment. A mixed-State contract would require CMS to administer different payment and quality methodologies within a single contract, creating unnecessary complexity and making accurate payment reconciliation and program oversight substantially more difficult.

We propose at § 516.150(b)(1) that, beginning in CY 2029, ADVaNCE MA model participants would be required to operate State-specific contracts for eligible plans, as described in proposed § 516.100(b)(1)(i) through (iv), whose service areas would fall entirely within a single Mandatory State. We further propose that such contracts must be designated in the General Enrollment Cohort, as defined in proposed § 516.5. Additionally, we propose at § 516.150(b)(2) that, beginning in CY 2029, ADVaNCE MA model participants that offer D-SNPs would be required to operate State-specific contracts containing only D-SNPs, as defined in proposed § 516.100(b)(1)(v), whose service areas fall entirely within a single Mandatory State, subject to the requirements in proposed § 516.100(c) (pertaining to State opt-out described in section VIII.D.2.c of this proposed rule). We further propose that such contracts must be designated as D-SNP cohort contracts, as defined in § 516.5. We believe that this additional separation is necessary to ensure that the Diamond Ratings system Cohort comparisons described in section VIII.F of this proposed rule, which would compare MA organizations within Cohorts defined in part by plan type, and any state-level D-SNP opt-out determinations can be cleanly administered at the contract level. Additionally, to account for the ADVaNCE MA model's innovative approaches to quality and supplemental benefits, we propose at § 516.150(b)(3) that beginning in CY 2029, no ineligible plan, as defined at § 516.100(b)(2), would be permitted in an ADVaNCE MA General Enrollment or D-SNP cohort contract. We note that, consistent with the plan eligibility proposals described in section VIII.D.2 of this proposed rule, D-SNPs would count as ineligible plans in a Mandatory State whose Medicaid Director elects to opt out under the process described in section VIII.D.2.c of this proposed rule. At § 516.150(b)(4) we propose to clarify that non-ADVaNCE MA contracts would refer to MA contracts that include ineligible plans, as defined at § 516.100(b)(2) within Mandatory States and/or eligible plans, as defined at § 516.100(b)(1), outside of Mandatory States.

Through its SMAC, a State Medicaid Agency can require that D-SNPs with exclusively aligned enrollment be offered under D-SNP only contracts, as outlined in 42 CFR 422.107(e). As

described in section VIII.I.2.a.2 of this proposed rule, we wish to clarify that because § 422.107(e) only applies when States elect to invoke it, the processes and requirements of § 422.107(e) would not generally apply to D-SNP only contracts created by CMS under the ADVaNCE MA model contract restructuring process unless a Mandatory State elects to invoke § 422.107(e) for D-SNPs with exclusively aligned enrollment.

We solicit comments on the model's proposed contract requirements. Additionally, we solicit comments on additional contract requirements that may support the goals of the ADVaNCE MA model. For example, whether CMS should consider multi-year contracting flexibilities, such as multi-year bidding and enrollment, that may help to align the structure of plans offered with ADVaNCE MA model intents, such as improving preventive care among vulnerable beneficiaries.

b. ADVaNCE MA Contract Structure and Splits

We propose to establish at § 516.150(c) an administrative process by which CMS, on behalf of MA organizations, would identify and apply contract number splits to an existing MA contract that contains both eligible and ineligible plans as described in proposed § 516.100(b). We propose, at § 516.150(c)(1), to establish eligibility criteria for existing MA contracts subject to contract splits. Specifically, we propose at (i)-(iii) that an existing MA contract would be subject to a contract split if it operates one or more eligible plans within a Mandatory State's service areas and either operates across multiple States or is confined within a Mandatory State while offering either a mix of eligible plans and ineligible plans or a mix of both eligible D-SNPs and eligible plans that are not D-SNPs.

We propose at § 516.150(c)(2)(i) that for CY 2029, CMS will split existing MA contracts meeting the proposed criteria at § 516.150(c)(1) into non-ADVaNCE MA contracts, General Enrollment cohort contracts, and D-SNP cohort contracts as applicable on behalf of applicable MA organizations without requiring the submission of application materials. Specifically, we would restructure the service areas of contracts involved in the split process to reflect the

previously established service areas of plans that qualify for either (1) ADVaNCE MA model contracts meeting the requirements proposed at § 516.150(b)(1) and (2); or (2) non-ADVaNCE MA model contracts. We note that restructured contracts that operate outside of the ADVaNCE MA model may continue to hold service areas within Mandatory States for the purposes of operating either ineligible plans proposed at § 516.100(b)(2) or D-SNPs that are ineligible in accordance with the proposal at § 516.100(c)(5). We also note that the proposal at § 516.150(c)(2) would be operationalized as described in section VIII.I.2.a.1 of this proposed rule, pursuant to our waiver authority under section 1115A of the Act.

For existing MA contracts meeting the criteria proposed at § 516.150(c)(1)(i) or § 516.150(c)(1)(ii), we propose at § 516.150(c)(2)(ii) that CMS would effectuate contract splits by retaining the existing contract number for the non-ADVaNCE MA contracts, establishing new contract numbers for General Enrollment cohort contracts and, subject to § 516.100(c), D-SNP cohort contracts. As part of this proposal, CMS would establish applicable service areas for all contracts involved in the contract split process as described in § 516.150(c)(2)(i).

For example, if contract Z9999 consists of eligible plans in both the General Enrollment and D-SNP cohorts and ineligible plans operating in a Mandatory State, such as State X, as well as plans operating in a non-Mandatory State, such as State Y, it would meet the proposed criteria for CMS-initiated contract restructuring. Under this proposal, CMS would split the contract and maintain the existing contract number for the non-ADVaNCE MA model contract and restructure its service areas to reflect those previously established for State Y, as well as those for ineligible plans, as proposed at § 516.100(b)(2), in State X. Additionally, CMS would establish two new contract numbers with service areas restricted to those previously established amongst plans in State X that qualify for the General Enrollment cohort contract and the D-SNP cohort contract.

Lastly, for existing MA contracts that meet the criteria proposed at § 516.150(c)(1)(iii) – operating exclusively in a Mandatory State whose Medicaid Director has not elected to opt out

and only offering eligible plans, including both eligible D-SNPs and eligible plans that are not D-SNPs – we propose at § 516.150(c)(2)(iii) that these contracts would be restructured by maintaining the existing contract number for eligible plans in the General Enrollment cohort and creating a new contract number for eligible plans in the D-SNP cohort. Under this scenario, service areas for the contracts would be restructured as described in § 516.150(c)(2)(i).

At § 516.150(c)(2)(iv), we propose that no contract splits would be applied to existing MA contracts meeting the requirements proposed at § 516.150(b)(1) (General Enrollment cohorts) or § 516.150(b)(2) (D-SNP cohorts). We also propose at § 516.150(c)(2)(v) that any MA organization seeking to establish new service areas with eligible plans that include counties in Mandatory States would be required to submit initial or service area expansion MA contract applications, and when applicable, SNP applications under § 422.501 in accordance with the model's contract structure requirements proposed at § 516.150(b). Lastly, we also propose at § 516.150(c)(2)(vi) to clarify that existing MA contracts that do not meet the eligibility criteria for contract splits, as described at § 516.150(c)(1), and operate outside of ADVaNCE MA Mandatory States would continue to operate under the standard MA regulatory framework at 42 CFR part 422 and would not be subject to restructuring described in this section.

At § 516.150(d), we propose additional responsibilities and considerations for model participants, as described below. First, at § 516.150(d)(1), we propose that all ADVaNCE MA model participants whose existing contracts are subject to splits would receive a preview of their restructured contracts and service areas before the deadline for the CY 2029 Notice of Intent to Apply (NOIA) as required under 42 CFR 422.501(b)(1). At § 516.150(d)(2), we propose that ADVaNCE MA participants would be responsible for allocating plans offered in each restructured contract through the MA bid process. Recognizing that this may require plan crosswalks that are not authorized under § 422.530, we propose at § 516.150(d)(3) that MA organizations whose existing contract is restructured through the process described in this section would be allowed to crosswalk enrolled beneficiaries, in accordance with the process at 42 CFR

422.530(d)(1), across restructured contracts as long as the crosswalks do not occur between different plan types. We note that the proposal at § 516.150(d)(3) would be operationalized as described in section VIII.I.2.a.3 of this proposed rule, pursuant to our waiver authority under section 1115A of the Act.

Overall, we believe this process is most effective from an operational standpoint, avoiding excessive burdens on CMS in conducting contract splits while also providing ADVaNCE MA model participants with flexibility and ample time to request additional structural changes to their MA contracts, both within and outside of the ADVaNCE MA model, in a manner that best suits their needs. We note that when applicable, ADVaNCE MA contracts for the D-SNP cohort would always receive a new contract number to accommodate CMS' operational infrastructure.

We solicit comment on the proposed policies set forth in § 516.150(c) for identifying existing MA contracts eligible for contract splits, as well as on CMS' proposed role at § 516.150(c) in establishing ADVaNCE MA model contracts on behalf of MA organizations. Specifically, we seek comments on whether alternative approaches to retaining the existing contract number should be considered. For example, should the portion of a split contract with the highest proportion of enrollment retain the existing contract number when an existing MA contract is subject to the ADVaNCE MA model's contract structure requirements? We also seek comments on the timing of the contract restructuring preview. For example, should the MA contract restructuring preview begin as soon as the NOIA period opens and would this provide adequate time for MA organizations to determine whether Service Area Expansions applications or contract consolidation requests need to be submitted for CY 2029 to achieve their business goals? We also seek comments regarding the impact of the proposed contract split process for MA organizations planning changes in ownership. Lastly, we seek comment on any impact that the ADVaNCE MA model's proposed contract structure requirements may have on MLR reporting requirements. For example, do State Medicaid Agencies believe MLR reporting among

D-SNP only contracts within the ADVaNCE MA model would improve spending transparency among D-SNPs or require additional considerations?

E. Risk Adjustment

1. Background

Risk adjustment allows CMS to pay MA organizations based on the health risk of the beneficiaries they enroll, rather than paying the same average amount for every beneficiary. Risk adjustment is accomplished through calculation of a risk score, a relative measure of a beneficiary's predicted health care expenditures based on demographic characteristics and documented health conditions. Risk scores are used to calculate risk adjusted payments to MA organizations. By adjusting plan payments to reflect a beneficiary's expected health care costs, CMS is able to make more accurate plan payments for enrollees with differences in expected costs, which are determined based on data that MA organizations submit to CMS.

By increasing payment for beneficiaries who are expected to require more costly care and decreasing payment for beneficiaries expected to require less costly care, risk adjustment is intended to reduce incentives for MA organizations to preferentially cover healthier beneficiaries and avoid sicker ones.[190] Accurate risk adjustment also helps support more meaningful comparisons between MA organizations' populations.

CMS, as required by section 1853(b) of the Act, annually provides MA organizations notification of proposed changes in the MA capitation rate methodology and risk adjustment methodology, and provides an opportunity for comment on the proposed changes prior to announcing the capitation rate for each MA payment area and the risk and other factors to be used in adjusting such rates for a given CY. CMS recently fully implemented the 2024 CMS-HCC (v28) risk adjustment model first introduced for the 2024 payment year. In addition to updating the data years of the model and a reclassification of the HCCs to base them on the

[190] Centers for Medicare & Medicaid Services, "Risk Adjustment," Innovation Center, last modified August 2023, https://www.cms.gov/priorities/innovation/key-concepts/risk-adjustment.

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes, rather than ICD-9-CM codes, the 2024 CMS-HCC model included additional constraints and the removal of several HCCs in order to improve payment accuracy.

CMS believes it is important to assess and update the CMS-HCC risk adjustment model regularly and continues to investigate new ways to accurately predict spending. As referenced in the RFI on Future Directions in Medicare Advantage (Risk Adjustment and Quality Bonus Payments)[191] released in 2025, this includes exploring the use of Super Intelligence (SI) / Machine Learning (ML) and inferred risk adjustment models within MA. We will continue to leverage the feedback that was collected in response to the RFI in the development of any SI/ML-inferred risk adjustment models.

2. CMMI Inferred Risk Adjustment Model

As part of the ADVaNCE MA model, CMS proposes to shadow test the use of risk scores generated from a CMMI Inferred Risk Adjustment Model starting in CY 2028, meaning this would begin during the ADVaNCE MA model's pre-implementation period. Shadow testing means that, in CY 2028, CMS will calculate risk scores for all MA organizations using a CMS developed CMMI Inferred Risk Adjustment Model and will release the scores privately to each MA organization for their applicable enrollees only via HPMS and the Medicare Advantage and Prescription Drug (MARx) system for informational purposes. These new risk scores would not be used for payment in the ADVaNCE MA model in CY 2028; CMS would continue to use a CMS-HCC risk adjustment model used for all MA organizations. The purpose of this shadow test is so MA organizations can evaluate the differences between the two risk adjustment models, the CMS-HCC model and the CMMI Inferred Risk Adjustment Model. The shadow test for our

[191] Centers for Medicare & Medicaid Services, "Medicare Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program" Proposed Rule (90 FR 54894) (November 28, 2025), https://www.federalregister.gov/documents/2025/11/28/2025-21456/medicare-program-contract-year-2027-policy-and-technical-changes-to-the-medicare-advantage-program.

new risk adjustment model would be solely implemented by CMS, there are no additional obligations placed on MA organizations to implement this shadow test.

As the new CMMI Inferred Risk Adjustment Model is developed, we are considering an approach that would integrate multiple factors designed to improve the accuracy of predicting beneficiaries' health risk. These factors might include the use of the comprehensive sets of data that CMS has available (that is, OM claims data, MA encounter data, enrollment data), new Super Intelligence and machine learning methodologies, clinical and inferential risk logic, such as leveraging select prescription drug classes that more directly imply the conditions for which an individual is being treated, and other advanced statistical methods not used in the current risk adjustment model.

In advance of releasing the initial round of CMMI inferred risk scores in CY 2028, CMS will release the finalized technical specifications of the CMMI Inferred Risk Adjustment Model, research papers, and other public facing materials in 2027.

We anticipate that we could, in future rulemaking, propose using risk scores generated from the CMMI Inferred Risk Adjustment Model for payment for ADVaNCE MA model participants in future years. Should we decide that such a policy is appropriate, the use of the CMMI Inferred Risk Adjustment Model for payment in the ADVaNCE MA model would be subject to completion of testing and validation, and additional rulemaking.

We seek comment on this proposal, the potential, future use of a CMMI Inferred Risk Adjustment Model for payment for ADVaNCE MA model participants, and the factors listed above or others for consideration in the development of a CMMI Inferred risk Adjustment Model.

3. Coding Pattern Adjustments

As set forth in section 1853(a)(1)(C)(ii) of the Act, within MA there is a required minimum 5.9 percent coding pattern adjustment, which in effect lowers the average MA risk score by 5.9 percent. This adjustment is made to reflect differences in coding patterns between

MA plans and providers under Parts A and B.[192] Despite possible nuances in the intensity of these coding pattern differences between a given MA contract and OM, the same coding pattern adjustment is applied to all MA plans.

While some of the difference in coding intensity between contracts may be attributable to differences in patient populations, CMS has noted that incentives created by risk adjustment may drive coding for payment maximization purposes, particularly around diagnoses that involve a substantial amount of discretion[193]. To better understand the effect of coding intensity at a more granular level we are considering leveraging the Demographic Estimate of Coding Intensity (DECI) method that has been used by MedPAC[194] to analyze the effect of coding intensity at the parent organization level. This method attempts to estimate coding intensity by comparing the difference in MA to OM diagnosis-based risk scores with the difference in MA to OM demographic-only predicted risk. Although the DECI method begins to estimate coding intensity at a more granular level, separating variation in risk scores driven by coding practices versus true condition prevalence within the underlying population becomes more difficult as you evaluate at a parent organization or contract level.[195]

To address differences in the effect of coding intensity between MA contracts and/or parent organizations, we are interested in gathering feedback on methodologies that could scale the coding pattern adjustment such that it is higher for contracts that are proven to disproportionately utilize coding as a means to generate higher risk scores and lower for contracts that are not engaging in such behavior. We note that if we were to propose a coding pattern adjustment for some contracts below the 5.9% statutory minimum, we would also have to

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[192] Section 1853(a)(1)(C)(ii) of the Act.
[193] Centers for Medicare & Medicaid Services, *Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies* (March 31, 2023), https://www.cms.gov/sites/default/files/2023-03/2024%20Rate%20Announcement%20033123_FINAL508.pdf.
[194] Stuart Hammond, Andy Johnson, Luis Serna, and Grace Oh, *The Medicare Advantage Program: Status Report* (Medicare Payment Advisory Commission, January 16, 2026), https://www.medpac.gov/wp-content/uploads/2026/01/Tab-N-MA_Status-Jan-2026.pdf.
[195] J. Michael McWilliams, "Risk Adjustment in Medicare Advantage Needs Fixing—There's Just One Catch," *Annals of Internal Medicine* 178, no. 5 (2025): 739–740, https://doi.org/10.7326/ANNALS-25-00549.

waive § 1853(a)(1)(C)(ii)(III)-(IV) in future rulemaking. This tiered coding intensity adjustment would rely on CMS' ability to accurately evaluate the effect of coding intensity at a contract level via analyses such as the DECI method, the difficulties of which are previously discussed.

We seek comments to inform possible proposals that would be included in future rulemaking on reliable methods, such as the DECI method mentioned above, to evaluate the effect of coding intensity at the parent organization and contract level and on approaches to a tiered coding intensity adjustment that would increase the adjustment for high outlier contracts while potentially lowering it for others. With regards to a tiered coding intensity adjustment, we seek input on the definition of a high outlier contract including what thresholds of coding intensity could warrant a higher or lower adjustment and what could the maximum and minimum adjustment be.

SEE I PAGES PART 1 FOR PRECEDING ADVaNCE MA SECTIONS

F. ADVaNCE MA Diamond Ratings System

The MA and Part D Star Ratings system evaluates MA contract quality, which directly influences QBPs, as authorized under section 1853(o) of the Act, and the amount of MA rebates, as authorized under section 1854(b) of the Act. In this proposed rule, as part of the ADVaNCE MA model, we are proposing to test the ADVaNCE MA Diamond Ratings system, a new quality framework that would replace participation in the MA and Part D Star Ratings and QBP system for eligible contracts in Mandatory States. The Diamond Ratings system would adopt all provisions of the Star Ratings program unless otherwise stated within this rule and at §§ 516.600(h) through (j) and 516.605. The Diamond Ratings system would provide payments based on quality performance (Diamond Ratings) within a Mandatory State. The Diamond Ratings system would compare performance of ADVaNCE MA model participants within cohorts of either General Enrollment contracts (contracts without any D-SNPs or ineligible plan types) ("General Enrollment cohorts") or D-SNP contracts (contracts that exclusively contain D-SNPs) ("D-SNP cohorts"). This proposed Diamond Ratings system bases its innovations in the three pillars of the CMS Innovation Center Strategy mentioned earlier: (1) promoting evidence-based prevention; (2) empowering people to achieve their health goals; and (3) driving choice and competition.

At § 516.5, we propose to define "ADVaNCE MA model Diamond Ratings system" as the quality assessment and payment framework described in Subpart C of proposed part 516, which covers our proposals addressing quality measurement, performance and payment years, scoring methodology, ADVaNCE MA Overall Diamond Ratings, ADVaNCE MA Individual Measure Diamonds, and the ADVaNCE MA Payment methodology.

Our proposed Diamond Ratings system would test pivotal reforms to MA quality by:

● Assessing quality of MA contracts in each Mandatory State at the parent organization level and within cohorts to hold parent organizations accountable for the quality of care for all

enrollees while accounting for differences in populations between cohorts. There are two cohorts, (1) the collection of eligible contract types that are not D-SNPs are all grouped into the "General Enrollment cohort" and (2) all D-SNP contracts are grouped into the "D-SNP cohort." The cohort delineation is done for all contracts held by a parent organization within a Mandatory State. Of note, as described in § 516.100(c), if a State opts out their D-SNPs from ADVaNCE MA, then that State would only have General Enrollment cohorts participating in the model. Differing from the current Categorical Adjustment Index[196] used in the MA and Part D Star Ratings to account for certain differences in a contract's enrolled population, the Diamond Ratings system proposes a cohort approach that would help ensure D-SNPs serving higher needs enrollees would not be penalized due to differences in health status relative to enrollees in General Enrollment contracts and so that beneficiaries considering D-SNPs will have quality scores most applicable to their performance within the State.

- Ensuring performance is incrementally acknowledged: Departing from the current approach of linking bonus payments to a single, discrete quality threshold, as required by sections 1853(o) and 1854(b)(1)(C)(v) of the Act, the Diamond Ratings system would use an incremental scale to ensure even small differences in quality performance can be rewarded.

- Providing more granularly displayed quality ratings: The Diamond Ratings system would display ADVaNCE MA Overall Diamond Ratings and ADVaNCE MA Individual Measure Diamonds, where possible, in smaller increments (for example, one-tenth) on Medicare Plan Finder. The current MA and Part D Star Ratings measure Stars are displayed in whole-Star increments and the MA and Part D Star Ratings system overall and summary ratings are displayed in half-Star increments.

- Restructuring payment: The Diamond Ratings system would include benchmark adjustments and rebates with the intention of offering rewards based on the ADVaNCE MA model participants' relative performance.

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[196] *See* 42 CFR 422.166(f)(2) and 423.186(f)(2).

In crafting proposals for the Diamond Ratings system, we sought to: (1) ensure predictability and fairness of quality scoring by assessing performance along an incremental scale; (2) avoid large swings in payment for minor changes in performance; and (3) stimulate competition between ADVaNCE MA model participants in Mandatory States by evolving the rewards structure to recognize quality differences on an incremental scale.

1. Schedule of Measurement, Display, and Payment

At § 516.200, we propose measurement periods, ratings display years, and payment years for the General Enrollment and D-SNP cohorts in the Diamond Ratings system.

a. Measurement Periods

At § 516.200(a)(1), we are proposing to assess ADVaNCE MA model participants' performance on each of the quality measures in the Diamond Ratings system measure set, described at § 516.205(a), during each of the respective measurement periods. We propose that measurement periods for the ADVaNCE MA model would align with the corresponding measurement periods under the MA and Part D Star Ratings system. For each measure, CMS would also use, as relevant, the same measurement period used under the MA and Part D Star Ratings system.

We recognize that different measures have different time periods for which performance is assessed depending on the measure's underlying data source (for example, HEDIS, CAHPS) and are proposing at § 516.200(a)(1) that such time periods in the Diamond Ratings system would remain the same as in the MA and Part D Star Ratings system for a given Diamond Ratings system measurement period across all applicable measures. For each measure, CMS will use, as applicable, the same measurement period used under the MA and Part D Star Ratings system. For example, if the measurement period for HEDIS measures is January 1, 2029 to December 31, 2029 for the MA and Part D Star Ratings system (impacting CY 2031 Star Ratings), then the measurement period for HEDIS measures in the Diamond Ratings system would be the same (impacting the CY 2031 ADVaNCE MA Overall Diamond Ratings).

In contrast, if the measurement period for CAHPS measures is January 1, 2030 to December 31, 2030 for the MA and Part D Ratings system (impacting CY 2031 Star Ratings), then the measurement period for CAHPS measures in the Diamond Ratings system would be the same (impacting the CY 2031 ADVaNCE MA Overall Diamond Ratings). We note that we are proposing to follow the current data collection requirements CMS uses for the MA and Part D Star Ratings. We are not proposing modifications to the data collection requirements for the first year of the Diamond Ratings system but may consider changes to the data collection and sampling methodology in future years, as needed, and would propose any such changes through rulemaking.

We are proposing at § 516.200(a)(2), that the first measurement period for ADVaNCE MA model participants would be the measurement period applicable to the 2031 Diamond Ratings. We also propose that the last measurement period for the ADVaNCE MA model would be the final measurement period applicable to the 2040 Diamond Ratings. ADVaNCE MA model participants would resume participation in the MA and Part D Star Ratings for the measurement period impacting CY 2041 Star Ratings. ADVaNCE MA Overall Diamond Ratings based on measurement periods impacting the 2038 through 2040 Diamond Ratings would continue to be used for ADVaNCE MA Payments through CY 2041. The last ADVaNCE MA Payment would be in CY 2041 meaning payments under the QBP would resume in CY 2042.

We seek comments on this approach, which would transition ADVaNCE MA model participants back to MA and Part D Star Ratings at the conclusion of the ADVaNCE MA model.

We also considered an alternative approach in which the final measurement period for the ADVaNCE MA model would be the final measurement period applicable to the 2037 Diamond Ratings, with ADVaNCE MA model participants resuming participation in MA and Part D Star Ratings for the measurement period impacting the CY 2038 Star Ratings. However,

we are not proposing this alternative because it would end measurement under the Diamond Ratings system before the conclusion of the 10-year ADVaNCE MA model performance period.

At § 516.200(a)(3), we are proposing that ADVaNCE MA model participants would be required, as applicable, to collect, analyze, report, or otherwise make available data that permit measurement of quality and outcome measures. We are proposing that ADVaNCE MA model participants would be required to provide unbiased, accurate, and complete quality data to CMS. We are also proposing that failure to adhere to reporting or data integrity requirements for a measure required under § 516.205(a) would result in a rescaled measure score of zero ("non-missing zero measure score"), as further described in section VIII.F.3.d(2) of this proposed rule, and an ADVaNCE MA Individual Measure Diamond of one Diamond, as further described in section VIII.F.3.c of this proposed rule. The resulting non-missing zero measure score would impact the ADVaNCE MA model participant's overall score and ADVaNCE MA Overall Diamond Rating, which in turn would impact the ADVaNCE MA model participant's ADVaNCE MA Payment. The non-missing zero measure score would count towards determining whether the ADVaNCE MA model participant has met the minimum reporting requirements, as further described in section VIII.F.3.d.(1) of this proposed rule. We believe the proposals at § 516.200(a)(3) would help ensure completeness, accuracy, and robustness of data reporting and collection. We also believe that the proposed requirements would ensure that ADVaNCE MA model participants provide complete reporting across all measures, regardless of their performance on each measure. This is consistent with the requirements in the MA and Part D Star Ratings system at 42 CFR 422.162(c)(2), 42 CFR 422.164(g), 42 CFR 423.182(c)(2), and 42 CFR 423.184(g).

b. Ratings Display Years

The MA and Part D Star Ratings system posts Star Ratings calculated pursuant to 42 CFR 422.166(h) and 423.186(h), following the applicable measurement period. To follow this

process while accounting for the transition period from Star Ratings to Diamond Ratings, we propose at § 516.200(b)(1)(i) that ADVaNCE MA model participants, as defined at proposed § 516.5, would remain subject to MA and Part D Star Ratings for CY 2029 and CY 2030. The resulting Star Ratings would be displayed on Medicare Plan Finder for CY 2029 and CY 2030. In the event of a contract consolidation, we propose to follow the existing regulation at 42 CFR 422.162(b)(3) regarding the CMS assignment of Star Ratings for contract consolidations.

CMS is considering an alternative to following 42 CFR 422.162(b)(3) for calculating measure data for the surviving contract of a consolidation to account for the geographic boundaries of the State-bound contracts created for participation in the ADVaNCE MA model. Under 42 CFR 422.162(b)(3), CMS assigns Star Ratings for the first and second years following the consolidation based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) as provided in 42 CFR 422.162(b)(3)(iv). This alternative would propose to adjust the 42 CFR 422.162(b)(3) process for purposes of the Diamond Ratings to only allow the calculation of measure data for the surviving contract to include the enrollment-weighted mean of the measure scores from the subset of contracts with service areas in the Mandatory States. This alternative is being considered to allow for the transition of measure scores from the Star Ratings system to the Diamond Ratings system while retaining the locally relevant quality scores component of the Diamond Ratings system.

For new entrants, as defined at § 516.5, we propose at § 516.200(b)(1)(ii) that the ADVaNCE MA model participant would have a display of "plan too new to be measured" in Medicare Plan Finder until sufficient data has been gathered to provide a score two years after entrance.

At § 516.200(b)(2), starting with CY 2031, we are proposing to follow the timing of display of Star Ratings, but proposing that ADVaNCE MA Overall Diamond Ratings calculated under § 516.220 would be displayed on Medicare Plan Finder in lieu of Star Ratings for ADVaNCE MA model participants. The first ADVaNCE MA Overall Diamond Ratings would

be displayed on Medicare Plan Finder in October of the calendar year prior to the first year of the Diamond Ratings (that is, October 2030 for the 2031 Diamond Ratings).

c. Payment Years

MA and Part D Star Ratings currently use a methodology with a multi-year interval between measurement and financial reward for MA contracts. For example, for the measurement period applicable to the 2029 Star Ratings[197], MA contracts will report their measure data to CMS in CY 2028. CMS will subsequently assess and aggregate data to determine 2029 MA and Part D Star Ratings for the MA and Part D Star Ratings, which will be published in October 2028. These Star Ratings impact the marketing of plans and are factored into MA contracts' annual June bid submission for the following year. Finally, in CY 2030, quality bonuses are factored into benchmarks based on CY 2029 Star Ratings.

Similar to the measurement period and payment schedule of the MA and Part D Star Ratings described above, we propose at § 516.200(c)(2) that ADVaNCE MA model participants, from CY 2032 through CY 2041, would receive ADVaNCE MA Payments — meaning changes to the ADVaNCE MA model participants' benchmarks and rebates as proposed and discussed under sections VIII.F.4 of this proposed rule — in the calendar year following the relevant Diamond Ratings year. For example, payments based on the 2031 Diamond Ratings would be made in 2032. Further, we propose to define the payment year at § 516.5.

Under this proposal, given the multi-year interval between measurement period and payment year, the first year that the ADVaNCE MA Diamond Ratings would be used for ADVaNCE MA model participants' payments would be the CY 2031 Diamond Ratings used for 2032 ADVaNCE MA Payments. Until payments for ADVaNCE MA contracts switch to being adjusted based on the Diamond Ratings system, at § 516.200(d)(1), we propose, for CY

[197] 42 C.F.R. § 422.162, "Medicare Advantage Quality Rating System," Electronic Code of Federal Regulations, https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-D/section-422.162.

2029 through CY 2031, that ADVaNCE MA model participants would receive ADVaNCE MA Payments based on their CY 2029 QBP ratings, CY 2030 QBP ratings, and CY 2031 QBP ratings, respectively. We propose that the new contracts created as proposed at § 516.150 would be subject to 42 CFR 422.166(d)(2)(vi)(A), which stipulates that a new contract under an existing parent organization that has other MA contract(s) with numeric Star Ratings in November when the preliminary QBP ratings are calculated for the contract year that begins 14 months later, the QBP rating assigned is the enrollment-weighted average highest rating of the parent organization's other MA contract(s) that are active as of the April when the final QBP ratings are released under 42 CFR 422.162(b)(4).

CMS is considering an alternative to following 42 CFR 422.166(d)(2)(vi)(A) to account for ADVaNCE MA model participants that are geographically limited, which impacts comparability when averaging a new contract's QBP rating based on its parent organization's other MA contract(s), which could be located anywhere. Under this alternative, new contracts in the ADVaNCE MA model under a parent organization that has other MA contract(s) would only be assigned a QBP rating calculated as the enrollment-weighted average of the highest rating of the parent organization's other MA contract(s) that are in a service area in that Mandatory State that is active as of the April when QBP ratings are finalized under 42 CFR 422.162(b)(4). This alternative would generate a QBP rating for new ADVaNCE MA contracts that is more focused on their local performance conditions.

Additionally, for new contracts that enter a Mandatory State and are under a parent organization that did not have a service area in such Mandatory State, we propose at § 516.200(c)(1) that the ADVaNCE MA model participant would receive an increase to their benchmark of 3.5 percentage points and a rebate of 65 percent. Finally, in considering the assignment of QBP ratings to new ADVaNCE MA contracts, we propose under § 516.200(c)(2) that in CY 2032 through CY 2041, ADVaNCE MA payment calculated under proposed § 516.230 will be received in the calendar year following the relevant Diamond Ratings year.

We believe our measurement and payment year proposals would maintain stability and predictability in quality assessment timing, because reporting periods measurement period, and payment years would remain largely consistent between the MA and Part D Star Ratings and Diamond Ratings system and aid in the transition to the Diamond Ratings system at the beginning of the model and the transition back to MA and Part D Star Ratings following the conclusion of the model.

As an alternative to the proposed measurement and payment years approach, we considered a concurrent measurement and payment approach where payment would be tied to current performance without the lag in payment from performance year to payment year. However, we are not proposing this alternative due to anticipated complexities in implementing and operationalizing this approach. This approach could result in heightened administrative and financial burden for both ADVaNCE MA model participants and CMS, further complicating its feasibility.

We seek comment on our proposals regarding the schedule of measurement periods, ratings display years, and payment years for CY 2029 and subsequent measurement periods. We also seek comment on the alternatives mentioned to address the possible consequences of the contract consolidation necessitated by model participation, including calculating measure data for the surviving contract of a consolidation and generating QBP ratings for geographically limited ADVaNCE MA model participants.

2. Quality Measurement

a. Proposed ADVaNCE MA Diamond Ratings System Measure Set

To maintain initial parity with the MA and Part D Star Ratings system, we are proposing, at § 516.205(a), that CMS would use the quality measure set used in MA and Part D Star Ratings to assess performance for ADVaNCE MA model participants during the same measurement period. For example, if MA and Part D Star Ratings includes Plan All-Cause

Readmissions in its measure set for the 2031 Star Ratings, then the Diamond Ratings system would similarly include this specific measure in its measure set for the 2031 Diamond Ratings.

b. Adding, Updating, and Removing ADVaNCE MA Diamond Ratings System Quality Measures

We intend to align the proposed Diamond Ratings system with the MA and Part D Star Ratings system initially to the greatest extent feasible, so 42 CFR 422.164 and 42 CFR 423.184 would remain fully applicable to the ADVaNCE MA model. We are proposing to initially align the ADVaNCE MA Diamond Ratings system quality measure set with the MA and Part D Star Ratings system so that ADVaNCE MA model participants would be familiar with the measures. However, we are proposing a 10-year ADVaNCE MA model, and during that time, we may determine that we would like to test alternative quality measures by diverging from the MA and Part D Star Ratings measure set. At § 516.205(b)(1), we propose that CMS may, independently from the MA and Part D Star Ratings system, add, remove, or update measures used to calculate ADVaNCE MA Individual Measure Diamonds and ADVaNCE MA Overall Diamond Ratings, subject to the requirements described at § 516.205(b)(2) through (b)(4).

At § 516.205(b)(2)(i), we propose that we may add new measures to the ADVaNCE MA model if the Secretary determines that a quality measure is meaningful to participating plans, addresses a priority area, supports or advances the overall goals of the ADVaNCE MA model, or improves the comprehensiveness of the ADVaNCE MA model quality measure set. In order to determine measures that we may want to add to the Diamond Ratings measure set, at § 516.205(b)(2)(ii), we are proposing that we may continue to review measures that are nationally endorsed and in alignment with the private sector, such as measures developed by National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA), or endorsed by the National Quality Forum (NQF) for adoption and use in the ADVaNCE MA Diamond Rating system. Additionally, we may explore developing our own measures when appropriate to measure and reflect performance specific to the Medicare

program, as proposed at § 516.205(b)(2)(iii). For example, we may need to develop independent measures when appropriate to measure and reflect performance specific to the proposed Diamond Ratings system. This aligns with the review of measures by major accrediting organizations and the development of measures by CMS used in QBP Star Ratings and codified at 42 CFR 422.164(c)(1) and 42 CFR 423.184(c)(1).

At § 516.205(a), we are proposing that the Diamond Ratings system would automatically add, remove, or make substantive or non-substantive updates to the measure set to remain in alignment with changes made in the MA and Part D Star Ratings system measure set, unless otherwise specified in rulemaking under § 516.205(b). Changes to the ADVaNCE MA Diamond Ratings system measure set would take effect in the same measurement period that the change would take effect in the MA and Part D Star Ratings system, unless the Diamond Ratings measure set deviates from the Star Ratings measure set, as specified by CMS in future rulemaking.

At § 516.205(b)(2) through (b)(4), we are proposing circumstances under which CMS would add, update, and remove measures in the Diamond Ratings pursuant to § 516.205(b)(1) when those additions, updates, or removals do not align with the Star Ratings measure set. The proposals below would apply only to measure additions, updates, or removals that do not correspond with a measure addition, update, or removal in the Star Ratings.

The regulations at 42 CFR 422.164 and 42 CFR 423.184 specify the criteria and procedures for adding, updating, and removing measures in the MA and Part D Star Ratings system. In accordance with 42 CFR 422.164(c)(2) and 42 CFR 423.184(c)(2), prior to the measurement period, CMS announces potential new measures and solicits feedback through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act, and then subsequently proposes and finalizes new measures through rulemaking. Potential new measures also go through the pre-rulemaking measure review process described in section 1890A(a) of the Act for the selection of quality and efficiency

measures. However, at § 516.205(b)(2)(iv), we propose that new measures for the Diamond Ratings may be proposed and finalized through rulemaking alone. To do so, at § 516.600(e)(1), we propose to waive section 1890A(a) of the Act to the extent necessary to allow CMS to add new measures to the Diamond Ratings system for purposes of the ADVaNCE MA model without applying the pre-rulemaking measure review process. We believe that proposing new measures through notice-and-comment rulemaking alone provides sufficient notice and opportunity for public input. Omitting the pre-rulemaking measure review process and the announcement of potential new measures in the Advance Notice for new Diamond Ratings measures not included in the Star Ratings would allow CMS to adopt new quality measures for use in the ADVaNCE MA model as quickly as possible, which is necessary in light of the ADVaNCE MA model's condensed timeline. As stated in the explanation of proposed § 516.600(e)(1) in this proposed rule, the pre-rulemaking process delays the adoption of measures beyond the standard NPRM timeline, and we believe it is important to preserve the ability to adopt new measures in the Diamond Ratings system as soon as possible to provide adequate time for impact and evaluation. Therefore, it is not feasible to include the pre-rulemaking measure review process for new measures to be added to the Diamond Ratings system. At § 516.600(e)(2), we propose that all other provisions under section 1890A of the Act remain in full force and effect.

Further, the MA and Part D Star Ratings system currently requires new measures to be added to the display page on the CMS website for a minimum of two years prior to becoming a Star Ratings measure (codified at 42 CFR 422.164(c)(3) and 42 CFR 423.184(c)(3)). However, at § 516.205(b)(2)(iv), we are proposing that new measures added to the ADVaNCE MA Diamond Ratings measure set would be displayed for a minimum of one year on the CMS website before being used in the calculation of ADVaNCE MA Overall Diamond Ratings and payment. Although this would shorten the display period from the current Star Ratings display of two years to a Diamond Ratings display of one-year, certain performance measures like

HEDIS measures have multi-year look-back or continuous enrollment requirements that may still require longer than one year of display before sufficient performance data exists, regardless of the proposed one-year display period. However, this would not apply to new measures added to the Star Ratings measure set, which would continue to be displayed for a minimum of two years before being used in the calculation of Star Ratings as codified at 42 CFR 422.164(c)(3) and 42 CFR 423.184(c)(3)). As proposed at § 516.205(b)(2)(iv), once data on the new measure has been collected and beginning one year after a new measure has been publicly displayed on the CMS website, new measures can be used in the calculation of ADVaNCE MA Overall Diamond Ratings. We believe that this is appropriate because participating plans would have at least one year to report new measures and make performance improvements before new measure information has implications for the ADVaNCE MA Overall Diamond Rating and payment. To account for a case where CMS finds reliability or validity issues with the measure specification, a measure will remain displayed on the CMS website for longer than one year, as proposed at § 516.205(b)(4)(i). As under 42 CFR 422.166(e)(2) and 42 CFR 423.186(e)(2), Diamond Ratings measures that are not also included in MA and Part D Star Ratings are assigned a weight of one for the first year they are used in the calculation of Overall Diamond Ratings and in subsequent years, new measures are assigned the weight associated with its category, as proposed at § 516.215(d)(2)(ii)(C). For measures that are included in both the MA and Part D Star Ratings system and the Diamond Ratings system, the measure will have the same weight in the Diamond Ratings system as in the MA and Part D Star Ratings system. Accordingly, measures new to both Diamond Ratings and MA and Part D Star Ratings will also have a weight of one for the first year.

The MA and Part D Star Ratings system may also update measures as described at 42 CFR 422.164(d) and 42 CFR 423.184(d). With respect to Diamond Ratings measure updates that do not align with Star Ratings measure updates and for measures that are already used for the ADVaNCE MA Diamond Ratings measure set, we propose at § 516.205(b)(3)(i) that CMS

would announce non-substantive updates to measures that occur (or are announced by the measure steward) during or in advance of the measurement period through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act (*i.e.*, the annual Advance Notice and Rate Announcement). Non-substantive measure specification updates include those listed at proposed § 516.205(b)(3)(i).

For substantive measure updates in the Star Ratings, consistent with the policy for adding measures, CMS initially solicits feedback on whether to make substantive measure updates through the Advance Notice in accordance with section 1853(b) of the Act, prior to proposing and finalizing the update through rulemaking. However, at § 516.205(b)(3)(ii), we propose that for Diamond Ratings measure updates that do not align with Star Ratings measure updates, substantively updated measures would be proposed and finalized through rulemaking alone and without putting the substantively updated measure through the pre-rulemaking measure review process, as proposed at § 516.600(e)(1). We believe that proposing substantively updated measures through notice-and-comment rulemaking provides sufficient notice and opportunity for public input as this change is responsive to prior RFI responses and the goal of the Diamond Ratings system to be better able to quickly react and more rapidly make changes to measures.

Furthermore, the MA and Part D Star Ratings system currently requires substantively updated measures to be added to the display page on the CMS website for a minimum of two years prior to becoming a Star Ratings measure (codified at 42 CFR 422.164(c)(3) and 42 CFR 423.184(c)(3)). However, we propose at § 516.205(b)(3)(ii) that, for Diamond Ratings measure updates that do not align with Star Ratings measure updates, substantively updated measures would be added to display on the CMS website for a minimum of one year prior to being used in the calculation of ADVaNCE MA Overall Diamond Rating. We believe that this is appropriate because participating plans would have at least one year to report any substantively updated measures and make performance improvements before substantively

updated measure information has financial implications in the ADVaNCE MA Overall Diamond Rating and payment. As proposed at § 516.205(b)(3)(ii), in accordance with 42 CFR 422.164(d)(2), CMS may continue collection of performance data for the legacy measure and include it in Diamond Ratings until the updated measure has been on display for one year to allow for flexibility in the use of Diamond Ratings measures. As under 42 CFR 422.166(e)(2) and 42 CFR 423.186(e)(2), Diamond Ratings measures that are not also included in the MA and Part D Star Ratings are assigned a weight of one for the first year that the substantively updated measure is used in the calculation of Overall Diamond Ratings. In subsequent years, substantively updated measures would be assigned the weight associated with its category. For measures that are included in both the MA and Part D Star Ratings system and the Diamond Ratings system, their measure weight in the MA and Part D Star Ratings system will carry over to the Diamond Ratings system. Accordingly, measures new to both Diamond Ratings and MA and Part D Star Ratings will also have a weight of one for the first year.

Lastly, 42 CFR 422.164(e) and 42 CFR 423.184(e) describe the current measure removal requirements established in the MA and Part D Star Ratings system. Currently, before a measure is removed from the MA and Part D Star Ratings system, CMS may announce the removal of the measure through the Advance Notice and Rate Announcement process in accordance with section 1853(b) of the Act or propose and finalize removal of the measure through rulemaking when any of the circumstances listed in 42 CFR 422.164(e)(1) and 42 CFR 423.184(e)(1) exist. If none of the circumstances specified in 42 CFR 422.164(e)(1) and 42 CFR 423.184(e)(1) exist, CMS will propose and finalize removal of the measure through rulemaking.

Further, we may propose to remove Diamond Ratings measures, absent a corresponding removal in the Star Ratings, to test a simplified measure set. At § 516.205(b)(4)(i), we are proposing that we would remove measures from the Diamond Ratings measure set if the Secretary determines that the quality measure is no longer meaningful for ADVaNCE MA

Diamond Ratings, if a measure shows low statistical reliability, if the measure steward other than CMS retires a measure, or if the clinical guidelines associated with the specifications of the measure change such that the specifications are no longer believed to align with positive health outcomes. For ADVaNCE MA Diamond Ratings, at § 516.205(b)(4)(ii), we are proposing that we would propose the removal of measures in rulemaking in advance of the measurement period. This process supports the goals of the Diamond Ratings to support the timely removal of quality measures and the prompt reporting of scores.

We seek comment on our proposed standards for adding, removing, and updating Diamond Ratings measures independently from the MA and Part D Star Ratings at § 516.205(b). Additionally, we seek comment on specific measures to add or remove in the Diamond Ratings system in future rulemaking.

3. Performance Scoring Methodology for the Diamond Ratings System

At § 516.215, we are proposing a scoring methodology for the Diamond Ratings system. In this section, we describe how ADVaNCE MA model participants' performance on the ADVaNCE MA Diamond Ratings system measure set would be assessed for the public display of ADVaNCE MA Individual Measure Diamonds and ADVaNCE MA Overall Diamond Ratings. We propose that the scoring and ratings in the Diamond Ratings system would assess quality at the parent organization level within each cohort and Mandatory State, would allow incremental improvements in performance to be reflected in payment, reducing the link between bonus payments and a single, discrete quality threshold within the statutory QBP system, and would account for differences in enrollee populations through cohort-based assessments within each parent organization and Mandatory State.

a. Cohort Grouping in the Diamond Ratings System

Currently, the MA and Part D Star Ratings system accounts for certain differences in a contract's enrolled population, such as social risk factors, by adjusting overall and summary MA and Part D Star Ratings using a Categorical Adjustment Index (CAI). Additionally, some

other measures in the MA and Part D Star Ratings program have additional adjustment applied.[198] The CAI adjusts for average within-contract disparity in performance associated with the percentages of DE, LIS, and disabled enrollees within that contract, as described at 42 CFR 422.166(f)(2) and 42 CFR 423.186(f)(2).

At § 516.600(j)(4), we are proposing to waive 42 CFR 422.166(f)(2) and 42 CFR 423.186(f)(2). Instead, we contemplate that the Diamond Ratings system would group participants within the Mandatory States into either a General Enrollment cohort or a D-SNP cohort based on the contract type. Measure level case-mix adjustments would be maintained for purposes of the Diamond Ratings.

At § 516.215(a), for scoring purposes, we are proposing to assign all of a parent organizations' participating contracts to one of two cohorts based on contract type offerings within the Mandatory State. The proposed cohort structure of the performance scoring methodology in the ADVaNCE MA Diamond Ratings system would account for differences in enrollee populations and allow for separate assessment of quality outcomes and comparisons for General Enrollment and D-SNP populations.

Our goal in proposing this cohort structure for the Diamond Ratings system is to further incentivize participating parent organizations to exert the full range of their influence and capabilities to deliver the highest quality care possible to their D-SNPs, and to be equally, but separately, accountable for the quality of their General Enrollment plans. We acknowledge this cohort structure does not account specifically for dual-eligible beneficiaries who have chosen General Enrollment contracts for their care but believe that this is the best way to focus on duals who select dual-specific plans.

We believe this proposal has the potential to incentivize higher quality of care in large part due to the changes in scoring methodology and competitive structure, and that the parent

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[198] Centers for Medicare & Medicaid Innovation, Categorical Adjustment Index (CAI), accessed June 2024, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Supplement-for-Categorical-Adjustment-Index-.pdf.

organizations of ADVaNCE MA model participants would be held accountable in both absolute and relative terms for their performance across both General Enrollment and D-SNP contracts. First, we believe that the scoring methodology, discussed further in sections VIII.F.3.b. through VIII.F.3.e., of this proposed rule rewards incremental progress, encouraging ADVaNCE MA model participants to work to achieve the absolute highest rating possible for their ADVaNCE MA Overall Diamond Ratings display as beneficiaries would use this information in selecting plans during each enrollment period. Second, we believe that the relative ADVaNCE MA payment structure, discussed further in section VIII.F.4. of this proposed rule, would incentivize ADVaNCE MA model participants to constantly strive to be the highest performer amongst their peers in the same Mandatory State and cohort in order to receive the largest adjustments to their benchmarks and rebates.

The use of cohorts would also incentivize better quality by providing greater transparency in performance differences. While the ADVaNCE MA model participants within the General Enrollment cohort may include dual eligible, LIS, and disabled enrollees, the D-SNP cohort would consist only of dual eligible enrollees actively enrolled in D-SNPs and provide a distinct ADVaNCE MA Overall Diamond Rating for the D-SNP contracts under a parent organization within a Mandatory State, providing a clearer view into their specific quality performance. Thus, we believe the cohort structure would generate more relevant quality measurement information for dual eligible enrollees by reporting quality data in a way that empowers them to make the best choice when selecting between both General Enrollment and D-SNP-specific plan offerings and make it possible to make a selection based on the highest quality D-SNP on Medicare Plan Finder.

Additionally, the cohort structure narrows potential disparities in payments for ADVaNCE MA model participants that have more D-SNPs. An ADVaNCE MA model participant's quality performance for the General Enrollment cohort would be compared with all other ADVaNCE MA model participants' quality performance within the General Enrollment

cohort for the same Mandatory State. Similarly, a D-SNP's quality performance would be compared with all other ADVaNCE MA model participants' D-SNP quality performance within the D-SNP cohort for the same Mandatory State.

We seek comment on our proposal to use two cohorts, one for General Enrollment contracts and another for D-SNP contracts, for scoring purposes in the Diamond Ratings system.

b. Measure Scoring

For the Diamond Ratings system, we are proposing at § 516.215(b) that the data reported for the measures by each ADVaNCE MA model participant under § 516.205 would be pooled with measure data reported by all other ADVaNCE MA model participants within the same parent organization, same cohort, and same Mandatory State using enrollment-weighted averages based on enrollment data from July of the measurement period, except for survey-based measures, consistent with the process used for consolidated contracts in the MA and Part D Star Ratings system under 42 CFR 422.162(b)(3).199 The survey-based measures would use the enrollment at the time the sample is pulled for the rating year for all ADVaNCE MA model participants within the same parent organization and same cohort in the same Mandatory State. Accordingly, all ADVaNCE MA model participants under a single parent organization and within the same cohort and same Mandatory State would receive one set of measure scores for each Diamond Ratings system quality measure. We believe that reporting measure data pooled across ADVaNCE MA model participants under each parent organization within each cohort would both provide more meaningful data for beneficiaries and help reduce complexity when selecting between plans on Medicare Plan Finder. Currently when beneficiaries search for plans in Medicare Plan Finder, they may see many different Star Ratings for each of the numerous contracts offered by a single parent organization.These ratings may represent the combined

[199] *See also* Centers for Medicare & Medicaid Services, 2026 Star Ratings Technical Notes (2025), https://www.cms.gov/files/document/2026-star-ratings-technical-notes.pdf.

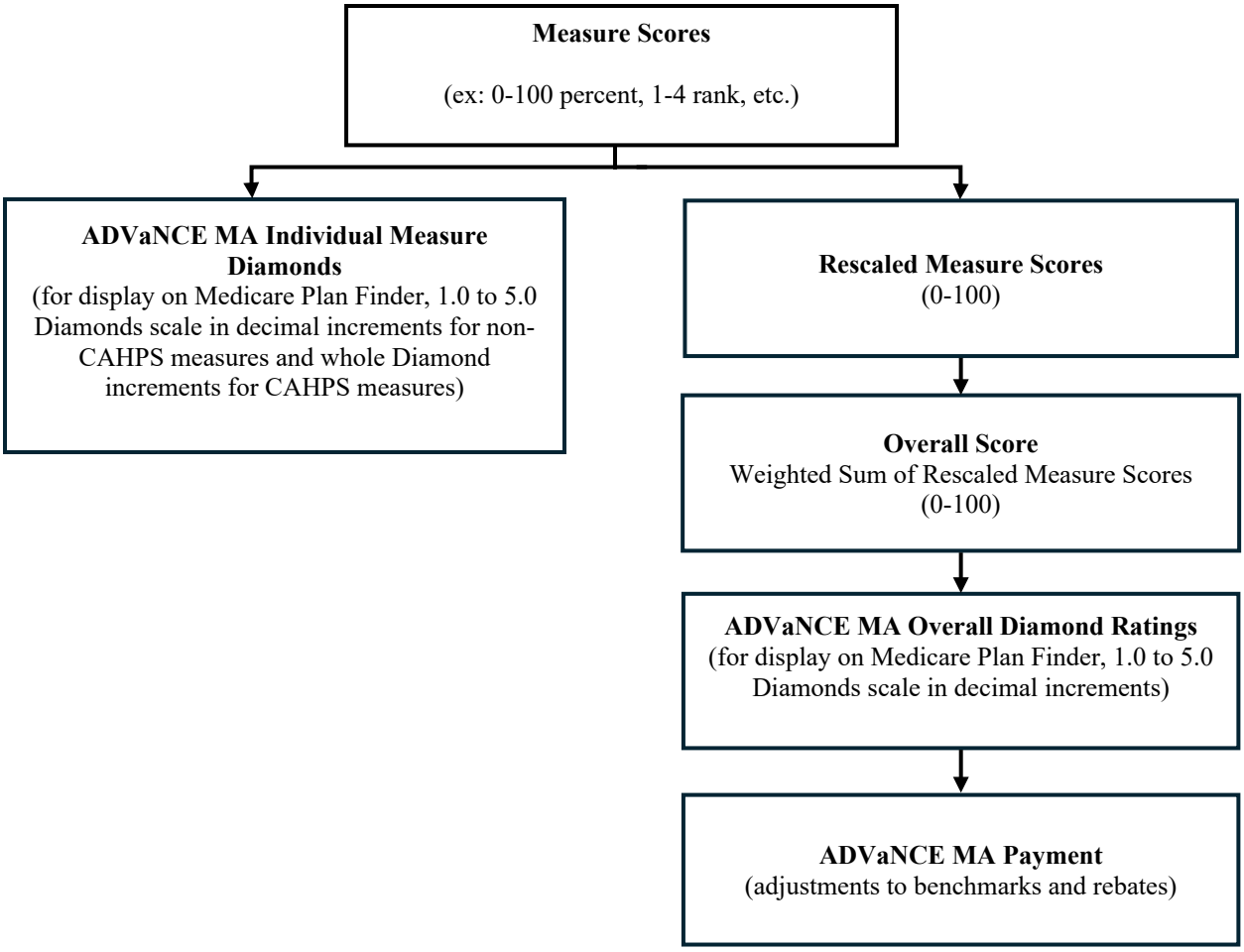
quality of care from a service area and network outside of the beneficiary's State of residence. Because ADVaNCE MA Overall Diamond Ratings would be specific to the quality of care received by beneficiaries within the Mandatory State, beneficiaries would be guaranteed that the quality ratings they see would reflect quality experienced by other beneficiaries in their Mandatory State. Furthermore, for a beneficiary choosing between multiple contracts under the current MA and Part D Star Ratings system, the beneficiary may encounter multiple plan choices across different carriers with identical Star Ratings. Under our proposal, we believe that the newly calculated ADVaNCE MA Overall Diamond Ratings could offer beneficiaries an option to quickly stratify their search by quality before looking to other factors, such as premiums, for the plan selection.

Under this proposed framework, ADVaNCE MA model participants under the same parent organization in a Mandatory State may have up to two distinct sets of measure scores, one for the General Enrollment cohort and one for the D-SNP cohort. For example, consider a parent organization that has three participating contracts in a Mandatory State, where one contract represents an HMO network that exclusively has General Enrollment contract offerings, the second contract represents a PPO network that exclusively has General Enrollment contract offerings, and a third contract that exclusively has D-SNP contract offerings. The HMO contract and PPO contract would independently collect measure data, according to the data collection requirements for contracts as specified by the MA and Part D Star Ratings system. The measure data for these two contracts under the General Enrollment cohort would be pooled together to create one set of measure scores to represent the performance of those ADVaNCE MA model participants under the same parent organization in the same Mandatory State within the General Enrollment cohort across all ADVaNCE MA measures. The third D-SNP contract would also independently collect measure data to create one set of measure scores that represents the ADVaNCE MA model participant's performance within the D-SNP cohort within the Mandatory State. We believe that pooling the measure data

across like ADVaNCE MA model participants within the same parent organization, same cohort, and same Mandatory State ensures that the measure scores reflect the quality of care specific to the services provided within the same State for similar enrollees, and parent organization, based on similar provider networks. It would also ensure that all contracts receive equitable resources from parent organizations, because the lowest performing contracts' scores are combined with the highest performing contracts.

We are proposing in § 516.5 to define "measure score" to have the same meaning set forth in 42 CFR 422.162. The measure scores for all available measures in the Diamond Ratings system measure set would be the basis for the quality assessment of the ADVaNCE MA model participants under a parent organization within each cohort and Mandatory State. The measure scores are, therefore, used to calculate and create both ADVaNCE MA Individual Measure Diamonds (for public display only) and ADVaNCE MA Overall Diamond Ratings (used for public display and payment), as described in the sections that follow and as outlined in FIGURE **IX-F1**.

FIGURE IX-F1: STEPS TO USE MEASURES SCORES FOR ADVANCE MA INDIVIDUAL MEASURE DIAMONDS, ADVANCE MA OVERALL DIAMOND RATINGS, AND ADVANCE MA PAYMENT



We seek comment on our proposal to pool ADVaNCE MA model participant-reported measure data together with other ADVaNCE MA model participants that have the same parent organization, same cohort, and same Mandatory State. We also seek comment on our proposal to assign each ADVaNCE MA model participant one set of measure scores based on the parent organization's performance in each Mandatory State and within each cohort for each Diamond Ratings system quality measure with sufficient enrollment and data reporting.

c. ADVaNCE MA Individual Measure Diamonds

Under the current MA and Part D Star Ratings system framework, CMS assigns measure stars for each numeric measure score using a clustering algorithm for non-CAHPS measures and a relative distribution for CAHPS measures, in accordance with 42 CFR 422.166(a)(2), 42 CFR 422.166(a)(3), 42 CFR 423.186(a)(2), and 42 CFR 423.186(a)(3).

Measure stars are displayed using a five-star scale ranging from one (lowest rating) to five (highest rating) and posted on the Medicare Plan Finder with whole star increments for the

cut points, as described in 42 CFR 422.166(a)(4) and 42 CFR 423.186(a)(4). MA and Part D Star Ratings program measures are assigned stars at the contract level.

At § 516.215(c)(1), we are proposing to assign ADVaNCE MA Individual Measure Diamonds for each measure score received by the ADVaNCE MA model participant, replacing the MA and Part D Star Ratings system framework. We also propose at § 516.215(c)(1)(i) that the ADVaNCE MA Individual Measure Diamonds would be displayed on Medicare Plan Finder on a five-Diamond scale ranging from one (lowest rating) to five (highest rating). We propose that CAHPS measures would be displayed to the nearest whole Diamond, consistent with how Measure Star Ratings are displayed by applying 42 CFR 422.166(a)(3) to ADVaNCE MA Individual Measure Diamonds.

For non-CAHPS measures, on the other hand, we propose to display such ADVaNCE MA Individual Measure Diamonds in one-tenth increments, whichc captures additional granularity in performance that would be beneficial for Medicare Plan Finder users seeking more nuance about differences in quality between parent organizations' quality performance.

We propose at § 516.215(c)(2)(i) that ADVaNCE MA model participants' ADVaNCE MA Individual Measure Diamonds would be publicly displayed beginning in CY 2031 reflecting the applicable measurement period through CY 2040. Additionally, we are proposing at § 516.215(c)(2) that failure to adhere to reporting or data integrity requirements for a measure required under § 516.205(a) would result in an ADVaNCE MA Individual Measure Diamond of one Diamond. This proposal is consistent with the MA and Part D Star Ratings system regulations at 42 CFR 422.164(g) and 42 CFR 423.184(g), which reduce a measure rating to one star for data inaccuracy, incompleteness, or bias.

At § 516.215(c)(2)(iii) and (iv), we propose using a modified clustering algorithm for non-CAHPS measures and relative distribution and significance testing for CAHPS measures that are based on the methodologies used by the MA and Part D Star Ratings system, as outlined in 42 CFR 422.166(a) and 42 CFR 423.186(a), to calculate the ADVaNCE MA Individual

Measure Diamonds for ADVaNCE MA model participants. To establish the distribution, we would use quality measurement data from the ADVaNCE MA model participants in the ADVaNCE MA model. At § 516.215(c)(2)(ii), we propose to determine cut points for the assignment of ADVaNCE MA Individual Measure Diamonds for each numeric measure score by applying either a modified clustering algorithm or the relative distribution and significance testing methodology, depending on whether the measure is non-CAHPS or CAHPS, respectively. For non-CAHPS measures, we propose to modify the clustering methodology to assign ADVaNCE MA Individual Measure Diamonds using one-tenth (0.1) Diamond increments across the 1.0-to-5.0 Diamond scale. Additionally, beginning with Individual Measure Diamonds calculations based on the second measurement period (applicable to the 2032 Diamond Ratings), and consistent with 42 CFR 422.166(a)(2) and 42 CFR 423.186(a)(2), we propose to add a guardrail, as defined under § 422.162(a), so that the measure-threshold-specific cut points for non-CAHPS measures would not increase or decrease more than the value of the cap from one year to the next. We propose to apply the cap as set forth in § 422.166(a)(2)(i), which provides that the cap is equal to five percentage points for measures having a zero to 100 scale or five percent of the restricted range for measures not having a zero to 100 scale.

The clustering method for non-CAHPS measures would be consistent with the current MA and Part D Star Ratings system, which uses mean resampling with hierarchical clustering of the current year's data. However, instead of producing five discrete measure ratings categories, we propose to expand the resulting cut points to support assignment of ADVaNCE MA Individual Measure Diamonds in one-tenth (0.1) Diamond increments across the 1.0 – to – 5.0 Diamond scale, which provides greater granularity. This would entail increasing the number of cut points within the clustering algorithm from four to 40 breaks, resulting in an increase in the number of discrete intervals from five to 41 bins. At § 516.215(c)(2)(iii)(B), we propose that for situations where there are not enough reporting units to create 41 intervals, CMS will

calculate the largest number of discrete intervals whose minimum number of reporting units is met. CMS will determine the maximum number of intervals, k, used in the clustering algorithm for which the number of reporting units with non-null, non-outlier measure scores, N, satisfies the floor $(0.9 \times N) \geq k$. The resulting Individual Measure Diamond will be reported in increments of $4/(k-1)$ Diamonds, rounded to the nearest hundredth and between 1.0 and 5.0. Additionally, we propose that only data collected from ADVaNCE MA model participants across all Mandatory States and cohorts would be used within the clustering algorithm for non-CAHPS measures.

We propose that the relative distribution and significance testing method for CAHPS measures would combine evaluating the relative percentile distribution with significance testing and accounts for the reliability of scores produced from survey data. Low reliability scores would be defined as those with at least 11 respondents, reliability greater than or equal to 0.60 but less than 0.75, as well as in the lowest 12 percent of ADVaNCE MA model participants within a cohort ordered by reliability. Consistent with the MA and Part D Star Ratings system's policies, no ADVaNCE MA Individual Measure Diamonds would be produced if the reliability of a CAHPS measure is less than 0.60. The rules outlined in 42 CFR 422.166(a)(3) and 42 CFR 423.186(a)(3) would also apply to the calculation of ADVaNCE MA Individual Measure Diamonds for any CAHPS measures in the Diamond Ratings system measure set.

The ADVaNCE MA Individual Measure Diamonds would replace the MA and Part D Individual Measure Star Ratings for any ADVaNCE MA model participant in a Mandatory State for CYs 2031 through 2040 for ADVaNCE MA model participants. On the Medicare Plan Finder tool, a user would input their relevant details, including their zip code, State (as needed), the type of plan they are searching for, and if they are enrolled or qualify for Medicaid (indicating dual eligibility status).

If the user is in a Mandatory State for the ADVaNCE MA model, the Medicare Plan Finder would only display the ADVaNCE MA Individual Measure Diamonds for cohorts

relevant to the user. We note that, because each ADVaNCE MA model participant with the same parent organization in the same cohort and the same Mandatory State would receive the same set of measure scores, such ADVaNCE MA model participants would also receive the same ADVaNCE MA Individual Measure Diamonds displayed on Medicare Plan Finder as all other ADVaNCE MA model participants under the same parent organization in the same cohort and Mandatory State. This is a departure from the MA and Part D Measure Star Ratings, which are assigned and displayed individually at the contract level. Assigning Star Ratings at the contract level may result in competition among contracts within the same parent organization. In contrast, under the proposed ADVaNCE MA competition structure, contracts under the same parent organization in the same cohort and Mandatory State would receive the same set of measure scores and ADVaNCE MA Individual Measure Diamonds to ensure parent organizations are accountable for performance in the Mandatory State, rather than receiving scores tied to contracts that may span many States. This moves the level of competition up to the parent organization within a Mandatory State, to compete for highest quality. p

We seek comment on all of these proposals, including but not limited to the proposals to attribute ADVaNCE MA Individual Measure Diamonds for each measure score received by an ADVaNCE MA model participant within its cohort in a Mandatory State, to use modified versions of the methods for clustering and relative distribution in the MA and Part D Star Ratings system, and to publicly display the ADVaNCE MA Individual Measure Diamonds on the Medicare Plan Finder using a scale of one to five with one-tenth of a Diamond cut points for non-CAHPS measures and whole Diamond cut points for CAHPS measures.

d. Overall Score

Under the current MA and Part D Star Ratings system, an overall Star Rating, Part C summary rating, and Part D summary rating are calculated for each MA-PD contract, as described in 42 CFR 422.162(b) and 423.182(b). The current system also has a Part C summary rating for each MA-only contract using the five-star rating system, as described in 42 CFR

422.162(b). Measures are assigned Star Ratings at the contract level and weighted in accordance with 42 CFR 422.166(e) and 42 CFR 423.186(e). Domain ratings are the unweighted mean of the individual measure Star Ratings under the topic area in accordance with 42 CFR 422.166(b) and 42 CFR 423.186(b). Part C and Part D summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with 42 CFR 422.166(c) and 42 CFR 423.186(c), with the applicable adjustments described in 42 CFR 422.166(f) and 42 CFR 423.186(f). Overall ratings are calculated by using the weighted mean of the individual measure ratings in accordance with 42 CFR 422.166(d) and 42 CFR 423.186(d), with the applicable adjustments provided in 42 CFR 422.166(f) and 42 CFR 423.186(f). CMS includes the MA and Part D Star Ratings measures in the overall and summary ratings that are associated with the contract type for the Star Ratings year.

For the Diamond Ratings system, and as shown in FIGURE **IX-F1** (Steps to Use Original Measure Scores) in section VIII.F.3.b (Measure Scoring) of this proposed rule, we would use each ADVaNCE MA model participant's measure scores to calculate: (1) ADVaNCE MA Individual Measure Diamonds, as discussed in section VIII.F.3.c. of this proposed rule and as proposed at § 516.215(c); and (2) overall scores that would then be translated into ADVaNCE MA Overall Diamond Ratings used on an incremental basis for determining ADVaNCE MA rebate and benchmark adjustments, as proposed at § 516.220 and § 516.230.

We propose at § 516.215(d) that an overall score would be calculated using an incremental performance-to-points scale to determine an ADVaNCE MA Overall Diamond Rating for display purposes on the Medicare Plan Finder tool, as described in section VIII.F.3.e of this proposed rule. ADVaNCE MA Overall Diamond Ratings would also be used to calculate ADVaNCE MA rebate and benchmark adjustments for all ADVaNCE MA model participants within a cohort in the same Mandatory State as described in section VIII.F.4. of this proposed rule.

(1) Minimum Reporting Requirements

The MA and Part D Star Ratings system requires that a contract have measure scores for at least 50 percent of measures required to be reported for the contract to have the summary rating calculated in accordance with 42 CFR 422.166(c)(2) and 42 CFR 423.186(c)(2). Similarly, we are proposing at § 516.215(d)(1) that a parent organization within each cohort and Mandatory State, would receive an overall score if the ADVaNCE MA model participants for that MA organization receive measure scores for at least 50 percent of all ADVaNCE MA Diamond Ratings system quality measures required to be reported in the ADVaNCE measure set. Similar to the MA and Part D Star Ratings system, we are proposing at § 516.215(d)(1)(i) that improvement measures will be excluded from the count of measures needed to be reported to receive an overall score. Unlike the MA and Part D Star Ratings system, reportability would be assessed at the parent organization, cohort, Mandatory State-level. As described earlier in section VIII.F.3.b. of this proposed rule (Measure Scoring), measure data reported by all ADVaNCE MA model participants under the same parent organization in the same cohort and within each Mandatory State would be pooled together to calculate one set of measure scores; therefore, minimum reporting would, in effect, be calculated at the parent organization-level. For example, consider a parent organization in a Mandatory State that has three participating contracts in the General Enrollment cohort. Each participating contract would collect and report data on each measure as it would under the MA and Part D Star Ratings system. However, under the Diamond Ratings system, for each measure, the measure calculations would be performed such that the measure denominator would include all enrollees under the parent organization's three participating contracts within the General Enrollment cohort for the Mandatory State. If future measure changes are made to the ADVaNCE MA Diamond Ratings system measure set, ADVaNCE MA model participants would still be required to meet the minimum reporting requirements described here, such that ADVaNCE MA model participants would need to have measure scores for at least 50 percent of the total measures (as pooled with

other ADVaNCE MA model participants with the same parent organization in the same cohort and same Mandatory State). Additionally, we note that as proposed in § 516.200(a)(3), if an ADVaNCE MA model participant fails to adhere to reporting or data integrity requirements for a measure required under § 516.205(a), such non-missing zero measure would contribute to the measures required to meet the minimum reporting requirements. The proposed process for calculating the overall score for all eligible ADVaNCE MA model participants is described in the sections that follow in this proposed rule.

We considered an alternative minimum reporting requirement that would require an ADVaNCE MA model participant to have measure scores for at least 50 percent of the total available measure weights to receive an overall score and ADVaNCE MA Overall Diamond Rating. Such an approach would sum the category weight assigned to each measure in the measure set (that is, Intermediate Outcome measures receive a weight of three, Process Measures receive a weight of one) and require that the sum of the weights of all measures that an ADVaNCE MA model participant reports equal at least 50 percent of that total. This option to use measure weights to establish the minimum reporting requirements for the Diamond Ratings system would result in contracts that are able to report more highly weighted measures to be more likely to receive a score. We believe these highly weighted measures, including outcome and improvement measures, would be most important in defining quality, and would ensure that at least some outcome measures are reported by ADVaNCE MA model participants in order to have sufficient reporting. However, we are not proposing to use measure weights in determining whether minimum reporting requirements have been met at this time in order to minimize the number of changes and to remain aligned with reportability in the MA and Part D Star Ratings system.

We seek public comment on our minimum reporting requirement proposal.

(2) Rescaled Measure Score

We are proposing at § 516.215(d)(2)(i) to convert all available measure scores to a rescaled measure score between zero and 100 as part of the broader overall score calculations and to define a "rescaled measure score" accordingly at § 516.5. Failure to adhere to reporting or data integrity requirements for a measure required under § 516.205(a) would result in a rescaled measure score of zero for such measure. To be clear, we would be assigning the rescaled measure score, not the measure score, a value of zero, so that the zero values would not be in effect prior to the rescaling process for each measure.

Before rescaling measure scores to a value between zero and 100, we propose at § 516.215(d)(2)(i)(A) to cap upper- and lower-bound outlying values across all measures using the process as described in the MA and Part D Star Ratings system at 42 CFR 422.166(a)(2) and 42 CFR 423.186(a)(2). The capping approach sets values exceeding the upper bound (the third quartile plus three times the inter-quartile range (IQR)) equal to the upper bound value, and sets values below the lower bound (the first quartile minus three times the IQR) equal to the lower bound value. We believe that identifying and capping the Tukey outer fence outliers, as defined under 42 CFR 422.162(a), prior to rescaling would alleviate the impact of any extreme outliers whose inclusion would compress the measure distributions and result in lesser differentiation when assessing quality measures. For example, if an ADVaNCE MA model participant has a measure score that is an extreme outlier with a significantly low score on a measure score, the measure score would be replaced with the value of the lower bound. We acknowledge that the MA and Part D Star Ratings system does not apply caps in this manner with respect to calculating overall Star Ratings. However, we believe this proposal is essential to making fair comparisons among ADVaNCE MA contracts under the comparative nature of the Diamond Ratings system.

After capping outlier values and incorporating case mix adjustments where applicable, we propose at § 516.215(d)(2)(i)(B) that all measure scores would be rescaled using the

following formula, where x is the ADVaNCE MA model participant's measure score on a given measure as calculated for the Diamond Ratings system, *min(x)* and *max(x)* are the minimum and maximum values for the measure score reported by all ADVaNCE MA model participants in their cohort who are eligible to receive an overall score across all Mandatory States to receive an overall score, and x' is the rescaled measure score on a zero to 100 scale.

$$x' = \frac{x - min(x)}{max(x) - min(x)} * 100$$

There are certain measures, such as Plan All Cause Readmissions, where a lower measure score equates to a better performance. After all measures are rescaled, we propose at § 516.215(d)(2)(i)(C) that measures for which a lower measure score indicates better performance would be subtracted from 100 to orient the score correctly for future steps in calculating Overall Diamond Ratings.

After re-orienting any applicable rescaled measures scores, we would then sum all the rescaled measure scores and multiply the sum total by the measure's respective measure weight to achieve the overall score, as described in section VIII.F.3.d.(3). of this proposed rule (Measure Weighting for ADVaNCE MA Diamond Ratings system measures). We believe that rescaling the measure scores using the previously noted formula to convert them to a zero to 100 scale would maintain the relative distribution of ADVaNCE MA model participants' performance on each measure and is necessary to align measures reported across different scales prior to measure weighting discussed below. For example, the Breast Cancer Screening measure is described as the percent of female plan members aged 50-74 who had a mammogram.[200] The range of all possible values for this measure is between zero percent to 100 percent, though the observed range of measure values after capping outliers may be narrower (for example, between 42 percent and 94 percent). Another measure, Monitoring Physical Activity, is described as the percent of senior plan members who discussed exercise with their doctor and were advised to

[200] 2026 Star Ratings Technical Notes, https://www.cms.gov/files/document/2026-star-ratings-technical-notes.pdf.

start, increase, or maintain their physical activity during the year. Possible values for this measure also range between zero percent to 100 percent, though the observed range of measure values may be narrower (for example, between 33 percent and 73 percent). To address this, the proposed methodology rescales each measure's observed range to a zero to 100 scale while preserving the shape of its underlying distribution. For example, before rescaling, the Breast Cancer Screening measure would have an observed range of 52 percentage points, compared to the observed range for the Monitoring Physical Activity measure of 40 percentage points. Without rescaling, Breast Cancer Screening would have greater influence in differentiating performance because its values vary more widely, even though both measures have a weight of one.

Additionally, to clarify, we propose to rescale measures separately for General Enrollment and D-SNP cohorts. That is, we would have one set of minimum and maximum measure scores for each measure for the General Enrollment cohort, and a second set of minimum and maximum measure scores for the D-SNP cohort. Our analysis indicates that rescaling measures within each cohort would account for differences in measure distributions observed between General Enrollment and D-SNP cohorts, and that both the highest and lowest scores should reflect the values observed within each cohort group.

We seek comment on these proposals, including our proposal to cap upper- and lower-bound outlying values across all measures and our proposal to rescale measure scores as part of the overall score methodology.

(3) Measure Weighting for ADVaNCE MA Diamond Ratings System Measures

Under the current MA and Part D Star Ratings system, different categories of measures are given different weights, which are then used in the calculation of overall and summary Star Ratings based on a weighted mean of the MA and Part D measure-level Star Ratings, as described at 42 CFR 422.166 and 42 CFR 423.186. Currently, process measures receive a weight of one, patients' experience and complaints measures and access measures receive a

weight of two, outcome and intermediate outcome measures receive a weight of three, and improvement measures receive a weight of five as outlined in 42 CFR 422.166(e)(1) and 42 CFR 423.186(e)(1). The weighting of the measure categories impacts ratings and reflects the relative importance of the measures' contributions to the goals of the MA and Part D Star Ratings system.

We are proposing at § 516.215(d)(2)(ii) that measure weights would be applied to all non-missing measures according to their weighting category. Moreover, we are proposing at § 516.215(d)(2)(ii)(A) that, except as provided at paragraph (d)(2)(ii)(B), CMS would assign weights for Diamond Ratings system measures that align with the measure category weighting of the MA and Part D Star Ratings system and weight measures based on measure categorization as described in 42 CFR 422.166(e) and 42 CFR 423.186(e). At § 516.215(d)(2)(ii)(B), we specify that we may add or change measure weighting categories in future years through rulemaking. Additionally, since we propose at § 516.205(a) that CMS would initially use the quality measure set used in the MA and Part D Star Ratings system for the Diamond Ratings system with the understanding that CMS would automatically add, remove, or make substantive or non-substantive updates to the Diamond Ratings measure set to align with the Star Ratings unless specified otherwise in rulemaking, we want to clarify our measure weighting for the Diamond Ratings system measures in the event of any changes to the measure set. As in the current MA and Part D Star Ratings system, at § 516.215(d)(2)(ii)(C), we propose that new measures added to the Diamond Ratings system under § 516.205(b)(2) would receive a weight of one for the first year they are used in the calculation of Overall Diamond Ratings. Substantively updated Diamond Ratings measures (treated as new measures) under § 516.205(b)(3)(ii) would receive a weight of one in their first year returning to the Diamond Ratings system after being on the CMS website. To clarify, for the 2031 Diamond Ratings, this would only apply if the new or substantively updated measure in the Diamond Ratings measure set is a new or substantively updated measure in the MA and Part D Star Ratings measure set

because the Diamond Ratings measure set would not have diverged from the Star Ratings measure set through rulemaking at that time. After the first year a measure is used in the calculation of Overall Diamond Ratings, the measure would be assigned the weight associated with its category as designated by CMS.

We seek comment on our measure weighting proposals.

(4) Overall Score Calculation

As part of the broader overall score calculations for the Diamond Ratings system, we are proposing at § 516.215(d)(2)(i) to rescale measure scores. To complement this process, the overall score calculations would also include the measure weighting for the Diamond Ratings system measures. Therefore, at § 516.215(d)(2)(iii)(A), we propose that for each ADVaNCE MA model participant, CMS would obtain a weighted average of the rescaled measure scores and respective measure weights in the Diamond Ratings system to calculate each overall score in each cohort in a Mandatory State. The weight of each non-missing measure would be applied to the value of the rescaled measure score, as proposed at § 516.215(d)(2)(iii)(B). Then, the total weighted points would be divided by the weighted count of all available measures.

Specifically, § 516.215(d)(2)(iii)(C) proposes the equation of this overall score that combines the rescaled measure scores, described in section VIII.F.3.d.(2) of this proposed rule, and the applicable measure weights in the Diamond Ratings system, described in section VIII.F.3.d.(3) of this proposed rule for each cohort in a Mandatory State. To calculate the overall score, the score would equal the sum of all non-missing measures reported by the ADVaNCE MA model participant, where x' is the rescaled measure score of each non-missing measure, w is the corresponding weight of each non-missing measure, and n indicates the number of all non-missing measures. The weight of each non-missing measure will be applied to the value of the rescaled measure score. Then, the total weighted points will be divided by the weighted count of all available measures.

$$Overall\ Score = \frac{\sum_{i=1}^{n} x'_i * w_i}{\sum_{i=1}^{n} w_i}$$

At § 516.215(d)(2)(iii)(D), we propose that the overall score would be a value between zero and 100. CMS will use overall scores to assess the relative performance of each ADVaNCE MA model participant in each cohort, to calculate ADVaNCE MA Overall Diamond Ratings for public display under § 516.220, and then to calculate ADVaNCE MA Payment amounts under § 516.230.

An overall score would be assigned to all ADVaNCE MA model participants who receive measure scores for the minimum required 50 percent of the measures (after pooling together the ADVaNCE MA model participant measure data for all ADVaNCE MA model participants under the same parent organization in the same cohort and the same Mandatory State). The overall scores would then determine an ADVaNCE MA model participant's ADVaNCE MA Overall Diamond Rating for display and ADVaNCE MA Payment amount. An ADVaNCE MA model participant that is ineligible to receive an overall score, due to not meeting the minimum data reporting requirements, would not receive an overall score or ADVaNCE MA Overall Diamond Rating as described in section VIII.F.3.e of this proposed rule.

We have included a scoring example in Table I-2 to demonstrate how overall scores would be calculated for an ADVaNCE MA model participant within a D-SNP cohort in a Mandatory State that has met the minimum reporting requirements. We refer readers to section VIII.F.3.d.(2) of this proposed rule on rescaled measure calculations, and section VIII.F.3.d.(3) of this proposed rule on measure weighting for more details on the proposed components of the overall score. We also note that as described in VIII.F.3.d.(1) of this proposed rule (Minimum Reporting Requirements) and proposed at § 516.215(d)(1), only ADVaNCE MA model participants who receive measure scores (as that measure data are pooled with other ADVaNCE MA model participants under the same parent organization, in the same cohort and in the same

Mandatory State) on at least 50 percent of the measures would receive overall scores and subsequent ADVaNCE MA Overall Diamond Ratings and ADVaNCE MA Payment calculations. If the ADVaNCE MA model participant's parent organization does not meet the minimum reporting requirements, the ADVaNCE MA model participant would not receive an overall score. For an ADVaNCE MA model participant that has insufficient data to meet the minimum reporting requirement, Medicare Plan Finder would display "not enough data available," as discussed in section VIII.F.3.e. of this proposed rule. Additionally, such an ADVaNCE MA model participant would receive a set benchmark and rebate adjustment as discussed in section VIII.F.4 of this proposed rule.

TABLE I-2: ILLUSTRATIVE EXAMPLE OF THE OVERALL SCORE COMPONENTS FOR AN ADVaNCE MA MODEL PARTICIPANT WITHIN A D-SNP COHORT

Measure Name	Measure Score (x)	Rescaled Measure Score (x')	Weight (w)	Rescaled Measure Score * Measure Weight ($x' * w$)
Annual Flu Vaccine	58.97	39.19	1	39.19
Breast Cancer Screening	NA	NA	1	NA
Care Coordination	81.50	52.58	2	105.16
Care for Older Adults - Medication Review	NA	NA	1	NA
Care for Older Adults - Pain Assessment	NA	NA	1	NA
Colorectal Cancer Screening	55.88	41.05	1	41.05
Controlling Blood Pressure	92.31	85.75	3	257.25
Diabetes Care - Blood Sugar Controlled	82.79	61.17	3	183.52
Diabetes Care - Eye Exam	72.95	57.76	1	57.76
Follow-up after Emergency Department Visit for People with Multiple High-Risk Chronic Conditions	67.21	63.15	1	63.15
Getting Appointments and Care Quickly	85.00	62.33	2	124.66
Getting Needed Care	81.74	55.56	2	111.11
Health Plan Quality Improvement	0.47	85.80	5	429.01
Improving Bladder Control	NA	NA	1	NA
Improving or Maintaining Mental Health	NA	NA	3	NA
Improving or Maintaining Physical Health	NA	NA	3	NA
Kidney Health Evaluation for Patients with Diabetes	66.67	65.58	1	65.58

Measure Name	Measure Score (x)	Rescaled Measure Score (x')	Weight (w)	Rescaled Measure Score * Measure Weight ($x' * w$)
Medication Reconciliation Post-Discharge	93.30	92.57	1	92.57
Monitoring Physical Activity	53.06	42.25	1	42.25
Osteoporosis Management in Women who had a Fracture	NA	NA	1	NA
Plan All-Cause Readmissions	NA	NA	3	NA
Rating of Health Plan	87.52	59.61	2	119.22
Reducing the Risk of Falling	80.00	79.54	1	79.54
Transitions of Care	71.01	62.13	1	62.13
Drug Plan Quality Improvement	0.00	50.00	5	250.00
Getting Needed Prescription Drugs	86.59	58.06	2	116.12
Medication Adherence for Cholesterol (Statins)	0.93	90.64	3	271.91
Medication Adherence for Diabetes Medications	0.90	75.49	3	226.47
Medication Adherence for Hypertension (RAS antagonists)	0.93	87.07	3	261.21
MTM Program Completion Rate for CMR	0.97	89.23	1	89.23
Rating of Drug Plan	89.90	69.64	2	139.29
Statin Use in Persons with Diabetes (SUPD)	0.90	60.13	1	60.13

We note that for the purposes of this illustrative example, we have rounded the values in Table I-2 and in our further examples in this section; however, at § 516.215(d)(2)(iii)(C), we are proposing that we would express our scoring and measure calculations up to two decimal places. In the example illustrated in Table I-2, all non-missing rescaled measure scores are multiplied by their measure weights. For the numerator in the overall score formula, products of the rescaled measure scores with their measure weights would then be summed, which in this example would equal 3287.51. The denominator of the overall score formula is the sum total of all measure weights for non-missing measures, which in this case is 48. We note that we would not include the measure weights for measures in which ADVaNCE MA model participants do not meet the measure reporting requirements (in this example, the measure weights without sufficient data would be Breast Cancer Screening, Care for Older Adults - Medication Review, Care for Older Adults - Pain Assessment, Improving Bladder Control, Improving or Maintaining Mental Health, Improving or Maintaining Physical Health, Osteoporosis

Management in Women who had a fracture, Plan All-Cause Readmissions). To calculate the overall score in this example, we would divide 3287.51 by 48, to obtain an overall score of 68.49. We believe that the proposed overall score calculation with an incremental scale would allow changes in quality to translate into potential changes in payments and recognize incremental improvement in quality for all ADVaNCE MA model participants.

We seek comment on our proposed calculation of an overall score.

e. ADVaNCE MA Overall Diamond Ratings

Under the MA and Part D Star Ratings program, CMS develops and publicly posts a five-star rating system for Part C and Part D contracts. The MA and Part D Star Ratings system is used to determine QBP ratings for MA contracts under section 1853(o) of the Act and the amount of MA beneficiary rebates under section 1854(b) of the Act. CMS uses multiple data sources based on the collection of different types of quality data to measure quality and performance of contracts, such as CMS administrative data, surveys of enrollees, and information provided directly from health and drug contracts. CMS regulations, including 42 CFR 422.162(c) and 42 CFR 423.182(c) require contracts to collect, analyze, and report data that permit measurement of health outcomes and other indices of quality. The methodology for the Star Ratings system is codified at 42 CFR 422.160 through 422.166 and 42 CFR 423.180 through 423.186.

We propose our policies for an ADVaNCE MA Overall Diamond Ratings at § 516.220.

(1) ADVaNCE MA Overall Diamond Rating Methodology

We are proposing at § 516.220(a) that we would translate each overall score into an ADVaNCE MA Overall Diamond Rating for both display in Medicare Plan Finder and for ADVaNCE MA Payment on a five-point scale ranging from one (lowest rating) to five (highest rating) Diamonds, displayed with the numerical value of the Diamond in one-tenth of a Diamond increments.

We are proposing at § 516.220(b) to convert overall scores to an ADVaNCE MA Overall Diamond Rating by applying the following bounded rescaling formula. Overall scores (m) would be bounded at the overall score value at the 1st percentile (p_1) and the overall score value at the 99th percentile (p_{99}) within each cohort. We propose that an ADVaNCE MA model participant must receive one Diamond if they are at or below the overall score at the 1st percentile within each cohort, and an ADVaNCE MA model participant would receive five Diamonds if they are at or above the overall score at the 99th percentile within each cohort. For all ADVaNCE MA model participants with overall scores between the 1st percentile and 99th percentile, their ADVaNCE MA Overall Diamond Rating would be rescaled linearly between the overall score values at the 1st percentile and 99th percentile within each cohort between one and five Diamonds.

$$ADVaNCE\ MA\ Overall\ Diamonds\ =$$

$$\begin{cases} 1\ Diamond, if\ m\ \leq\ p_1 \\ 1\ +\ (5\ -\ 1)\left(\dfrac{m\ -\ p_1}{p_{0.99}\ -\ p_1}\right)\ Diamonds, if\ p_1 < m\ < p_{99} \\ 5\ Diamonds, if\ m\ \geq\ p_{99} \end{cases}$$

We believe that applying the bounded rescaling method within each cohort would ensure that differences in the range and distribution of the overall scores between the General Enrollment and D-SNP cohorts remain distinct from each other. That is, an ADVaNCE MA Overall Diamond Rating of five within the General Enrollment cohort would reflect the highest quality rating among its ADVaNCE MA model participants within the Mandatory States (i.e., an overall score at or above the 99th percentile within the cohort), and an ADVaNCE MA Overall Diamond Rating of five within the D-SNP cohort would reflect the highest quality rating among its ADVaNCE MA model participants within the Mandatory States (that is, an overall score at or above the 99th percentile within the cohort). While the separate bounded rescaling method may make comparing ADVaNCE MA Overall Diamond Ratings between D-SNP and General Enrollment plans more challenging, a Diamond Rating of five would always represent the best possible quality rating within the applicable cohort (i.e., at or above the 99th

percentile). We also believe that the bounding of overall score values at the 1st and 99th percentiles would limit the influence of extreme observations while retaining variation in overall scores between those bounds. Additionally, we believe that a linear rescaling function would preserve the shape of the underlying overall score distribution.

Under § 516.220(b)(1), we are proposing to round ADVaNCE MA Overall Diamond Ratings to the one-tenth decimal. For ADVaNCE MA Overall Diamonds calculated from the bounded rescaling formula ending in five to nine in the hundredths decimal place, we would round the ADVaNCE MA Overall Diamond Rating to the next tenth place for display on the Medicare Plan Finder.

We considered proposing a function to convert overall scores to an ADVaNCE MA Overall Diamond Rating by imposing a truncated normal distribution with a mean centered around three Diamonds and a standard deviation of 0.6 Diamonds and restricting the minimum and maximum at one and five Diamonds, respectively, across each cohort. We believe that enforcing a normal distribution for ADVaNCE MA Overall Diamond Ratings such that the average is three Diamonds would ensure that beneficiaries are easily able to judge the relative performance of MA organizations. That is, achieving above a three ADVaNCE MA Overall Diamond Rating would always mean that the ADVaNCE MA model participant is in the top 50 percent of ADVaNCE MA model participants in terms of quality. However, we believe that forcing a normal distribution would limit the number of ADVaNCE MA model participants that could achieve a high ADVaNCE MA Overall Diamond Rating and may distort the shape of the underlying distribution. Therefore, we are not proposing this methodology but are seeking comment on this alternative. The truncated distribution would be defined by the following formula:

$$ADVaNCE\ MA\ Overall\ Diamond\ Ratings$$

$$= 3 + \sigma\Phi^{-1}\left(\Phi\left(\frac{1-3}{\sigma}\right) + p_i\left[\Phi\left(\frac{5-3}{\sigma}\right) - \Phi\left(\frac{1-3}{\sigma}\right)\right]\right)$$

Where:

- σ = chosen spread (standard deviation) for the distribution
- Φ = the standard normal Cumulative Density Function (CDF)
- Φ^{-1} = the inverse standard normal CDF
- p_i = the percentile rank of the overall score within each cohort

We seek comment on our proposed calculation of the ADVaNCE MA Overall Diamond Ratings using a bounded recalling formula.

(2) Posting and Display

We propose at § 516.220(c) that ADVaNCE MA Overall Diamond Ratings would be publicly displayed on Medicare Plan Finder in place of the MA and Part D Star Ratings for ADVaNCE MA model participants' plans in each Mandatory State. For ADVaNCE MA model participants, ADVaNCE MA Overall Diamond Ratings would be displayed beginning in CY 2031 reflecting the applicable measurement period through CY 2040.

We note, again, that if there are multiple ADVaNCE MA model participants under the same parent organization, same cohort, and same Mandatory State, those ADVaNCE MA model participants would receive the same measure score, overall score, and ADVaNCE MA Overall Diamond Rating, which is displayed on Medicare Plan Finder. This is a departure from the Part C summary rating, Part D summary rating, and the Overall MA-PD rating, which are assigned and displayed at the individual contract level. Additionally, at § 516.220(d)(1), we are proposing that if the ADVaNCE MA model participant's parent organization does not meet the minimum reporting requirements under § 516.215(d)(1), the posting and display for any plan(s) under that ADVaNCE MA model participant would read "not enough data available." At § 516.220(d)(2), we propose that if the ADVaNCE MA model participant's parent organization is a new entrant as defined in § 516.5, the posting and display for any plan(s) under that ADVaNCE MA model participant would be "plan too new to be measured." We note that under our proposed definition at § 516.5, new entrants would not have any prior MA or QBP

participation in the Mandatory State for at least one performance year, and a parent organization can be a new entrant in either or both cohorts in a Mandatory State in a given year. At § 516.220(d)(3), we propose that if the parent organization of an ADVaNCE MA model participant has low enrollment, as defined in § 516.5, the posting and display for any plan(s) under that ADVaNCE MA model participant would be "not enough data available." We are also considering other ways to delineate the posting and display of a plan of an ADVaNCE MA model participant's parent organization that does not meet the minimum reporting requirements under § 516.215(d)(1), such as "non-compliant with reporting requirements," so that it is differentiated on Medicare Plan Finder from an ADVaNCE MA model participant that has low enrollment.

At § 516.220(e), we propose posting and display rules for new ADVaNCE MA model participants depending on their parent organization participation status. At § 516.220(e)(1), we propose that if the ADVaNCE MA model participant's parent organization has existing Medicare Advantage contracts outside of all Mandatory States and enters a Mandatory State in CY 2030 or subsequent years of the model, any posting and display of Diamond Ratings for any plan(s) under that ADVaNCE MA model participant would be "plan too new to be measured" for the participant's first two years in the model, until it has an ADVaNCE MA Overall Diamond Rating or other applicable designation. As an alternative, we considered proposing calculation of an enrollment-weighted average highest rating of the parent organization's contracts outside of Mandatory States for display and posting as the quality rating on Medicare Plan Finder. We believe that this option would allow for new ADVaNCE MA model participants in a Mandatory State to receive quality performance ratings more rapidly in the ADVaNCE MA model. However, we also believe that displaying enrollment-weighted ratings may be confusing to beneficiaries when assessing and comparing quality across plans offerings in a Mandatory State where ADVaNCE MA Overall Diamond Ratings would also be displayed.

Additionally, at § 516.220(e)(2), we propose that if the ADVaNCE MA model participant's parent organization has existing Medicare Advantage contracts in another Mandatory State(s) and enters a Mandatory State in CY 2030 or subsequent years of the model, any posting and display of Diamond Ratings for any plan(s) under that ADVaNCE MA model participant would also be "plan too new to be measured" for the participant's first two years in the model, until it has an ADVaNCE MA Overall Diamond Rating or other applicable designation.

We also considered proposing to calculate an enrollment-weighted average of the ADVaNCE MA Overall Diamond Ratings from the parent organization's ADVaNCE MA model participants in other Mandatory States and cohort for display and posting on Medicare Plan Finder. Similarly, we believe this option would allow for new ADVaNCE MA model participants in a Mandatory State to receive quality performance ratings more rapidly. However, we believe that using the quality performance rating of an ADVaNCE MA model participant in other States would be less aligned with the goals of the model to ensure that quality ratings displayed for beneficiaries are reflective of an ADVaNCE MA model participant's parent organization's quality performance specific to their Mandatory State.

As a note, ADVaNCE MA model participants with insufficient data, ADVaNCE MA model participants that are new entrants, ADVaNCE MA model participants with low enrollment, and ADVaNCE MA model participants that are new to a Mandatory State would not affect the relative performance of other existing ADVaNCE MA model participants in each Mandatory State and would still be subject to other provisions under the ADVaNCE MA model, such as ADVaNCE MA benchmark adjustments (as described at § 516.230(b)(1)), rebate percentages (as described at § 516.230(b)(4) and (b)(5)), and supplemental benefit flexibilities.

We seek comment on the posting and display of Diamond Ratings for ADVaNCE MA participants, especially new entrants and the verbiage in the display used to indicate an ADVaNCE MA model participant's parent organization that does not meet the minimum

reporting requirements to distinguish it from an ADVaNCE MA model participant with low enrollment. Additionally, we seek comment on the proposed definition of low enrollment at § 516.5, which would assign the low enrollment designation to an ADVaNCE MA model participant whose parent organization has fewer than 500 enrollees across all of its ADVaNCE MA contracts in a given cohort within a Mandatory State.

(3) ADVaNCE MA Preview Period

Similar to the MA and Part D Star Ratings system, which provides for plan preview periods as set forth at 42 CFR 422.166(h)(2) and 42 CFR 423.186(h)(2), we propose at § 516.220(f) CMS would have preview periods before each ADVaNCE MA Overall Diamond Ratings release, during which ADVaNCE MA model participants would be able preview their ADVaNCE MA Overall Diamond Ratings data in the Health Plan Management System (HPMS) prior to display on Medicare Plan Finder. During preview periods, ADVaNCE MA model participants would have an opportunity to review their Individual Measure Diamonds and ADVaNCE MA Overall Diamond Ratings, and to submit questions regarding this information.

We seek comment on our proposals related to the preview period of ADVaNCE MA Overall Diamond Ratings for ADVaNCE MA model participants.

(4) Alternatives Considered

The Diamond Ratings system aligns payment with quality performance through a ranked, incremental scoring scale. CMS acknowledges that alternative approaches where payment is partially or fully decoupled from quality metrics[201] may merit exploration. Such approaches could reduce administrative burden for both CMS and MA organizations and direct financial incentives may be important drivers of plan quality investment. We considered not ranking parent organizations for purposes of payment. However, we determined that would not address the areas of improvement for which the Diamond Ratings system is designed, including

[201] Vilsa Curto, Liran Einav, Jonathan Levin, and Jay Bhattacharya, Can Health Insurance Competition Work? Evidence from Medicare Advantage, NBER Working Paper no. 20818 (Cambridge, MA: National Bureau of Economic Research, December 2014), table 6, 50, https://doi.org/10.3386/w20818

the alignment of quality incentives with the quality outcomes sought by enrollees and more transparent geographically based quality rankings to inform beneficiary choice and foster a more dynamic competitive environment in MA.

CMS solicits comment on whether and to what extent payment should be decoupled from quality metrics and whether any such approach should be tested within the ADVaNCE MA model. We acknowledge analysis on the current program and the ability for financial linkage to quality to incentivize work to achieve the goal of higher quality.[202] The Diamond Ratings system as proposed as part of the ADVaNCE MA model strives to incentivize continued quality improvement, a more rapidly responsive measure set, and overall quality scores in a way geographically helpful to beneficiaries when making plan selection. We are considering an alternative that would fully decouple payment from quality performance.

This alternative approach draws from current dialogue on the topic and could be pursued with varying levels of benchmark and rebate percentages. If quality scores did not impact benchmarks and rebates, a standard rebate amount could be considered or the rebate amount could be based on local differences between bid and benchmarks. Quality could be monitored through more swift repercussions for poor performance as outlined in the article, "Charting a Path Forward for Medicare Advantage: Expert Consensus on Policy Priorities and Trade-Offs."[203] In exploring this option there is the consideration of what standard rebate percentage would be appropriate. CMS solicits comment on this alternative approach to be considered in future rulemaking, including but not limited to what benchmark and rebates percents should be if decoupled from quality performance and what, if any, additional constraints would be needed in conjunction to ensure the continued pursuit of high-quality care provision.

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[202] Markovitz, Adam A., John Z. Ayanian, Devraj Sukul, and Andrew M. Ryan. "The Medicare Advantage Quality Bonus Program Has Not Improved Plan Quality." *Health Affairs* 40, no. 12 (2021): 1918–25. https://doi.org/10.1377/hlthaff.2021.00606.

[203] Khodyakov, Dmitry, Erin A. Taylor, Christine Buttorff, Hannah James, Melony E. Sorbero, Rachel O. Reid, and Michael Dworsky. "Charting a Path Forward for Medicare Advantage: Expert Consensus on Policy Priorities and Trade-Offs." *Health Affairs* 45, no. 10 (2026): 1125–32. https://doi.org/10.1377/hlthaff.2025.01724.

4. ADVaNCE MA Payment

We are proposing an ADVaNCE MA payment approach for each cohort in a Mandatory State that provides benchmark adjustments and plan rebate percentages relative to performance on ADVaNCE MA Overall Diamond Ratings and on a continuous scale. We believe our approach both leverages the existing infrastructure of the QBP ratings that is familiar to MA organizations and reduces the importance of discrete quality thresholds in the current statutorily required payment structure. Further, we believe this approach could incentivize incremental quality improvement and establish a framework that would support an overall reduction of program expenditures.

As discussed further in this section, our proposed payment approach would reward all ADVaNCE MA model participants for improvements in quality by using incremental scales to determine changes to benchmarks and rebates. The QBP ratings existing approach, required by section 1853(o) of the Act, provides contracts with a four-Star Rating or above with a five-percentage point increase in the development of their benchmarks. Also, low enrollment contracts and new contracts under new parent organizations do not have calculated ratings and are provided a 3.5 percentage point increase in the development of their benchmarks. The quality bonus increase (either zero, 3.5, or five percentage points) is added to the applicable percentage defined at section 1853(n)(2)(B) of the Act and MA contracts with a four-Star Rating or above in qualifying "double bonus" counties receive a 10-percentage point increase for quality as required by section 1853(o)(2) of the Act. While there is an increased rebate retention for plans with 3.5 stars compared to three stars, the statutorily required approach provides no quality bonus increase for contracts with a QBP rating of less than four stars, resulting in an "all or nothing" approach that does not incentivize incremental improvements for

poorly performing plans. As outlined in research[204,205,] this statutorily required payment structure does not allow any modifications to or the removal of the payment thresholds applicable to QBPs in the Medicare Advantage program.

The CMS Innovation Center's waiver authority is necessary to test whether an alternative to the payment thresholds applicable to QBPs in the Star Ratings system leads to a reduction in program expenditures and better overall quality.

The ADVaNCE MA model, as discussed in more detail in the next section, would instead incentivize all parent organizations of ADVaNCE MA model participants to make improvements in quality by establishing an incremental scale that would reward each ADVaNCE MA model participant relative to their performance and remove the double bonus structure, as proposed in § 516.600(j)(2) and described further in section VIII.H.3.b.(1) of this rule. Using relative performance to determine payments promotes competition among ADVaNCE MA model participants to achieve the highest ADVaNCE MA Overall Diamond Rating possible.

CMS is also testing whether utilizing an incremental scale to determine rebates would promote the stability of benefit offerings so that ADVaNCE MA model participants and their enrollees do not experience significant year-to-year shifts in rebates.

We note that our proposed rebate approach is intended to align with our proposals under section G of this proposed rule to enable ADVaNCE MA model participants to focus rebates towards prevention efforts for enrollees who may benefit from such efforts the most and who may disproportionately drive overall plan costs.

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[10] Medicare Payment Advisory Commission (MedPAC), Report to the Congress: Medicare and the Health Care Delivery System (Washington, DC: MedPAC, June 2020), https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_reporttocongress_sec.pdf.

[205] Leavitt Partners, Future Visions of Reform (Salt Lake City, UT: Leavitt Partners, March 2024), https://leavittpartners.com/wp-content/uploads/2024/04/Future-Visions-of-Reform-March-2024.pdf.

CMS will ensure appropriate updates are made to the Bid Pricing Tool (BPT) and downstream systems associated with payment processes to operationalize the proposed payment approach described in this section

a. Changes to the Applicable Benchmark Percentage Increase for the ADVaNCE MA Payments

Under § 516.230(a), we are proposing that the ADVaNCE MA model would leverage the existing regulatory approach at 42 CFR 422.258 for providing percentage changes to ADVaNCE MA model participants' benchmarks (rather than, for example, an entirely new value incentive framework) for ADVaNCE MA model participants from CY 2032 through CY 2041. We believe this would ensure the process and structure for ADVaNCE MA payments is familiar to ADVaNCE MA model participants by structuring payment ramifications into the existing bidding and benchmarking process. However, we are proposing that for purposes of the ADVaNCE MA model, 42 CFR 422.258(d)(7), which determines increases to the applicable percentages for quality, would not apply instead proposed § 516.230(b)(1) through (b)(5) would apply, which would change theapplicable percentage quality increase for the ADVaNCE MA model based on ADVaNCE MA Overall Diamond Ratings on an incremental scale. As discussed in section VIII.F.1.c of this proposed rule, the ADVaNCE MA Payment would be provided up to three years following the applicable measurement period. Because the first measurement period under the ADVaNCE MA model would be applicable to the 2031 Diamond Ratings, ADVaNCE MA Payments would begin for ADVaNCE MA model participants in CY 2032, based on the 2031 Diamond Ratings. The last ADVaNCE MA Payment for ADVaNCE MA model participants would be based on the 2040 Diamond Ratings, largely based on the 2038 measurement period, with the final payments being distributed in CY 2041.

(1) ADVaNCE MA Mandatory States and Cohorts with Three or More Parent Organizations that have ADVaNCE MA model participant(s) that Receive an ADVaNCE MA Overall Diamond Rating.

Under § 516.230(b)(1), for ADVaNCE MA Mandatory States and cohorts with three or more parent organizations that have ADVaNCE MA model participant(s) that receive an ADVaNCE MA Overall Diamond Rating, we are proposing that each ADVaNCE MA model participant's applicable percentage quality increase in their benchmark would be based on an incremental scale relative to the performance of ADVaNCE MA model participants that receive an ADVaNCE MA Overall Diamond Rating within each Mandatory State and cohort. Specifically, we are proposing that we would use the following formula to determine the applicable percentage quality increase for each cohort within a Mandatory State, where x is the ADVaNCE MA model participant's ADVaNCE MA Overall Diamond Rating, min(x) is the ADVaNCE MA Overall Diamond Rating for the lowest performing ADVaNCE MA model participant in the Mandatory State and cohort, and max(x) is the ADVaNCE MA Overall Diamond Rating for the highest performing ADVaNCE MA model participant in the Mandatory State and cohort, using traditional rounding rules, as defined under 42 CFR 422.162(a), to the nearest 0.1 percentage point:

$$Benchmark\ Adjustment\ =\ 5\%\ *\frac{x-min(x)}{max(x)\ -\ min(x)}$$

For example, if a Mandatory State's General Enrollment cohort has five parent organizations with the following ADVaNCE MA Overall Diamond Ratings: 2.6 Diamonds, 3.5 Diamonds, 3.8 Diamonds, 4.5 Diamonds, and 4.8 Diamonds, the benchmark adjustments would be zeropercentage points, 2.0 percentage points, 2.7 percentage points, 4.3 percentage points, and five percentage points, respectively.

We believe that this linear function rewards ADVaNCE MA model participants for even small increases in quality, rather than for attaining a single fixed ADVaNCE MA Overall Diamond Rating threshold and reduces the impact of the payment thresholds of the existing

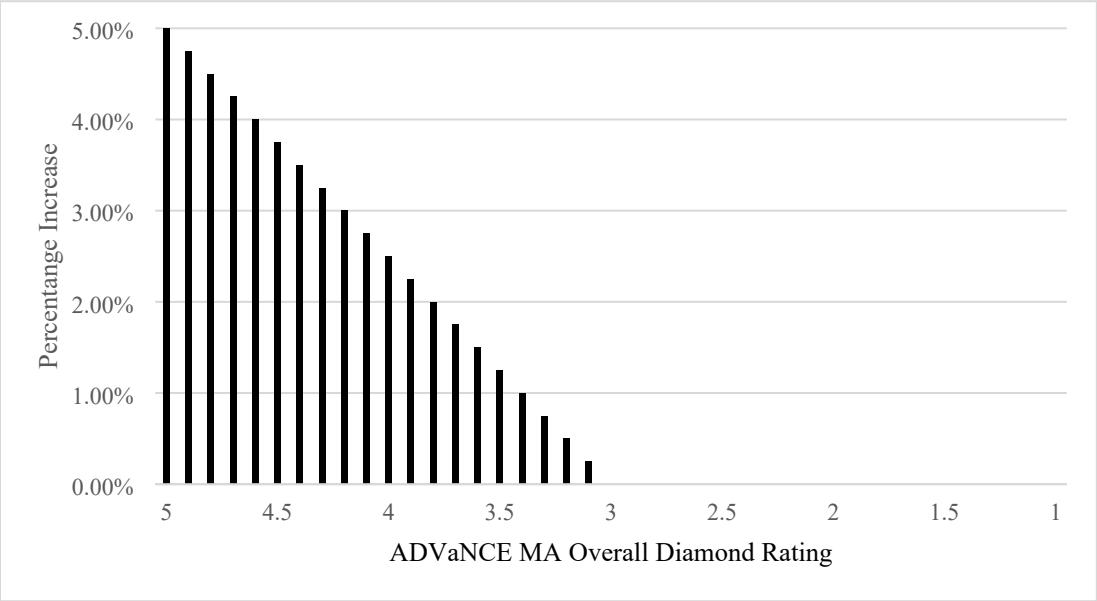
Quality Bonus Payment system, as we have previously discussed. This is a departure from the current system and it is important to note that Diamond Ratings are not directly comparable in their calculation to Star Ratings and are calculated using a different algorithm that limits direct comparisons between the two. We further believe that by establishing the incremental scale relative to each Mandatory State and cohort with three or more parent organizations that we are ensuring ADVaNCE MA model participants are receiving payment adjustments relative to other ADVaNCE MA model participants that are serving similar types of enrollees (General Enrollment or D-SNP cohort) and in similar market conditions (their Mandatory State). This linear function would effectively rank parent organizations in a Mandatory State and by cohort so that the value of a given ADVaNCE MA Overall Diamond Rating (in terms of a quality bonus increase to their applicable percentage) is relative to the performance of other ADVaNCE MA model participants in the same Mandatory State and cohort, as we discuss in further detail below.

Specifically, we are proposing that we would establish a ceiling where the ADVaNCE MA model participant with the highest ADVaNCE MA Overall Diamond Rating for a cohort within a Mandatory State would receive the highest percentage increase, a five-percentage point bonus to their applicable percentage. This means that the top performing ADVaNCE MA model participant in each Mandatory State and for each cohort would receive a five-percentage point increase to their applicable percentage, regardless of their relative performance on a national scale. This could mean that in one Mandatory State the highest scoring ADVaNCE MA model for the General Enrollment cohort could have 4.6 Diamonds while the highest scoring ADVaNCE MA model participant for the D-SNP cohort could have 3.8 Diamonds and both ADVaNCE MA model participants could receive a five-percentage point bonus increase to their applicable percentage. Using this logic, if the lowest ranked plan unexpectedly leaves the market, by default, the next lowest ranking plan would experience a decrease in their benchmark, regardless of quality performance.

For ADVaNCE MA model Mandatory States and cohorts with three or more parent organizations that are able to report an ADVaNCE MA model Overall Diamond Rating, we are similarly proposing at § 516.230(b)(1), that the ADVaNCE MA model participant with the lowest ADVaNCE MA model Overall Diamond Rating for a cohort within a Mandatory State would not receive an increase to their applicable percentage, or in other words, a zero percentage point increase. As proposed at § 516.230(b)(1), all other ADVaNCE MA model participants would receive an increase to their applicable percentage correlated with their ADVaNCE MA model Overall Diamond Rating based on a linear scale between the highest and lowest performing participants for their Mandatory State and cohort. This could mean that in one Mandatory State the lowest scoring participant for the General Enrollment cohort could have 2.1 Diamonds while the lowest scoring participant for the D-SNP cohort could have 2.3 Diamonds and both participants would not receive any bonus, that is, a zero-percentage point increase, to their applicable percentage.

Figure IX-F2 illustrates an example of one Mandatory State and cohort where the top scoring participant with five Diamonds receives a five-percentage point increase to their applicable percentage, and a participant with a score of three Diamonds, the lowest ADVaNCE MA Overall Diamond Rating, does not receive any increase to their applicable percentage, and all other scores between three Diamonds and five Diamonds are scaled linearly between these two points. Under such an approach, an ADVaNCE MA model participant with a 3.1 Diamonds (just higher than three Diamonds) would receive, for example, a 0.3 percentage-point increase to their applicable percentage, with the quality bonus percentage increasing linearly in conjunction with participants' ADVaNCE MA Overall Diamond Ratings. An ADVaNCE MA model participant with an Overall Diamond Rating of 4.9 would receive an applicable percentage increase of 4.8 percent.

FIGURE IX-F2: EXAMPLE OF PROPOSED QUALITY BONUS INCREASES FOR ADVANCE MA OVERALL DIAMOND RATINGS



IX-F2 illustrates an example of one Mandatory State and cohort where the top scoring participant with five Diamonds receives a five percentage point increase to their applicable percentage, and a participant with a score of three Diamonds, the lowest ADVaNCE MA Overall Diamond Rating, does not receive any increase to their applicable percentage, and all other scores between three Diamonds and five Diamonds are scaled linearly between these two points. Under such an approach, an ADVaNCE MA model participant with a 3.1 Diamonds (just higher than three Diamonds) would receive, for example, a 0.3 percentage points increase to their applicable percentage, with the quality bonus percentage increasing linearly in conjunction with participants' ADVaNCE MA Overall Diamond Ratings. An ADVaNCE MA model participant with an Overall Diamond Rating of 4.9 would receive an applicable percentage increase of 4.8 percent.

Our proposal ensures that the highest performing ADVaNCE MA model participant in a Mandatory State and in a cohort with three or more parent organizations that are able to report an ADVaNCE MA Overall Diamond Rating is always rewarded with the highest increase to

their applicable percentages and that all other ADVaNCE MA model participants are rewarded for small and incremental increases in quality.

Alternatively, to the maximum five-percentage point benchmark increase, we have explored using the same linear scale approach as described at § 516.230(b)(1), however with a maximum benchmark adjustment of less than 5-percentage points but greater than or equal to 2-percentage points for the top performer in each Mandatory State and cohort with three or more parent organizations that are able to report an ADVaNCE MA model Overall Diamond Rating. These alternative maximum benchmark adjustments would still reward and incentivize high quality and enable greater revenue predictability for MA organizations each year and therefore stable benefits for enrollees, while generating possible savings for CMS.

We have also considered modifying our proposed methodology of assigning benchmark and rebate changes linearly based on the individual performance of each parent organization but comparing performance to the representative sample of all parent organization across all ADVaNCE MA Mandatory States (rather than our proposed method of comparing performance to other ADVaNCE MA model participants in their Mandatory State only). This would mean that in certain States where no ADVaNCE MA model participant performs above average, no ADVaNCE MA model participant would receive a benchmark adjustment nor enhanced rebate percentage.

We seek comment on the appropriate maximum benchmark adjustment percent for the top performer in each Mandatory State and cohort with three or more parent organizations that are able to report an ADVaNCE MA model Overall Diamond Rating and on modifying our proposed methodology to the representative sample of all parent organization across all ADVaNCE MA Mandatory States.

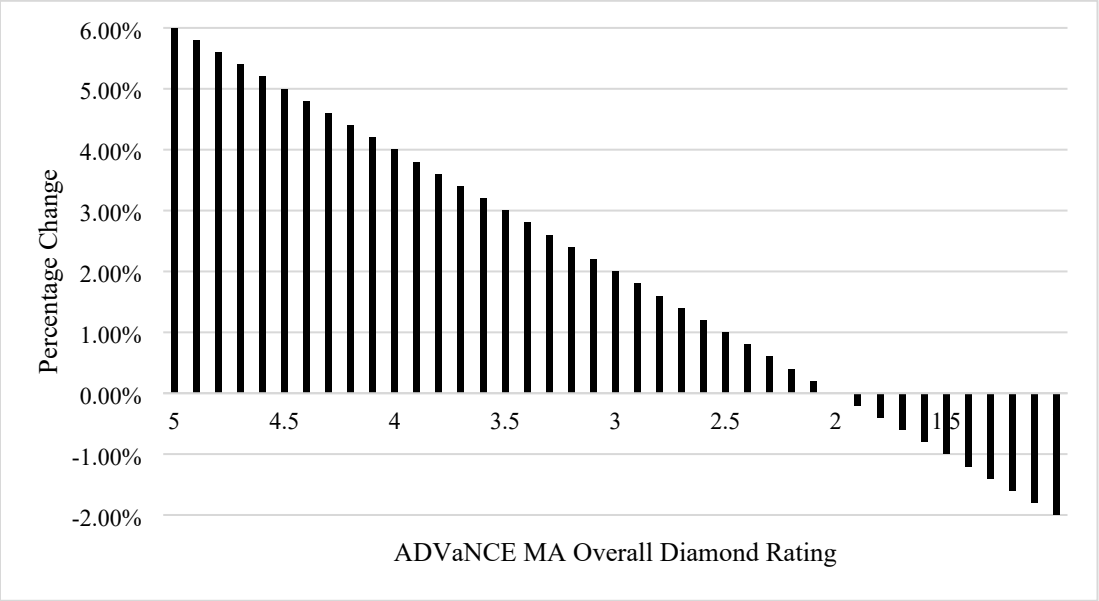
Alternatively, we considered several alternative strategies for setting adjustments based on Overall Diamond Rating performance. First, we explored using a linear scale where the maximum percentage point increase in the development of the benchmark would be set at six

percentage points for ADVaNCE MA model participants with the highest ADVaNCE MA Overall Diamond Rating and ADVaNCE MA model participants with the lowest ADVaNCE MA Overall Diamond Ratings would receive a negative percentage adjustment of two percentage points in the development of their applicable benchmark, with all scores in between scaled with a linear function, for example:

$$Benchmark\ Adjustment = \ -2\% \ + \ 8\% * \frac{x \ - \ min(x)}{max(x) \ - \ min(x)}$$

For example, if a Mandatory State's General Enrollment cohort has five parent organizations with the following ADVaNCE MA Overall Diamond Ratings — 2.6 Diamonds, 3.5 Diamonds, 3.8 Diamonds, 4.5 Diamonds, and 4.8 Diamonds — the benchmark adjustments would be —two percentage points, 1.3 percentage points, 2.4 percentage points, 4.9 percentage points, and six percentage points, respectively. F3 shows an example graph of this alternative where there are both increases and decreases to ADVaNCE MA model participants' applicable benchmarking percentages. In this example, an ADVaNCE MA model participant with five Diamonds would receive a six-percentage point increase to their applicable benchmarking percentage, an ADVaNCE MA model participant with two Diamonds would receive no increase to their applicable benchmarking percentage, and an ADVaNCE MA model participant with one Diamond would receive a negative two percentage point adjustment (decrease) to their applicable benchmarking percentage. We considered this alternative where participants with the lowest scores for a Mandatory State and cohort would receive penalties as decreases to their benchmarks. These decreases would be used to partially offset the cost of the increases to participants with higher scores, thus creating a framework that would penalize lower-performing participants and create a strong incentive to attain the highest ADVaNCE MA Overall Diamond Rating possible and avoid such penalties. Offsetting the cost of the increases to higher performing plans would bring additional cost-savings to the ADVaNCE MA model relative to the current costs of the MA and Part D Star Ratings system.

FIGURE IX-F3: ALTERNATIVE 1 CONSIDERED. BENCHMARK EXAMPLE PERCENTAGE INCREASES AND DECREASES BASED ON ADVANCE MA OVERALL DIAMOND RATINGS

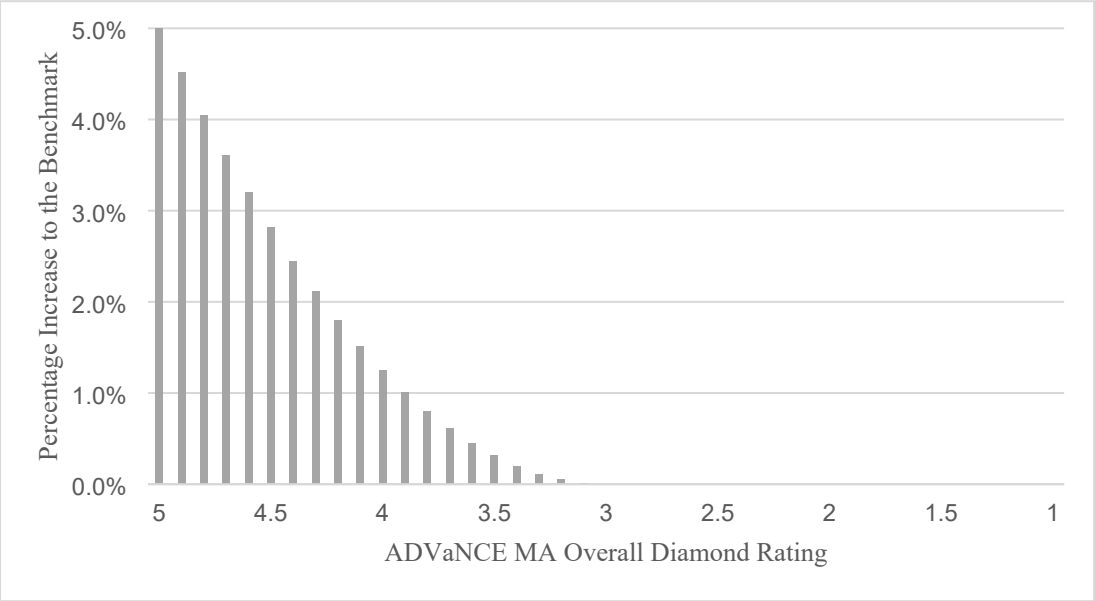


We also considered using a parabolic function to assign percentages. We considered using a parabolic function curve because it would provide stronger incentives for incremental increases in performance for participants with the very highest scores, such as a larger increase between 4.8 Diamonds to five Diamonds than between three Diamonds and 3.2 Diamonds, for example. An example of the parabolic function we considered is:

$$Benchmark_{parabola} = 5 * \left(\frac{x - min(x)}{max(x) - min(x)}\right)^2$$

F4 shows a graph of the parabolic function we considered as alternative two, with increases based on ADVaNCE MA Overall Diamond Ratings between the highest and lowest ADVaNCE MA model participants for a Mandatory State and cohort using a parabolic function. For example, if a Mandatory State's General Enrollment cohort has five ADVaNCE MA model participants with the following ADVaNCE MA Overall Diamond Ratings — 2.6 Diamonds, 3.5 Diamonds, 3.8 Diamonds, 4.5 Diamonds, and 4.8 Diamonds — the benchmark adjustments would be 0 percentage points, 0.8 percentage points, 1.5 percentage points, 3.7 percentage points, and five percentage points, respectively.

FIGURE IX-F4: ALTERNATIVE 2 CONSIDERED. EXAMPLE PARABOLIC SCALE FOR PERCENTAGE INCREASES TO BENCHMARKS



A goal of the ADVaNCE MA model is to decrease Medicare program expenditures while incentivizing quality improvement. To support this goal, we also considered an alternative of replacing the fixed five percentage point maximum benchmark increase with a lower maximum determined annually. Under this alternative, we would set the maximum such that projected aggregate MA payments to model participants would not exceed the total revenue Medicare would otherwise pay to those same participants for the same payment year under the Star Rating methodology, modified to reflect the proposed elimination of the additional quality bonus for qualifying counties. We would calculate each participant's benchmark adjustment using the following formula:

$$Benchmark\ Adjustment = M * \frac{x - min(x)}{max(x) - min(x)}$$

Here, *M* is the annually determined maximum expressed in percentage points and set below 5.0. The highest-rated ADVaNCE MA model participant in each Mandatory State and cohort would receive that maximum, the lowest-rated ADVaNCE MA model participant would receive zero, and other participants would receive proportionate adjustments.

To determine the maximum benchmark bonus amount, *M*, we would compare two payment scenarios. First, the amount payable under the Star Rating methodology after the elimination of the additional quality bonus for qualifying counties. For example, for the maximum benchmark bonus amount used for the 2032 payments, we would calculate the 2031 Star Ratings and QBP Ratings for each ADVaNCE MA model participant. We would then, using 2031 approved bids, estimate the total aggregate 2031 Medicare program expenditures, modified to reflect the proposed elimination of the additional quality bonus for qualifying counties for ADVaNCE MA model participants in ADVaNCE MA model Mandatory States using the calculated 2031 Star Ratings and QBP Ratings. The calculated 2031 Star Ratings and QBP Ratings would include all relevant measure changes, for each given year, in order to accurately create an appropriate baseline.

Second, we would estimate the amount payable under the ADVaNCE MA model at the candidate maximum, *M*. For example, for the maximum benchmark bonus amount used for 2032 payments, we would calculate the Diamond Rating for 2031 for each ADVaNCE MA model participant. We would then, using 2031 approved bids, estimate the total aggregate 2031 Medicare program expenditures for ADVaNCE MA model participatants in ADVaNCE MA Mandatory States using the Diamond Ratings system for the maximum benchmark bonus amount, *M*. The maximum benchmark bonus amount, *M*, would be determined such that the aggregate amounts from this second step is lower than the first step. CMS would make this determination prior to the annual release of the Diamond Ratings and announce the maximum with the annual release of the Diamond Ratings.

We seek comment on the reward structure with three or more parent organizations in a Mandatory State and cohort, as well as the alternatives considered.

(2) ADVaNCE MA Mandatory States and Cohorts with Two Parent Organizations that have ADVaNCE MA Model Participant(s) that Receive an ADVaNCE MA Overall Diamond Rating

Under § 516.230(b)(2), we propose the applicable benchmark percentage increases for Mandatory States and cohorts with two parent organizations with ADVaNCE MA model participant(s) that receive an ADVaNCE MA Overall Diamond Rating. Specifically, at § 516.230(b)(2)(i), we propose that the ADVaNCE MA model participant(s) with the higher ADVaNCE MA Overall Diamond Rating for the Mandatory State and cohort would have their applicable benchmark percentage increased by five percentage points. For the ADVaNCE MA model participant(s) with the lower of the two ADVaNCE MA Overall Diamond Ratings, we propose under § 516.230(b)(2)(ii) that if such rating is greater than or equal to the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all ADVaNCE MA model participants of the same cohort across all Mandatory States, their applicable benchmark percentage would be increased by 2.5 percentage points. If their ADVaNCE MA Overall Diamond Rating is less than the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all ADVaNCE MA model participants of the same cohort across all Mandatory States, we propose that the applicable benchmark percentage for such a participant would be increased by zero percentage points. We believe that in the context of a Mandatory State and cohort that only has two parent organizations with ADVaNCE MA model participant(s) that can report ADVaNCE MA Overall Diamond Ratings, it is appropriate to vary the increase to the applicable benchmarking percentage relative to the broader performance across all Mandatory States for the cohort, so that the ADVaNCE MA model participant(s) with the lower ADVaNCE MA Overall Diamond Rating is evaluated in the context of the national performance of the ADVaNCE MA model.

Finally, in a Mandatory State and cohort that has only two parent organizations with ADVaNCE MA model participants that receive ADVaNCE MA Overall Diamond Ratings, we are proposing under § 516.230(b)(2)(iii) that if the ADVaNCE MA model participants receive

ADVaNCE MA Overall Diamond Ratings that are within 0.2 Diamonds of each other then the benchmark adjustment would depend on whether the ADVaNCE MA Overall Diamond Ratings are greater than or equal to the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort. If the ADVaNCE MA model participant's ADVaNCE MA Overall Diamond Rating is above the average, the benchmark must be increased by five percentage points. If such ADVaNCE MA Overall Diamond Rating is less than the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, the applicable benchmarking percentage for the ADVaNCE MA model participants must be increased by 2.5 percentage points. If the scores straddle the average, both will receive a five-percentage point increase.

For example, if the two ADVaNCE MA model participants in the General Enrollment cohort receive ADVaNCE MA Overall Diamond Ratings of 2.6 Diamonds and 2.8 Diamonds and the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the General Enrollment cohort is 3.4 Diamonds, then both ADVaNCE MA model participants would receive a 2.5 percentage point increase to their applicable benchmark percentages. However, if the two ADVaNCE MA model participants were to score 4.3 Diamonds and 4.8 Diamonds for the same cohort and Mandatory State (a difference of 0.5 Diamonds) and the enrollment-weighted average ADVaNCE MA Overall Diamond Rating is 3.4 Diamonds, the ADVaNCE MA model participant with the higher ADVaNCE MA Overall Diamond Rating would receive a five percentage point increase to their applicable benchmark percentage and the ADVaNCE MA model participant with the lower ADVaNCE MA Overall Diamond Rating that is still above the enrollment-weighted average would receive a 2.5 percentage point increase to their applicable benchmark percentage, as proposed previously, because it is above the enrollment-weighted average ADVaNCE MA Overall Diamond Rating for the cohort. Similarly, if the two ADVaNCE MA model participants receive ADVaNCE MA Overall Diamond Ratings of 3.6 Diamonds and 3.1 Diamonds for the same cohort and

Mandatory State, and the enrollment-weighted average ADVaNCE MA Overall Diamond Rating is 3.4 Diamonds, then the ADVaNCE MA model participant with the higher ADVaNCE MA Overall Diamond Rating would receive a five percentage point increase to their applicable benchmark percentage and the ADVaNCE MA model participant with the lower ADVaNCE MA Overall Diamond Rating that is below the enrollment-weighted average would receive a zero percentage point increase to their applicable benchmark percentage, as proposed previously, because it is below the enrollment-weighted average ADVaNCE MA Overall Diamond Rating.

As an alternative, we considered proposing that in a Mandatory State and cohort with only two parent organizations that have ADVaNCE MA model participant(s) that receive an ADVaNCE MA Overall Diamond Rating, that the ADVaNCE MA model participant(s) with the higher ADVaNCE MA Overall Diamond Rating would receive a five percentage point increase to their applicable benchmark percentage and the ADVaNCE MA model participant(s) with the lower ADVaNCE MA Overall Diamond Rating would receive a zero percentage point increase to their applicable benchmarking percentage, regardless of how their performance compares with other ADVaNCE MA Mandatory States. We believe this could also be appropriate as it effectively applies the linear scale we have proposed for Mandatory States and cohorts with three or more participants to those with two participants.

An additional alternative considered would be to weigh the coinciding benchmarks to account for distance from the average score, especially in the instance of scores within 0.2 Diamonds. The goal of the current proposal (above) is to ensure that parent organizations are not unfairly penalized against each other, but to also encourage parent organizations to consistently seek to improve quality against the national average. The associated benchmark bonuses assigned to those below the national average are designed not to overly penalize plans, but to provide an opportunity to improve. However, one potential limitation with this approach is that it may create a steep threshold that the ADVaNCE MA model is being designed to avoid.

An alternative strategy that we considered is, instead of having a specific reward percentage based on if the dyad is above or below the national average, to set the benchmark and rebate proportional to the national average so that dyads that are far below the national average have lower bonuses and rebates and those that are far above the national average have higher bonuses and rebates, comparatively. This could potentially be done by assigning scores according to the national distribution of Diamond (for example, if the dyad's scores are below the 25th percentile nationally they receive a 25 percent lower benchmark and rebate, or if they perform above the 75th percentile, they receive a higher score).

We seek comment on the reward structure with two parent organizations in a Mandatory State and cohort, as well as the listed alternatives including alternative ways to reward against the national average.

(3) ADVaNCE MA Mandatory States and Cohorts with One Parent Organization that has an ADVaNCE MA Model Participant(s) that Receives an ADVaNCE MA Overall Diamond Rating

Under § 516.230(b)(3), for ADVaNCE MA Mandatory States and cohorts with one parent organization with an ADVaNCE MA model participant(s) that is able to report an ADVaNCE MA Overall Diamond Rating, we propose that if the ADVaNCE MA model participant(s) has an ADVaNCE MA Overall Diamond Rating greater than or equal to the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all ADVaNCE MA model participants of the same cohort across all Mandatory States, their applicable benchmark percentage would increase by five percentage points. We further propose that if the ADVaNCE MA Overall Diamond Rating is less than the enrollment-weighted average of ADVaNCE MA Overall Diamond Ratings across all ADVaNCE MA model participants of the same cohort across all Mandatory States, the ADVaNCE MA model participant(s)' applicable benchmark percentage would increase by zero percentage points; in other words, the participant(s) would not receive an increase. We believe it is appropriate to vary the percentage

increase to such ADVaNCE MA model participant(s)' benchmark compared to the broader performance across all Mandatory States for the cohort, so that the ADVaNCE MA model participant(s) is evaluated in the context of the national performance of the ADVaNCE MA model.

As an alternative, we considered proposing that in a Mandatory State and cohort with one parent organization that has an ADVaNCE MA model participant(s) that is able to report an ADVaNCE MA Overall Diamond Rating, that parent organization's ADVaNCE MA model participant(s) would receive a flat 2.5 percentage point increase to their applicable benchmarking percentage, regardless of their performance. This would effectively provide ADVaNCE MA model participant(s) with the average benchmarking increase for a given Mandatory State and cohort with three or more parent organizations (as if their ADVaNCE MA Overall Diamond Ratings were the mid-point in a Mandatory State and cohort with more participants).

We seek comment on this proposal to account for a Mandatory State with a single parent organization and the alternative.

(4) Insufficient Data, Low Enrollment, and New Entrants

We also propose changes to benchmark percentage increases for ADVaNCE MA model participants that do not meet the minimum reporting requirements, meet the definition of low enrollment, are new entrants to the ADVaNCE MA model, and/or are new entrants to a Mandatory State.

At § 516.230(b)(4), we propose that parent organizations in Mandatory States with insufficient data, as defined in § 516.5, would receive an increase to their applicable benchmark of 3.5 percentage points. We note that under both our proposed definition of low enrollment and under our minimum reporting requirements, measure data is pooled with all other ADVaNCE MA model participants under the same parent organization in the same cohort and in the same

Mandatory State. We also propose that new entrants, as defined at § 516.5, would also receive an increase to their applicable benchmark of 3.5 percentage points.

At § 516.230(b)(5), we propose that for new ADVaNCE MA model participants that enter a Mandatory State in CY 2030 or subsequent years of the model, the applicable benchmarking increase would be 3.5 percentage points for the new ADVaNCE MA model participant for their first three years in the model. We believe this would incentivize existing parent organizations to enter into a Mandatory State or expand into additional Mandatory States. We also considered providing a 2.5 percentage point increase but are proposing a 3.5 percentage point increase because it provides benchmarking percentages that are similar to the MA and Part D Star Ratings system under 42 CFR 422.258(d)(7)(v), and we believe this would provide predictability for ADVaNCE MA model participants that are familiar with the MA and Part D Quality Bonus Payment system.

We considered two alternatives each for new ADVaNCE MA model participants that fall into group (1) parent organizations with existing MA contracts outside of the ADVaNCE MA Mandatory State, or (2) parent organizations that have contracts in another Mandatory State, and that enter a Mandatory State in year two or subsequent years of the Model.
For the first group, we considered determining the applicable benchmarking percentage increase by calculating an enrollment-weighted average of the highest rating for the parent organization's contracts in all other States. We first considered applying QBPs based on their enrollment weighted Star Ratings, maintaining the payment thresholds as experienced in the MA and Part D Quality Bonus Payment system. While we believe this option would reflect the familiarity of the current MA and Part D Quality Bonus Payment system for a new participant in the ADVaNCE MA model, we believe this is less aligned with the intention of the model to reduce the effects of the current payment thresholds.

We also considered using their enrollment-weighted average Star Ratings within the linear increase formula as described earlier in this section to determine the applicable

benchmark percentage increase. While we believe this option would enable a new ADVaNCE MA model participant to more quickly integrate within the ADVaNCE MA Payment structure, we believe there may be timing challenges in the calculations of the enrollment-weighted average Star Ratings within a bidding cycle and inequivalence in comparing their enrollment-weighted average Star Ratings against ADVaNCE MA Overall Diamond Ratings.

For the second group, we considered determining the applicable benchmarking percentage increase by calculating an enrollment-weighted average of the ADVaNCE Overall Diamond Ratings for the parent organization's contracts in other Mandatory States within the ADVaNCE MA model. Similarly, we first considered applying QBP ratings based on their enrollment-weighted ADVaNCE MA Overall Diamond Ratings, maintaining the payment thresholds applicable to QBPs. We also considered using their enrollment-weighted ADVaNCE MA Overall Diamond Ratings within the linear increase function to determine the applicable benchmarking percentage increase. While we believe this option would enable new ADVaNCE MA model participants to more quickly integrate within the ADVaNCE payment structure, we believe this solution may unfairly reward ADVaNCE MA model participants with higher performance in other Mandatory States and incentivize their parent organizations to expand into lower average quality states, receiving a bonus without reflecting their performance within the Mandatory State they entered. This option also does not maintain the goal of having quality scores reflect the specific Mandatory State.

We seek comment on the reward structure with one parent organization in a Mandatory State and cohort and the listed alternatives.

b. Calculation of Rebates for the ADVaNCE MA model

Under the MA and Part D Star Ratings program, pursuant to 42 CFR 422.266(a)(2)(ii), contracts that receive a rating of at least 4.5 stars receive a 70 percent rebate, contracts that receive between 3.5 and 4.5 stars receive a 65 percent rebate, and contracts that receive less than 3.5 stars receive a 50 percent rebate as required by section 1854(b)(1)(C)(v) of the Act.

At § 516.230(c), we are proposing that the ADVaNCE MA model would similarly leverage the existing regulatory structure for rebates under 42 CFR 422.266; however, 42 CFR 422.266(a)(2)(ii) would not apply and proposed § 516.230(c)(1) through (5) would apply instead. Thus, rather than a fixed distribution of rebates as currently exists, we are proposing at § 516.230(c)(1) that we would use an incremental scale, similar to the scale used for determining the applicable percentage change in benchmarks under § 516.230(b)(1), to assign rebate percentages to ADVaNCE MA model participants specific to their Mandatory State and cohort based on their ADVaNCE MA Overall Diamond Ratings. We believe this incremental scale would ensure that ADVaNCE MA model participants receive rebates that incrementally increase with their ADVaNCE MA Overall Diamond Ratings so that participants are incentivized to make even small improvements in quality. We further believe that by establishing the incremental scale relative to each Mandatory State and cohort that we are ensuring participants are receiving rebate percentages relative to other ADVaNCE MA model participants that are serving similar types of enrollees (General Enrollment or D-SNP cohort) and in similar market conditions (their Mandatory State). This linear function would effectively rank ADVaNCE MA model participants in a Mandatory State and by cohort so that the value of a given ADVaNCE MA Overall Diamond Rating (in terms of a rebate percentage) is relative to the performance of other model participants in the same Mandatory State and cohort, as we discuss in further detail below.

(1) Mandatory States and Cohorts with Three or More Parent Organizations with ADVaNCE MA Model Participants that Receive an ADVaNCE MA Overall Diamond Rating.

Under § 516.230(c)(1), for Mandatory States and cohorts with three or more parent organizations with ADVaNCE MA model participants that receive an ADVaNCE MA Overall Diamond Rating, we are proposing that each ADVaNCE MA model participant's rebate percent would be based on an incremental scale relative to the performance of all ADVaNCE MA participants for each Mandatory State and cohort.

Specifically, we are proposing that we would establish a ceiling where the ADVaNCE MA model participant(s) with the highest ADVaNCE MA Overall Diamond Rating for a cohort within a Mandatory State would receive the highest rebate, a 70 percent rebate. This means that the top-performing ADVaNCE MA model participant(s) in each Mandatory State and for each cohort would always receive a 70 percent rebate, regardless of their performance on a national scale. This could mean that in one Mandatory State the highest scoring ADVaNCE MA model participant for the General Enrollment cohort could have 4.7 Diamonds, while the highest scoring ADVaNCE MA model participant for the D-SNP cohort could have 4.3 Diamonds, and both ADVaNCE MA model participants would receive a 70 percent rebate.

We are similarly proposing that the ADVaNCE MA model participant with the lowest ADVaNCE MA Overall Diamond Rating for a cohort within a Mandatory State would receive a 50 percent rebate. All other ADVaNCE MA model participants would receive rebates correlated with their ADVaNCE MA Overall Diamond Rating based on a linear scale between the highest and lowest performing participants for their Mandatory State and cohort. This could mean that in one Mandatory State the lowest scoring ADVaNCE MA model participant for the General Enrollment cohort could have 3.2 Diamonds, while the lowest scoring ADVaNCE MA model participant for the D-SNP cohort could have 2.9 Diamonds, and both ADVaNCE MA model participants would receive a 50 percent rebate.

Specifically, at § 516.230(c)(1) we are proposing that we would use the following function to determine the applicable rebate percentage for each cohort within a Mandatory State, where x is the ADVaNCE MA model participant's Overall Diamond Rating, min(x) is the ADVaNCE MA Overall Diamond Rating for the lowest performing ADVaNCE MA model participant in a Mandatory State and cohort, and max(x) is the ADVaNCE MA Overall Diamond Rating for the highest performing ADVaNCE MA model participant in a Mandatory State and cohort using traditional rounding rules, as defined under 42 CFR 422.162(a), to the nearest whole percentage point:

$$Rebate\ \% = \ 50\% + 20\% \ * \frac{x - min(x)}{max(x) \ - \ min(x)}$$

For example, if a Mandatory State's General Enrollment cohort has five ADVaNCE MA model participants with the following ADVaNCE MA Overall Diamond Ratings — 2.6 Diamonds, 3.5 Diamonds, 3.8 Diamonds, 4.5 Diamonds, and 4.8 Diamonds — the rebate percentages would be 50 percent, 58 percent, 61 percent, 67 percent, and 70 percent, respectively.

We considered the same alternative functions as described in section VIII.F.4.a.(1) and note that the function for the rebate calculation would mimic that used for the benchmark percentage increase.

We seek comment on our rebate proposal for Mandatory States with three or more parent organizations with ADVaNCE MA Overall Diamond Ratings and the listed alternative.

(2) Rebate Percentages for Mandatory States and Cohorts with Two Parent Organizations with ADVaNCE MA Model Participants that Receive an ADVaNCE MA Overall Diamond Rating.

Under § 516.230(c)(2), we propose the rebate percentage for Mandatory States and cohorts with two parent organizations with ADVaNCE MA model participants that receive an ADVaNCE MA Overall Diamond Rating. Specifically, at § 516.230(c)(2)(i), we propose that the ADVaNCE MA model participant(s) with the higher ADVaNCE MA Overall Diamond Rating for the Mandatory State and cohort would have a rebate percentage of 70 percent of the average per capita savings. We believe that it is appropriate that the higher scoring participant(s) would receive the highest possible rebate percentage. For the ADVaNCE MA model participant(s) with the lower of the two ADVaNCE MA Overall Diamond Ratings, we propose under § 516.230(c)(2)(ii) that if this rating is greater than or equal to the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, their rebate percentage would be 65 percent of the average per capita savings. If their ADVaNCE MA Overall Diamond Rating is less than the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, we

propose that their rebate percentage would be 50 percent of the average per capita savings. We believe it is appropriate to vary the rebate percentage relative to the broader performance across all Mandatory States for the cohort when there are two parent organizations with ADVaNCE MA model participants that receive an ADVaNCE MA Overall Diamond Ratings in the Mandatory State and cohort, so that the ADVaNCE MA model participant(s) is evaluated in the context of performance across all mandatory States for the same cohort.

Finally, in a Mandatory State and cohort that has only two parent organizations with ADVaNCE MA model participants that receive ADVaNCE MA Overall Diamond Ratings, we are proposing under § 516.230(c)(2)(iii) that if the ADVaNCE MA model participants receive ADVaNCE MA Overall Diamond Ratings that are within 0.2 Diamonds of each other, that the final applicable rebate percentage will depend on if the ADVaNCE MA Overall Diamond Ratings are greater than or equal to the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort. If the ADVaNCE MA model participant's ADVaNCE MA Overall Diamond Rating is above the average, they would receive a rebate percentage of 60 percent of the average per capita savings. If such ADVaNCE MA Overall Diamond Rating is less than the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, they would receive a rebate percentage of 65 percent of the average per capita savings. If the scores straddle the average, both will receive a rebate percentage of 60 percent of the average per capita savings. For example, if the two ADVaNCE MA model participants in the General Enrollment cohort receive ADVaNCE MA Overall Diamond Ratings of 2.6 Diamonds and 2.8 Diamonds and the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the General Enrollment cohort is 3.4 Diamonds, then both ADVaNCE MA model participants would receive a rebate percentage of 70 percent. However, if the two ADVaNCE MA model participants were to score 4.3 Diamonds and 4.8 Diamonds for the same cohort and Mandatory State (a difference of 0.5 Diamonds) and the enrollment-weighted average

ADVaNCE MA Overall Diamond Rating is 3.4 Diamonds, the ADVaNCE MA model participant with the higher ADVaNCE MA Overall Diamond Rating would receive a rebate percentage of 70 percent and the ADVaNCE MA model participant with the lower ADVaNCE MA Overall Diamond Rating that is still above the enrollment-weighted average would receive a rebate percentage of 65 percent, as proposed previously, because it is above the enrollment-weighted average ADVaNCE MA Overall Diamond Rating. Similarly, if the two ADVaNCE MA model participants receive ADVaNCE MA Overall Diamond Ratings of 3.6 Diamonds and 3.1 Diamonds for the same cohort and Mandatory State, and the enrollment-weighted average ADVaNCE MA Overall Diamond Rating is 3.4 Diamonds, then the ADVaNCE MA model participant with the higher ADVaNCE MA Overall Diamond Rating would receive a rebate percentage of 70 percent and the ADVaNCE MA model participant with the lower ADVaNCE MA Overall Diamond Rating that is below the enrollment-weighted average would receive a rebate percentage of 50 percent, as proposed previously, because it is below the enrollment-weighted average ADVaNCE MA Overall Diamond Rating.

As an alternative, we considered proposing that in a Mandatory State and cohort with only two parent organizations with ADVaNCE MA model participant(s) that receive an ADVaNCE MA Overall Diamond Rating, that the participant(s) with the higher ADVaNCE MA Overall Diamond Ranking would receive a flat 70 percent rebate, regardless of their performance. The participant(s) with the lower ADVaNCE MA Overall Diamond Rating would receive 50 percent rebate, regardless of their performance. We believe this could also be appropriate as it effectively applies the linear scale we have proposed for Mandatory States and cohorts with three or more participants to those with two participants.

An additional alternative considered would be to weigh the coinciding rebates to account for distance from the average score, especially in the instance of scores within 0.2 Diamonds. The goal of the current proposal (above) is to ensure that parent organizations are not unfairly penalized against each other, but to also encourage parent organizations to consistently seek to

improve quality against the national average. The associated benchmark bonuses assigned to those below the national average are designed not to overly penalize plans, but to provide an opportunity to improve. However, one potential limitation with this approach is that it may create a steep threshold that the ADVaNCE MA model is being designed to avoid. An alternative strategy that we considered is, instead of having a specific reward percentage based on if the dyad is above or below the national average, to set the benchmark and rebate proportional to the national average so that dyads that are far below the national average have lower bonuses and rebates and those that are far above the national average have higher comparatively. This could potentially be done by assigning scores according to the national distribution of Diamond (for example, if the dyad's scores are below the 25th percentile nationally they receive a 25 percent lower benchmark and rebate, or if they perform above the 75th percentile, they receive a higher score).

We seek comment on the reward structure with two parent organizations in a Mandatory State and cohort, as well as the listed alternatives including alternative ways to reward against the national average.

We seek comment on our rebate proposal for Mandatory States with two parent organizations on their with ADVaNCE MA Overall Diamond Ratings and the listed alternative.

(3) Rebate Percentages for Mandatory States and Cohorts with One Parent Organization with an ADVaNCE MA Model Participant(s) that Receives an ADVaNCE MA Overall Diamond Rating.

Under § 516.230(c)(3), for Mandatory States and cohorts with one parent organization with an ADVaNCE MA model participant(s) that receives an ADVaNCE MA Overall Diamond Rating, we propose that if the participant(s) has an ADVaNCE MA Overall Diamond Rating greater than or equal to the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, their rebate percentage must be 70 percent of the average per capita savings. We further propose that if the ADVaNCE MA Overall

Diamond Rating is less than the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, the rebate percentage for the ADVaNCE MA model participant(s) must be 50 percent of the average per capita savings. We believe it is appropriate to vary the rebate percentage relative to the broader performance across all Mandatory States for the cohort when there is one parent organization with ADVaNCE MA model participant(s) that receive an ADVaNCE MA Overall Diamond Rating, so that the ADVaNCE MA model participant(s) is evaluated in the context of the national performance of the ADVaNCE MA model.

As an alternative, we considered proposing that in a Mandatory State and cohort with one parent organization with ADVaNCE MA model participant(s) that receive an ADVaNCE MA Overall Diamond Rating, the ADVaNCE MA model participant(s) would receive a flat 65 percent rebate, regardless of their performance. This would effectively provide them with the average rebate for a given Mandatory State and cohort with three or more ADVaNCE MA model participant(s).

We seek comment on our rebate proposal for Mandatory States with one parent organization with ADVaNCE MA Overall Diamond Ratings and the listed alternative.

(4) Insufficient Data, Low Enrollment, and New Entrants

We also propose policies for rebate percentages for ADVaNCE MA model participants that do not meet the minimum reporting requirements, meet the definition of low enrollment, or are new entrants to the ADVaNCE MA model. At § 516.230(c)(4), we propose that ADVaNCE MA model participants that are new entrants, as defined under § 516.5; have low enrollment, as defined under § 516.5; or have insufficient data under § 516.230(c)(4) would receive a final applicable rebate adjustment of 65 percent of the average per capita savings. Although under the MA and Part D Star Ratings system, low enrollment contracts (42 CFR 422.266(a)(2)(iii)) and new MA plans (42 CFR 422.266(a)(2)(iv)) are treated differently with respect to applicable rebate percentages, we believe it appropriate to treat ADVaNCE MA model participants that are

new entrants, as defined under § 516.5, have low enrollment, as defined under § 516.5, or have insufficient data, under § 516.215(d)(1), as subject to the rebate percentage under 42 CFR 422.266(a)(2)(iv) where a rating of 3.5 stars receives the applicable rebate percentage of 65, under 42 CFR 422.266(a)(2)(ii)(B). We believe this would provide predictability for ADVaNCE MA model participants. We note that under our proposed definition of low enrollment and insufficient data, an ADVaNCE MA model participant's measure data is pooled with all other ADVaNCE MA model participants under their parent organization in the same cohort and in the same Mandatory State. We also note that under our proposed definition for new entrant, a parent organization that is new to the Mandatory State has no prior MA or QBP participation in the Mandatory State for at least one performance year. A parent organization can be a new entrant in either or both cohorts in a Mandatory State in a given year. We also considered an alternative in which such a rebate would be 60 percent as it would be the midpoint within the rebate range of 50 to 70 percent in the Quality Bonus Payment system. However, we decided to maintain a rebate of 65 percent because it is similar to the MA and Part D Quality Bonus Payment system policy for new entrants.

Under § 516.230(c)(5), we propose that if a new ADVaNCE MA model participant enters a Mandatory State in CY 2030 or subsequent years of the model, the new ADVaNCE MA model participant would receive a final applicable rebate adjustment of 65 percent of the average per capita savings for its first three years in the model. We also considered an alternative in which such a rebate would be 60 percent as it would be the midpoint within the rebate range of 50 to 70 percent in the MA and Part D Quality Bonus Payment system. However, we decided to maintain a rebate of 65 percent because it is similar to the Quality Bonus Payment system policy for new entrants.

We considered the same two alternatives each as discussed in section VIII.F.4.a.(3) of this proposed rule for groups (1) and (2). However, for the reasons explained regarding the benchmark percentage increase, we are proposing the rebate policy for these ADVaNCE MA

model participants as discussed above. We seek comment on our proposal for rebate percentages in the ADVaNCE MA model.

c. *QBP-related benchmark adjustment, rebate, and Star Ratings display for consolidated contracts during the post-implementation period*

Within the post-implementation period of the ADVaNCE MA model (the three calendar years after the final performance year), a parent organization may consolidate previous model contracts with non-model contracts. In the MA and Part D Star Ratings program, the assignment of Star Ratings and QBP status for consolidated contracts is governed by 42 CFR 422.162(b)(3) where 42 CFR 422.162(b)(3)(ii)-(iii) describe how CMS assigns QBP status for the first and second years following a contract consolidation. The QBP status is based on the enrollment-weighted mean of the QBP status of the surviving and consumed contract(s) in the first year following consolidation and, in subsequent years, is based on the consolidated contract's Star Ratings, as provided by 42 CFR 422.162(b)(3)(iv). Because prior model contracts would be assigned Diamond Ratings instead of Star Ratings in the post-implementation period, the process described at 42 CFR 422.162(b)(3)(i)-(iii) would not apply to consolidated contracts consisting of model and non-model contracts in the post-implementation period.

As such, we propose to waive 42 CFR 422.162(b)(3)(i)-(iii) at § 516.605(c)(1) and instead propose at § 516.230(d)(1) that the QBP related benchmark adjustment and rebate for a newly consolidated contract containing at least one prior model contract throughout the post-implementation period would be calculated using an enrollment weighted average of what would have been the QBP related benchmark adjustment and rebate percent assigned to model contracts as part of the Diamond Ratings program and the QBP related benchmark adjustment and rebate percent that would have been assigned to non-model contracts as part of the Star Ratings program. The enrollment used in the weighted average calculation would be based on the contract enrollment in November of the year the preliminary QBP ratings were released, consistent with the methodology at 42 CFR 422.162(b)(3)(ii).

Previous model contracts that do not consolidate with non-model contracts during the post-implementation period would continue to be paid solely based on the Diamond Ratings system. They would continue to have their Diamond Ratings appear on the CMS website until there is sufficient data to fully transition back to the Star Ratings system at the conclusion of the post-implementation period.

During the post-implementation period, the display on the CMS website regarding consolidated contracts combining non-model and previous model contracts would focus on Star Ratings. Because Star Ratings and Diamond Ratings may be based on different measure sets by the end of the ADVaNCE MA model's performance period, either by combining Individual Measure Diamonds with Measure Stars, or the Overall Star Rating and the Overall Diamond Rating, using a similar enrollment weighted average would not give beneficiaries an accurate picture of contract quality because the underlying contracts may be based on different measure sets. As such, we propose at § 516.605(c)(2) to waive 42 CFR 422.162(b)(3)(iv), which governs the calculation of Star Ratings for consolidated contracts, and instead propose at § 516.230(d)(2) to display the enrollment weighted average measure ratings and Overall Star Ratings based on the consolidated contract's non-model contracts only. This would provide a clearer view of the contract's quality performance under the Star Ratings program and would be easier to apply at the contract level.

We seek comment on our proposal to waive 42 CFR 422.162(b)(3)(i)-(iv) and our proposals for calculating QBP amounts and rebates for consolidated contracts consisting of previous model and non-model contract in the post-implementation period and the use of an enrollment weighted average of non-model contracts' Star Ratings only for display on the CMS website.

G. Supplemental Benefits to Enhance Access to Prevention and Caregiver Support

1. Background

In the Part C program, MA organizations may offer supplemental benefits to enrollees – items or services that are not covered by OM and for which the MA organization incurs a non-zero direct medical cost or, for Special Supplemental Benefits for the Chronically Ill (SSBCI), a non-zero direct non-administrative cost.[206] With the exception of SSBCI, supplemental benefits must be primarily health related. Under 42 CFR 422.100(c)(2)(ii), supplemental benefits are "primarily health related" if they are used to diagnose, prevent, or treat an illness or injury; compensate for physical impairments; act to ameliorate the functional/psychological impact of injuries or health conditions; or reduce avoid emergency and health care utilization."[207] CMS has provided examples of allowable primarily health related supplemental benefits, such as support for caregivers of enrollees, in sub-regulatory guidance.[208] With some exceptions, MA organizations must offer supplemental benefits uniformly to all enrollees in a plan benefit package.[209]

Authorized by the Bipartisan Budget Act of 2018 and effective beginning Contract Year 2020, SSBCI are an exception to this uniformity requirement.[210] Through SSBCI, MA organizations can offer primarily health related supplemental benefits, non-primarily health related supplemental benefits, or both non-uniformly to certain qualifying enrollees, so long as the supplemental benefits have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. Specifically, MA organizations can offer SSBCI to enrollees

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[206] 42 C.F.R. § 422.100(c)(2), Electronic Code of Federal Regulations, https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-C/section-422.100.

[207] Centers for Medicare & Medicaid Services, Medicare Managed Care Manual, Chapter 4, "Benefits and Beneficiary Protections" (Rev. 121, issued April 22, 2016), https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c04.pdf.

[208] HPMS Memorandum; Reinterpretation of 'Primarily Health Related' for Supplemental Benefits; April 27, 2018; available at https://www.cms.gov/research-statistics-data-and-systems/computer-data-and-systems/hpms/hpms-memos-archive-weekly-items/syshpms-memo-2018-week4-apr-23-27.

[209] 42 C.F.R. § 422.100(d)(2)(i), Electronic Code of Federal Regulations, https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-C/section-422.100.

[210] Bipartisan Budget Act of 2018, Pub. L. 115–123, sec. 50322(a), 132 Stat. 64, 201 (2018) (codified at section 1852(a)(3)(D) of the Act).

who have at least one complex and life-threatening chronic condition, high risk of hospitalization, and require intensive care coordination. In April 2019, we released guidance[211] containing the following non-exhaustive list of non-primarily health related SSBCI:

- Meals (beyond a limited basis).
- Food and produce.
- Transportation for Non-Medical Needs.
- Pest Control.
- Indoor Air Quality Equipment and Services.
- Social Needs Benefits.
- Complementary Therapies.
- Services Supporting Self-Direction.
- Structural Home Modifications.
- General Supports for Living (such as rent or utilities assistance).

As discussed previously in section VIII.A of this proposed rule, in 2025, the CMS Innovation Center released a renewed strategy[212] comprised of three pillars: (1) promoting evidence-based prevention, (2) empowering people to achieve their health goals, and (3) driving choice and competition for people. We stated that future models would seek to increase the access and uptake of primary, secondary, and tertiary prevention. That is, activities to avoid disease occurrence, detect early signs of disease before symptoms, and slow the progression of existing chronic disease, respectively. Given these strategic pillars – and their relevance to supplemental benefits – we are proposing under the ADVaNCE MA model to enhance access to certain supplemental benefits relating to nutrition, transportation, and caregiver support. As discussed later in this section of the proposed rule, we believe each of these three areas

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[211] HPMS Memorandum; Implementing Supplemental Benefits for Chronically Ill Enrollees; April 24, 2019; available at https://www.cms.gov/medicare/health-plans/healthplansgeninfo/downloads/supplemental_benefits_chronically_ill_hpms_042419.pdf.

[212] Abe Sutton, "CMS Innovation Center Strategy to Make America Healthy Again," Centers for Medicare & Medicaid Services (May 13, 2025), https://www.cms.gov/priorities/innovation/about/cms-innovation-center-strategy-make-america-healthy-again.

(nutrition, transportation, and caregiver support) have the potential to address the strategic pillars, improve quality, and reduce future health care expenditures.

Importantly, when designing the proposed ADVaNCE MA model, we leveraged lessons learned from the VBID model and its associated costs. We believe our proposed supplemental benefit policies would better enable CMS to reduce Medicare expenditures, relative to the VBID model. Prior evaluations found the VBID model was associated with increases in targeted beneficiaries' risk scores (and, therefore, increased costs to CMS), likely driven by the model's design elements which encouraged beneficiaries to engage with providers, "creating opportunities to identify additional diagnoses that increased beneficiaries' risk scores."[213] For example, as noted in the evaluation reports, the VBID model allowed flexibilities and requirements related to Rewards & Incentives programs, reduced Part C cost-sharing, and Wellness and Healthcare Planning (WHP) which might have encouraged beneficiaries to use more care and schedule annual wellness visits. Likewise, the VBID model's Part D reduced cost-sharing flexibilities might have required more interactions with providers to get a prescription.

Lastly, evaluators noted that the novel chronic-condition based targeting flexibility introduced under the VBID model may have contributed to increased costs. "To offer benefits to people with these conditions, insurers participating in VBID needed to develop approaches to identify and track eligible beneficiaries. It is possible that these beneficiary identification approaches helped insurers uncover or reestablish diagnoses that previously might not have been properly documented."[214] By contrast, none of these VBID model design elements (rewards and incentives for care engagement, reduced Part C or D cost-sharing, WHP, chronic-

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[213] Dmitry Khodyakov et al., Evaluation of the Medicare Advantage Value-Based Insurance Design Model: 2020–2024, RAND Health (March 2026). https://www.cms.gov/priorities/innovation/data-and-reports/2026/vbid-exec-sum-2020-2024.

[214] Christine Eibner, Michael Dworsky, Dmitry Khodyakov, Julie Lai, Erin A. Taylor, and Shiyuan Zhang, The Association Between the Medicare Advantage Value-Based Insurance Design Model Test and Beneficiary Risk Scores: Supplementary Analyses of 2023 Evaluation Report Findings, RAND Health Care (December 2024). https://www.cms.gov/priorities/innovation/data-and-reports/2024/vbid-riskscores-2023evalsupp.

condition based supplemental benefit targeting) are proposed within the ADVaNCE MA model. Based on these evaluation findings, we believe the ADVaNCE MA model's focus on testing targeting of certain supplemental benefits (including healthy food and produce) to LIS-eligible individuals has the potential to yield greater cost-savings relative to the VBID model.

2. Enhancing Access to Nutrition, Transportation, and Caregiver Supports under the ADVaNCE MA Model

We propose at § 516.300 to allow ADVaNCE MA model participants to offer certain supplemental benefits in a non-uniform manner if offering the specified supplemental benefits based on an individual's eligibility for Part D LIS. The flexibility to target these supplemental benefits to LIS-eligible individuals, as defined in 42 CFR 423.34(b)(2), is hereafter referred to as "LIS-targeting" or the ability to "LIS-target," as applicable.

By including this flexibility in the ADVaNCE MA model, we aim to reward innovative approaches to address and prevent chronic illness among beneficiaries at high risk for development of chronic conditions,[215] but who might not meet all the criteria for SSBCI (which, among other items, requires that an eligible beneficiary already have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee).[216] This expanded access to prevention-focused benefits – particularly supplemental benefits that promote primary prevention (that is, the avoidance of disease occurrence) – is expected to generate cost-savings for the MA program through reduced future medical expenditures.

As such, throughout this preamble section, we propose to waive specified statutes and regulations that currently: (a) prohibit the provision of healthy food and produce, transportation for non-medical needs (TNMN), and support for caregivers supplemental benefits in a non-

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[215] Gabriel A. Benavidez, Whitney E. Zahnd, Peiyin Hung, and Jan M. Eberth, "Chronic Disease Prevalence in the US: Sociodemographic and Geographic Variations by Zip Code Tabulation Area," Preventing Chronic Disease 21 (February 29, 2024): E14, https://doi.org/10.5888/pcd21.230267.

[216] 42 C.F.R. § 422.102(f)(1)(i)(A), Electronic Code of Federal Regulations, https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-C/section-422.102.

uniform manner; and (b) prohibit the provision of healthy food and produce and TNMN supplemental benefits outside of SSBCI. Of note, following the conclusion of the VBID model at the end of CY 2025, MA organizations may offer healthy and produce and TNMN supplemental benefits exclusively as SSBCI. In order to test this core component of the ADVaNCE MA model – that is, whether LIS-targeting of certain supplemental benefits would improve quality outcomes while reducing Medicare program expenditures – we find it necessary to waive the statutes and regulations listed in the following paragraph.

We propose at § 516.600(k) to exercise our waiver authority pursuant to section 1115A(d)(1) to waive uniformity requirements at sections 1852(a)(3)(D)(ii)(II), 1852(d)(1)(A), and 1854(c) of the Act and 42 CFR 422.2 (uniformity requirement in the definition of "MA plan"), 422.100(d)(2), 422.102(a)(2), 422.102(a)(6)(ii), 422.254(b)(2), and 422.262(c)(1). We also propose to waive sections 1852(a)(3)(A), 1852(a)(3)(D)(i) and 1852(a)(3)(D)(ii)(I) of the Act and 42 CFR 422.100(c)(2)(ii)(A) to the extent they require supplemental benefits to be "primarily health related" unless offered as SSBCI. We propose waiving these provisions only to the extent necessary to allow ADVaNCE MA model participants to target healthy food and produce supplemental benefits, TNMN supplemental benefits, and support for caregivers supplemental benefits to LIS-eligible individuals (as that term is defined at 42 CFR 423.34(b)(2)). This proposal would not modify the SSBCI pathway, which continues to apply on its existing terms; all other requirements of those provisions would remain in full force and effect. Further information on LIS, as described in section 1860D-14 of the Act, is available at 42 CFR Part 423 subpart P and in the Plan Communication User Guide (PCUG) for MA prescription drug plans (MA-PDs).[217]

[217] Centers for Medicare & Medicaid Services, "MAPD Plan Communications User Guide (PCUG)" (last modified September 2026), https://www.cms.gov/data-research/cms-information-technology/access-cms-data-application/mapd-plan-communication-user-guide.

a. Testing Socioeconomic Status Targeting of Healthy Food/Produce Supplemental Benefits

We propose at § 516.300(a)(1)(i) that an ADVaNCE MA model participant be allowed to offer healthy food and produce in a non-uniform manner if targeting healthy food and produce to LIS-eligible individuals as defined at § 423.34(b)(2). Additionally, we propose at § 516.300(d) that ADVaNCE MA model participants would be subject to the "healthy food" standard for supplemental benefits set forth at proposed 42 CFR 422.102(h) and described in section III.A of this proposed rule, if this standard is finalized, based on the same rationale as provided in section III.A.

As discussed in section III.A of this proposed rule, a clear affirmative standard for what constitutes healthy food would promote CMS' ability to conduct meaningful compliance and enforcement work. For CMS to determine whether MA plans offer food benefits that are primarily health related or are appropriate as SSBCI, CMS is proposing to specifically require food-related supplemental benefits to be limited to "healthy food," and to define what it means by "healthy food" for this purpose. As food-related supplemental benefit spending continues to grow, so does the importance of ensuring that such spending is directed toward foods that genuinely support improved health outcomes. This aligns with the Make America Healthy Again (MAHA) initiative,[218] which emphasizes improving population health by addressing upstream drivers of chronic disease—particularly diet and nutrition, alongside broader efforts across HHS to translate the new 2025–2030 Dietary Guidelines for Americans (DGA)[219,220] into more practical standards for program design and administration. MAHA reflects a broader shift in federal health policy toward ensuring that public programs not only provide access to services, but also promote healthier choices, particularly in areas like food where poor nutrition

[218] U.S. Department of Health and Human Services, "Make America Healthy Again," https://www.hhs.gov/maha/index.html.
[219] U.S. Department of Health and Human Services and U.S. Department of Agriculture, Dietary Guidelines for Americans, 2025–2030, 2026, https://cdn.realfood.gov/DGA.pdf.
[220] U.S. Department of Health and Human Services and U.S. Department of Agriculture, The Scientific Foundation for the Dietary Guidelines for Americans, 2025-2030 (Washington, DC: HHS and USDA, 2026), https://cdn.realfood.gov/Scientific%20Report_1.8.26.pdf.

can contribute to worsening health outcomes.[221] Clearly defining "healthy food" for purposes of MA supplemental benefit offerings supports MAHA's core objective of aligning federal health spending with interventions that improve long-term health and reduce diet-related disease.

Establishing a clear definition of "healthy food" to be required for supplemental benefit offerings directly supports these objectives by creating a consistent baseline for nutrition quality across the MA program – ensuring that all food-related supplemental benefits are contributing to better health outcomes rather than simply expanding access to food. The DGAprovides the nutritional foundation for this proposal. In developing this proposed definition, CMS worked closely with experts throughout HHS involved in the development of the DGA. The 2025–2030 DGA rests on a documented evidence-review process: subject-matter experts were selected through a federal contracting process; standardized protocols — covering inclusion criteria, risk of bias, synthesis, and evidence grading — were set in advance by a methodology expert; the review relied on rapid systematic reviews, umbrella reviews, and literature syntheses; and the review was subject to external peer review coordinated by the NIH Office of Nutrition Research, with two independent reviewers assigned to each topic. Reviewer financial interests were disclosed as part of this process.[222]

CMS recognizes that the information and guidelines contained in the DGA are based on the preponderance of the scientific and medical knowledge which is current at the time the DGA is prepared and is subject to ongoing refinement as new research emerges. CMS believes this iterative process makes the DGA the most appropriate and reliable scientific anchor currently available for this definition, notwithstanding the inherent limitations of any evolving scientific field. Because the "healthy food" standard is anchored to the DGA rather than to a fixed

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[221] President's Make America Healthy Again Commission, Make Our Children Healthy Again: Assessment (May 2025), https://www.whitehouse.gov/wp-content/uploads/2025/05/MAHA-Report-The-White-House.pdf.
[222] U.S. Department of Health and Human Services and U.S. Department of Agriculture, The Scientific Foundation for the Dietary Guidelines for Americans, 2025-2030 (Washington, DC: HHS and USDA, 2026), https://cdn.realfood.gov/Scientific%20Report_1.8.26.pdf.

guideline or definition, the standard can evolve as the science changes and future DGA cycles are completed, rather than being bound to a static standard that cannot adapt over time.

CMS recognizes that the DGA provides broad nutrition guidance for the general population and is not written as regulatory standards for MA supplemental benefits. CMS therefore developed this proposed definition to translate the core nutritional principles reflected in the DGA into a clear, administrable standard for MA plans offering food-related supplemental benefits to Medicare beneficiaries. Accordingly, at § 516.300(d), we propose that the "healthy food" standard for MA supplemental benefits, proposed to be codified at 42 CFR 422.102(h), would apply to supplemental benefits that are LIS-targeted under the ADVaNCE MA model.

We identified healthy food and produce as high priority for LIS-targeting under the ADVaNCE MA model by reviewing a variety of items and activities and evaluating which: (1) have strong likelihood to improve or maintain the health outcomes of LIS-eligible individuals; (2) most closely align with the CMS Innovation Center's strategic focus on prevention and HHS's priority of ending the chronic disease epidemic;[223] and (3) have the greatest potential to generate cost-savings for the Medicare program.

Related to the first criterion of improving or maintaining health outcomes, HHS and external researchers have repeatedly noted the link between food insecurity, adverse health outcomes, and increased avoidable health care utilization.[224,225,226] In the Fiscal Year 2023

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[223] U.S. Department of Health and Human Services, "HHS Priorities" (last reviewed September 30, 2025), https://www.hhs.gov/about/priorities/index.html.

[224] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, "Access to Foods That Support Healthy Dietary Patterns," Healthy People 2030, https://odphp.health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/access-foods-support-healthy-dietary-patterns#top.

[225] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, "Food Insecurity," Healthy People 2030, https://odphp.health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/food-insecurity.

[226] Seth A. Berkowitz, Sanjay Basu, James B. Meigs, and Hilary K. Seligman, "Food Insecurity and Health Care Expenditures in the United States, 2011–2013," Health Services Research 53, no. 3 (June 2018): 1600–1620, https://doi.org/10.1111/1475-6773.12730.

Hospital Inpatient Prospective Payment System Final Rule,[227] CMS pointed to the availability of high-quality scientific evidence linking food insecurity (among other unmet needs) to adverse health outcomes and increased health care utilization, including hospitalizations, and associated costs. Also in that final rule, we noted food insecurity is associated with diminished mental and physical health, increased risk for chronic conditions, and high-cost health care utilization including Emergency Department (ED) visits and hospitalizations; it also can impede self-management of chronic diseases like diabetes and heart disease and requires beneficiaries to make trade-offs between food purchases and other medical needs, including prescription refills and preventive health services.

Evidence suggests that healthy food and produce programs have the potential to reduce food insecurity and improve health outcomes, particularly among individuals with low-income.[228,229] For example, an evaluation of nine such programs across twelve states found that among individuals (recruited from clinics serving low-income neighborhoods) who, for a median of six months, received a median of 63 dollars per month to purchase fruits and vegetables at grocery stores or farmers markets, the odds of being food-insecure dropped by one-third and self-reported health status improved.[230] Additionally, in this same study, among adults with hemoglobin A1c (HbA1c) > 6.5 percent, HbA1c declined by 0.29 percentage points. Among adults with hypertension, systolic blood pressure declined by 8.38 mmHg and diastolic blood pressure declined by 4.94 mmHg.

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[227] "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs," 87 Fed. Reg. 48,780 (August 9, 2022), https://www.federalregister.gov/d/2022-16472.

[228] Xiao, Y., Xiao, X., Zhang, X. et al. Mediterranean diet in the targeted prevention and personalized treatment of chronic diseases: evidence, potential mechanisms, and prospects. EPMA Journal 15, 207–220 (2024). https://doi.org/10.1007/s13167-024-00360-w.

[229] Wang, P., Song, M., Eliassen, A.H. et al. Optimal dietary patterns for prevention of chronic disease. Nat Med 29, 719–728 (2023). https://doi.org/10.1038/s41591-023-02235-5.

[230] Kurt Hager et al., "Impact of Produce Prescriptions on Diet, Food Security, and Cardiometabolic Health Outcomes: A Multisite Evaluation of 9 Produce Prescription Programs in the United States," *Circulation: Cardiovascular Quality and Outcomes* 16, no. 9 (September 2023): e009520, https://doi.org/10.1161/CIRCOUTCOMES.122.009520.

Such results also lend support to the primary (disease avoidance) prevention value of healthy food benefits. As seen in separate literature, individuals with type 2 diabetes who maintain HbA1c < 6.5 percent have significantly reduced odds of being diagnosed with cardiovascular disease, metabolic disease, neuropathy, nephropathy, and cerebrovascular disease, relative to individuals with type 2 diabetes and HbA1c > 6.5 percent.[231] Related to hypertension, additional research has found that each 5-mmHg reduction in systolic blood pressure can lower stroke risk by 22 percent.[232] Given this peer-reviewed literature demonstrating the preventive effects of healthy food and produce,[233,234] we believe that the ADVaNCE MA model would serve as a further test of the cost and quality impacts of expanded access to healthy food and produce supplemental benefits on a set of high-needs enrollees who do not necessarily meet the eligibility requirements of SSBCI.

Related to the third and final criterion (greatest potential to generate Medicare cost savings), our proposal considers both internal and external cost-savings estimates which suggest healthy food and produce offers the greatest potential for cost-savings among all benefits assessed for LIS-targeting under the ADVaNCE MA model. Notably, our internal review identified potential savings related to the food benefit (when provided on a debit card, in contrast to other methods of administering food and produce benefits) from fundamentally reduced medical expenditures, particularly through hospitalizations and ED visits. For example, we performed in-depth literature reviews including, but not limited to, reviews of the studies

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[231] Kamlesh S. Boye et al., "The Association Between Sustained HbA1c Control and Long-Term Complications Among Individuals with Type 2 Diabetes: A Retrospective Study," *Advances in Therapy* 39, no. 5 (May 2022): 2208–21, https://doi.org/10.1007/s12325-022-02106-4.

[232] Ahsan Mohammad et al., "Hypertension and Risk of Stroke: A Systematic Review and Meta-Analysis," *Cureus* 17, no. 12 (December 2025): e99863, https://doi.org/10.7759/cureus.99863.

[233] Trevor Arnason, Peter Tanuseputro, Meltem Tuna, and Douglas Manuel, "Municipal Transportation Policy as a Population Health Intervention: Estimating the Impact of the City of Ottawa Transportation Master Plan on Diabetes Incidence," Canadian Journal of Public Health 110, no. 3 (June 2019): 285–293, https://doi.org/10.17269/s41997-018-0168-9.

[234] Daniel P. Miller and Taryn W. Morrissey, "SNAP Participation and the Health and Health Care Utilisation of Low-Income Adults and Children," Public Health Nutrition 24, no. 18 (December 2021): 6543–6554, https://doi.org/10.1017/S1368980021003815.

that were included in literature reviews conducted by the Commonwealth Fund[235,236] looking at impacts of several benefits, such as general supports for living and home/bathroom safety assistance modifications. The strongest evidence for supplemental benefits was in the food and produce category, though the range of evidence-based, short-term returns-on-investment (ROIs) varied by population. Specifically, beneficiaries with low-income were more positively impacted by nutrition support than beneficiaries with higher incomes through experiencing a reduction in food insecurity, improved health outcomes, decreased avoidable health care utilization, and increased disease prevention.[237,238] As discussed, food insecurity is linked to increased health care costs because it increases vulnerability to adverse health outcomes and subsequent increased health care utilization.[239] While our review was focused on debit card delivery given the prevalence of that delivery method among MA supplemental benefits, we note (as also cited earlier in this section) that healthy food and produce programs delivered through other methods have also been associated with improved health outcomes and cost-savings, particularly for Medicare beneficiaries.[240]

Given this identified potential for improved quality and greater cost-savings from healthy food and produce supplemental benefits when targeted to enrollees with low-income, we included healthy food and produce within our proposal at § 516.300 to allow targeting of

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[235] The Commonwealth Fund, ROI Calculator for Partnerships to Address the Social Determinants of Health: Evidence Review (July 1, 2019), https://www.commonwealthfund.org/sites/default/files/2019-07/COMBINED-ROI-EVIDENCE-REVIEW-7-1-19.pdf.

[236] Douglas McCarthy, Corinne Lewis, Celli Horstman, Alexandra Bryan, and Tanya Shah, ROI Calculator for Partnerships to Address the Social Determinants of Health: Guide to Evidence for Health-Related Social Needs Interventions: 2022 Update, The Commonwealth Fund (September 2022), https://www.commonwealthfund.org/sites/default/files/2022-09/ROI_calculator_evidence_review_2022_update_Sept_2022.pdf.

[237] Barbara A. Laraia, Tashara M. Leak, June M. Tester, and Cindy W. Leung, "Biobehavioral Factors That Shape Nutrition in Low-Income Populations: A Narrative Review," American Journal of Preventive Medicine 52, no. 2, suppl. 2 (February 2017): S118–S126, https://pubmed.ncbi.nlm.nih.gov/28109413/.

[238] Peter J. Cunningham, "Why Even Healthy Low-Income People Have Greater Health Risks Than Higher-Income People," To the Point (blog), The Commonwealth Fund (September 27, 2018), doi:10.26099/y2gb-wa98, https://www.commonwealthfund.org/blog/2018/healthy-low-income-people-greater-health-risks.

[239] 87 FR 48780. https://www.federalregister.gov/d/2022-16472

[240] Lu Wang et al., "Health and Economic Impact and Cost-effectiveness of Produce Prescriptions for Diabetes in 50 U.S. States: A Microsimulation Study," *Diabetes Care* 48, no. 10 (October 2025): 1783–93, https://doi.org/10.2337/dc25-0144.

certain supplemental benefits to LIS-eligible individuals, operationalized at § 516.600(k) using our waiver authority pursuant to section 1115A(d)(1) of the Act, as previously described. Under this proposal, MA organizations in the ADVaNCE MA model would be allowed to offer healthy food and produce supplemental benefits as SSBCI (as currently authorized), or to target healthy food and produce supplemental benefits to LIS-eligible individuals (as proposed in § 516.300), or both.

In addition to the direct prevention and cost-savings impacts discussed previously, we believe there may be additional, indirect advantages of our proposal to enhance access to healthy food and produce. For example, MA organizations have previously conveyed their challenges effectively communicating benefit eligibility to enrollees when not all plan enrollees are eligible. This would be mitigated under this policy for contracts where all enrollees are LIS-eligible, as may be the case in D-SNP cohort contracts proposed at § 516.150(b)(2).

Additionally, we recognize that smaller or newer MA organization market entrants may face challenges implementing the existing supplemental benefit programs, such as SSBCI, due to limited funding, staffing, and/or data systems. SSBCI eligibility must be determined on an individual basis by the MA organization following a beneficiary's enrollment in a contract, using a multi-step process that requires clinical documentation of a diagnosis and independent eligibility determinations by the MA organization. Conversely, LIS eligibility can be determined by the Social Security Administration or a State Medicaid Office (rather than the MA organization) and certain groups of Medicare beneficiaries (such as full-benefit dually eligible beneficiaries) automatically qualify for LIS and therefore can easily be identified by the MA organization.[241] Peer-reviewed literature and interviews with MA organizations found that smaller, less-resourced MA organizations were less likely than medium or large MA organizations to offer new SSBCI and that, among other challenges to offering robust

[241]Centers for Medicare & Medicaid Services, Guidance to States on the Low-Income Subsidy (February 2009), https://www.cms.gov/medicare/eligibility-and-enrollment/lowincsubmedicareprescov/downloads/statelisguidance021009.pdf.

supplemental benefits, identifying and tracking SSBCI eligibility was particularly challenging when enrollees do not have a designated care manager.[242,243]

Relatedly, we believe that this proposed model test could address another CMS Innovation Center strategic pillar (driving choice and competition for people) by potentially enabling smaller, less-resourced MA organizations to better compete with larger, well-resourced MA organizations in offering attractive, evidence-based supplemental benefits that promote prevention. Additionally, it would test whether this kind of intervention would help address HHS' priority of encouraging healthy food for all people to improve their long-term health.

We believe that providing LIS-targeting flexibility to ADVaNCE MA model participants could allow MA organizations to maximize opportunities for a meaningful ROI – by focusing their resources on enrollees who are most likely to generate savings as a result of supplemental benefit utilization – and further build an evidence base for cost and quality impacts of interventions targeted to those who may have the greatest unmet needs.

We seek comment on the proposal to permit ADVaNCE MA model participants to target healthy food and produce supplemental benefits to LIS-eligible individuals, including the proposed waiver of requirements that would otherwise limit the offering of non-primarily health related benefits outside the SSBCI pathway.

b. Testing Socioeconomic Status Targeting of Transportation for Non-Medical Needs Supplemental Benefits

Additionally, at § 516.300(a)(1)(ii), we propose to allow ADVaNCE MA model participants to target TNMN supplemental benefits to LIS-eligible individuals as defined at 42

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[242] David J. Meyers, Emily A. Gadbois, Joan Brazier, Emma Tucher, and Kali S. Thomas, "Medicare Plans' Adoption of Special Supplemental Benefits for the Chronically Ill for Enrollees With Social Needs," JAMA Network Open 3, no. 5 (May 12, 2020): e204690, https://doi.org/10.1001/jamanetworkopen.2020.4690.

[243] Molly Knowles, Jennifer Howard, Amarilys Bernacet, Cleanthe Kordomenos, Edith Walsh, Michelle Herman Soper, and Nancy Archibald, Comparing New Flexibilities in Medicare Advantage with Medicaid Long-Term Services and Supports: Final Report, RTI International and Center for Health Care Strategies, prepared for the Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services (February 15, 2022), https://aspe.hhs.gov/sites/default/files/documents/80cb7c162b2c930d5b610048fe9ce0b9/medicare-advantage-medicaid-ltss.pdf.

CFR 423.34(b)(2). This proposal would allow ADVaNCE MA model participants to offer LIS-eligible individuals transportation to obtain non-medical items and services (for example, for grocery shopping or banking) outside of the existing SSBCI pathway.

We identified TNMN as a high priority for targeting under the ADVaNCE MA model by reviewing a variety of items and activities and evaluating which: (1) have strong likelihood to improve or maintain the health outcomes of LIS-eligible individuals; (2) most closely align with the CMS Innovation Center's strategic focus on prevention and HHS's priority of ending the chronic disease epidemic;[244] and (3) have the greatest potential to generate cost-savings for the Medicare program.

Related to the first criterion (improving or maintaining health outcomes), HHS and external researchers have repeatedly noted the link between unmet transportation needs and adverse health outcomes as well as increased avoidable health care utilization.[245,246,247] In the Fiscal Year 2023 Hospital Inpatient Prospective Payment System Final Rule,[248] CMS pointed to the existence of high-quality scientific evidence linking unmet transportation (among other unmet needs) to adverse health outcomes and increased health care utilization, including hospitalizations, and associated costs. This final rule goes on to state that unmet transportation to destinations required for all aspects of daily living contributes to postponement of routine medical care and preventive services, which ultimately leads to chronic illness exacerbation and

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[244] U.S. Department of Health and Human Services, "HHS Priorities" (last reviewed September 30, 2025). https://www.hhs.gov/about/priorities/index.html

[245] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, "Access to Foods That Support Healthy Dietary Patterns," Healthy People 2030. https://odphp.health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/access-foods-support-healthy-dietary-patterns#top

[246] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, "Food Insecurity," Healthy People 2030. https://odphp.health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/food-insecurity

[247] Leslie Saxon, Rebecca Ebert, and Mona Sobhani, "Health Impacts of Unlimited Access to Networked Transportation in Older Adults," Journal of mHealth (2019). https://thejournalofmhealth.com/health-impacts-of-unlimited-access-to-networked-transportation-in-older-adults/.

[248] Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. 48,780–49,203 (Aug. 9, 2022), https://www.federalregister.gov/d/2022-16472.

more frequent utilization of high-cost health care services including emergency medical services, ED visits, and hospitalizations.[249]

To determine which supplemental benefits might be highest priority for proposed LIS-targeting, we considered alignment with the Innovation Center's strategic goal of prevention, particularly primary prevention. We recognize there are multiple supplemental benefits that could align with the Innovation Center's strategic pillar to promote prevention. That is, we do not purport that TNMN and healthy food and produce are the only supplemental benefits capable of promoting prevention. However, our priority for LIS-targeting under the ADVaNCE MA model test remains those supplemental benefits which could directly address needs which CMS tied to adverse health outcomes and increased avoidable health care utilization in the CY 2023 Medicare Hospital Inpatient Prospective Payment Systems Final Rule, as well as those supplemental benefits which have robust evidence of primary prevention (meaning avoiding disease occurrence) rather than solely tertiary prevention (meaning slowing the progression of existing chronic disease). We believe the following evidence further demonstrates that TNMN, compared to many other supplemental benefits, more closely aligns with those priorities.

For example, this proposal also builds upon evidence from the CMS Innovation Center's Accountable Health Communities (AHC) model. Over a five-year period beginning in 2017, the AHC model tested whether systematically identifying and addressing the upstream drivers of health of Medicare and Medicaid beneficiaries through screening, referral, and community navigation services would impact health care costs and reduce health care utilization. The third evaluation report on the AHC model found that a lack of transportation for daily living was a barrier to beneficiary engagement in other prevention-based activities. It stated that "Community Service Providers (CSP) noted that the lack of reliable, affordable transportation can preclude beneficiaries from accessing affordable housing, childcare, work, and community

[249] Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. 48,780–49,205 (Aug. 9, 2022), https://www.federalregister.gov/d/2022-16472.

activities." One CSP called transportation "the ultimate shared interest" because society bears the costs when people cannot access services they need. Beneficiaries agreed, providing examples of challenges accessing doctor's appointments or getting to work and noting the inadequacy of bus networks.[250] As such, we believe that improving access to TNMN would reduce health care costs by enabling LIS-eligible individuals to access critical activities and services (such as groceries, employment, or parks/gyms for physical fitness) that help delay and prevent chronic disease progression before more costly clinical care is needed. We also believe it is worth testing LIS-targeting of TNMN in a model to see if that hypothesis comes to fruition.[251,252]

Additionally, the AHC evaluation noted limited options for "transportation to assist with food, housing, or utility-related needs" across both rural and urban areas.[253] We believe MA organizations could help further address this issue if eligibility for TNMN supplemental benefits were expanded. Of note, the AHC model evaluation also highlighted potential benefit utilization barriers which we encourage MA organizations to consider in their ADVaNCE MA model supplemental benefit offering design and implementation; for instance, some AHC beneficiaries felt unsafe using select modes of transportation due to mistrust in driver safety, bus routes through unsafe neighborhoods, or unsafe pickup and drop-off points where beneficiaries must meet drivers.

Related to the third and final criterion (greatest potential for Medicare cost-savings), our proposal considers both internal and external cost-savings estimates which suggest

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[250] RTI International, "Accountable Health Communities (AHC) Model Evaluation Third Evaluation Report," report prepared for the Centers for Medicare & Medicaid Services (November 2024), https://www.cms.gov/priorities/innovation/data-and-reports/2024/ahc-3rd-eval-report.

[251] Kjelstrom, S., R. W. Hass, and R. K. McIntire, "Association Between Lack of Access to a Neighborhood Park and High Blood Pressure in the Philadelphia Metropolitan Area," Preventing Chronic Disease vol. 20, 230098 2023. http://dx.doi.org/10.5888/pcd20.230098.

[252] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, "Healthy People 2030 Literature Summary: Employment," Healthy People 2030. https://odphp.health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/employment.

[253] RTI International, "Accountable Health Communities (AHC) Model Evaluation Third Evaluation Report," report prepared for the Centers for Medicare & Medicaid Services, November 2024. https://www.cms.gov/priorities/innovation/data-and-reports/2024/ahc-3rd-eval-report.

transportation benefits offer the second greatest potential for cost-savings among all benefits which were assessed, second only to healthy food and produce. Again, we performed in-depth literature reviews including studies captured in literature reviews conducted by the Commonwealth Fund[254,255] looking at impacts of several benefits, such as general supports for living and home/bathroom safety assistance modifications. The second strongest evidence for cost-savings associated with supplemental benefits was in the transportation category. As with food support, beneficiaries with low incomes were more impacted by transportation benefits than beneficiaries with relatively higher incomes.[256]

Given this identified potential for improved quality and greater cost-savings from transportation when targeted to individuals with low incomes, we included TNMN within our proposal at § 516.300 to allow targeting of certain supplemental benefits to LIS-eligible individuals, operationalized at § 516.600(k) using our waiver authority pursuant to section 1115A(d)(1) of the Act, as previously described. Under this proposal, MA organizations would be allowed to offer TNMN supplemental benefits to SSBCI-eligible enrollees in a contract under the ADVaNCE MA model through SSBCI (as currently authorized), or to target TNMN supplemental benefitsto LIS-eligible individuals in the contract (as proposed in § 516.300), or both.

Our intent with this proposal – in the cases of healthy food and produce supplemental benefits and TNMN supplemental benefits – is to level the playing field between smaller, less resourced MA organizations and their larger competitors, while expanding access to prevention-

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[254] The Commonwealth Fund, "ROI Calculator for Partnerships to Address the Social Determinants of Health: Evidence Review," July 1, 2019. https://www.commonwealthfund.org/sites/default/files/2019-07/COMBINED-ROI-EVIDENCE-REVIEW-7-1-19.pdf.

[255] Douglas McCarthy, Corinne Lewis, Celli Horstman, Alexandra Bryan, and Tanya Shah, "ROI Calculator for Partnerships to Address the Social Determinants of Health: Guide to Evidence for Health-Related Social Needs Interventions: 2022 Update," The Commonwealth Fund, September 2022. https://www.commonwealthfund.org/sites/default/files/2022-09/ROI_calculator_evidence_review_2022_update_Sept_2022.pdf.

[256] Amanda E. Ng, Dzifa Adjaye-Gbewonyo, and James J. Dahlhamer, "Lack of Reliable Transportation for Daily Living Among Adults: United States, 2022," *NCHS Data Brief*, no. 490 (January 2024): 1–8, https://www.cdc.gov/nchs/products/databriefs/db490.htm.

focused supplemental benefits that would otherwise exclusively be available to individuals who are eligible for SSBCI, in contrast to a broader (while still high-needs) population of LIS-eligible individuals. Our internal analyses indicate that the LIS population in Mandatory States would be larger than the applicable SSBCI population, resulting in increased access to healthy food and produce supplemental benefits and TNMN supplemental benefits. Additionally, as proposed, ADVaNCE MA model participants may continue to offer healthy food and produce supplemental benefits, TNMN supplemental benefits, or both, as SSBCI.

We believe the proposed LIS-targeting of TNMN supplemental benefits would have similar indirect advantages to our proposal related to healthy food and produce, including improved enrollee satisfaction and improved competition between smaller and larger MA organizations. Additionally, increasing access to TNMN supplemental benefits could have the advantage of facilitating formal and informal caregiver support by supplementing an important and time-consuming service provided by caregivers. Evidence suggests increased transportation assistance for non-medical needs such as work, groceries, or banking can serve as a form of caregiver support given that family caregivers provided 1.4 billion rides for older loved ones in 2009 alone[257] and that 79 percent of caregivers (49.8 million people in total) in 2025 reported assisting with transportation.[258] In the same 2025 survey, 28 percent of caregivers reported that it is very difficult to access affordable services in their care recipient's community – "like delivered meals, transportation, or in-home health services" – that would help with their care.[259]

We believe our proposal at § 516.300 that ADVaNCE MA model participants be allowed to target TNMN to LIS-eligible individuals (allowing TNMN to be offered outside of

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[257]National Aging and Disability Transportation Center (NADTC), "Unique Issues Related to Older Adults and Transportation," n.d. https://www.nadtc.org/about/transportation-aging-disability/unique-issues-related-to-older-adults-and-transportation/.

[258]National Alliance for Caregiving and American Association of Retired Persons, "Caregiving in the U.S. 2025 Report," July 2025., 35. https://www.aarp.org/content/dam/aarp/ppi/topics/ltss/family-caregiving/caregiving-in-us-2025.doi.10.26419-2fppi.00373.001.pdf.

[259]National Alliance for Caregiving and American Association of Retired Persons, "Caregiving in the U.S. 2025 Report," July 2025., 39. https://www.aarp.org/content/dam/aarp/ppi/topics/ltss/family-caregiving/caregiving-in-us-2025.doi.10.26419-2fppi.00373.001.pdf.

SSBCI) has the potential to increase demand for transportation services in ADVaNCE MA model beneficiaries, while promoting prevention. We also believe it could allow MA organizations to maximize opportunities for a meaningful ROI and further build the evidence-base for cost and quality impacts of interventions targeted to those who may have unmet health needs.

We seek comment on the proposal to permit ADVaNCE MA model participants to target TNMN supplemental benefits to LIS-eligible individuals, including the proposed waiver of requirements that would otherwise limit the offering of non-primarily health related benefits outside the SSBCI pathway.

c. Testing Socioeconomic Status Targeting of Support for Caregivers Supplemental Benefits

At § 516.300(a)(1)(iii), we propose to allow ADVaNCE MA model participants to target support for caregivers of enrollees supplemental benefits to LIS-eligible individuals as defined at 42 CFR 423.34(b)(2).

Currently, in the Part C program, MA organizations can offer support for caregivers of enrollees as a primarily health related supplemental benefit. Support for caregivers of enrollees supplemental benefits are sometimes referred to as "caregiver supports" supplemental benefits. These supplemental benefits can entail respite care provided through a personal care attendant for short periods of time (examples in our April 2018 memorandum on primarily health related supplemental benefits include a few hours each week, a two-week period, and a four-week period) and may include services such as counseling and training courses for caregivers of enrollees.[260]

However, research indicates that family caregivers often do not self-identify as such and, therefore, may not utilize existing caregiver supports.[261] Caregivers are broadly defined as

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[260] HPMS Memorandum; Reinterpretation of 'Primarily Health Related' for Supplemental Benefits; April 27, 2018; available at https://www.cms.gov/research-statistics-data-and-systems/computer-data-and-systems/hpms/hpms-memos-archive-weekly-items/syshpms-memo-2018-week4-apr-23-27.

[261] Elise K. Eifert, Robert Adams, William Dudley, and Michael Perko, "Family Caregiver Identity: A Literature Review," American Journal of Health Education 46, no. 6 (2015): 357–367, https://doi.org/10.1080/19325037.2015.1099482.

family members, friends, or neighbors who provide unpaid assistance to a person with a chronic illness or disabling condition.[262] By proactively identifying and addressing the needs of their care recipients, caregivers help beneficiaries manage serious illnesses and stay in their communities, rather than in more costly institutionalized care settings. To help MA organizations target their efforts in offering caregiver supports supplemental benefits – and accordingly engaging beneficiaries and caregivers to utilize such supports – we propose at § 516.300(a)(1)(iii) to allow ADVaNCE MA model participants to target support for caregivers of enrollees supplemental benefits to LIS-eligible individuals. We also propose at § 516.600(k) to use our ADVaNCE MA model authority under section 1115A(d)(1) of the Act and waive the uniformity requirements at sections 1852(a)(3)(D)(ii)(II), 1852(d)(1)(A), and 1854(c) of the Act and 42 CFR 422.2 (uniformity requirement in the definition of "MA plan"), 422.100(d)(2), 422.102(a)(2), 422.102(a)(6)(ii), 422.254(b)(2), 422.262(c)(1) only to the extent necessary to allow MA organizations to target support for caregivers of enrollees benefits to LIS-eligible individuals.

Since MA organizations may currently offer caregiver supports supplemental benefits to all plan enrollees uniformly, we seek to test whether providing LIS-targeting flexibility would increase opportunities for ADVaNCE MA model participants to achieve meaningful ROI by focusing their benefit offerings on a subset of high-needs enrollees. Additionally, we seek to test whether ADVaNCE MA model participants could achieve greater success in their benefit awareness and engagement strategies by focusing their enrollee engagement staff and resources on a more targeted population of high-needs enrollees through LIS-targeting.

[262] Centers for Medicare & Medicaid Services, "Caregiver Partners," last modified January 22, 2025, https://www.cms.gov/training-education/partner-outreach-resources/partner-with-cms/caregiver-partners.

Lastly, we believe this proposal could reduce the cost of care by avoiding or delaying utilization of home health and institutional care providers as caregivers would be better supported in their roles.[263,264,265,266,267]

Of note, as with our proposals to permit ADVaNCE MA model participants to LIS-target of healthy food and produce supplemental benefits and TNMN supplemental benefits, we do not propose any unique modifications to which items and services (for example, caregiver training or counseling) CMS allows to be offered as support for caregivers supplemental benefits.

We seek comment on the proposal to allow ADVaNCE MA model participants to target caregiver supports supplemental benefits to LIS-eligible individuals.

3. Supplemental Benefit Operational Details

a. General

We propose at § 516.300(a) that ADVaNCE MA model participants may offer certain supplemental benefits to LIS-eligible individuals, as defined at 42 CFR 423.34(b)(2). At the time of publication of this proposed rule, § 423.34(b)(2) defines a low-income subsidy (LIS)-eligible individual as "an individual who meets the definition of full subsidy eligible (including full benefit dual eligible individuals as set forth in this section) or other subsidy eligible in 42 CFR 423.772 of this part." The Inflation Reduction Act of 2022 (IRA, P.L. 117-169) modified

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[263] Priya Chidambaram, Anna Mudumala, Alice Burns, and Robin Rudowitz, "Experiences of Direct Care Workers and Family Caregivers of Home- and Community-Based Services (HCBS)," KFF (October 30, 2024), https://www.kff.org/medicaid/experiences-of-direct-care-workers-and-family-caregivers-of-home-and-community-based-services-hcbs/.

[264] Administration for Community Living, "Caregiving and Direct Care Workforce," accessed July 14, 2026, https://acl.gov/programs/caregiving-and-direct-care-workforce.

[265] Office of the Assistant Secretary for Planning and Evaluation, Office of Behavioral Health, Disability, and Aging Policy, Identifying Employer Supports for Family Caregivers of Older Adults (December 17, 2024), https://aspe.hhs.gov/sites/default/files/documents/4c6c3767f2fc13b0162f72fad2fcfb0a/employer-supports-older-adult-caregivers.pdf.

[266] Pamela Nadash, Taylor Jansen, Eileen J. Tell, and Marc A. Cohen, In Their Own Words: Family Caregiver Priorities and Recommendations—Results from a Request for Information, LeadingAge LTSS Center @UMass Boston and Community Catalyst (February 2021), https://eadn-wc03-8290287.nxedge.io/wp-content/uploads/2022/12/caregiver-priorities-and-recommendations-2.pdf.

[267] National Alliance for Caregiving and AARP, Caregiving in the U.S. 2025 Report (Washington, DC: National Alliance for Caregiving and AARP, July 2025), https://www.aarp.org/content/dam/aarp/ppi/topics/ltss/family-caregiving/caregiving-in-us-2025.doi.10.26419-2fppi.00373.001.pdf.

the eligibility for LIS such that "other low-income subsidy eligible individual" applies only for plan years beginning before January 1, 2024. Regulatory changes to LIS were necessary in order to implement the changes in law made by the IRA at §§ 423.773(b)(1), 423.773(b)(2)(iii), 423.773(d), and 423.780(d). In effect, the IRA sunset the LIS sliding scale at § 423.780(d) for LIS-eligible individuals with incomes between 135 percent of the federal poverty level (FPL) and 150 percent of the FPL. Instead, it established that all individuals with incomes at or below 150 percent and who meet the resource requirements now qualify for the full LIS for all plan years beginning CY 2024. Since the ADVaNCE MA model performance period spans CY 2029 through CY 2038, ADVaNCE MA model participants would have the choice under proposed § 516.300(a) to offer the specified supplemental benefits to all LIS-eligible individuals (with no further sub-categorization) or to not take up the LIS-targeting flexibility offered under the ADVaNCE MA model.

To align with the contract structure of the ADVaNCE MA model, we also propose at § 516.300(b)(2) that if a MA organization chooses to offer one or more of the supplemental benefits set forth at § 516.300(a)(1) to LIS-eligible individuals within an ADVaNCE MA contract, then it must offer the applicable supplemental benefit(s) to all LIS-eligible individuals enrolled in the applicable contract. Stated another way, if an ADVaNCE MA model participant chooses to offer a relevant supplemental benefit to LIS-eligible individuals in one plan benefit package within an applicable contract, then it must target that supplemental benefit in all plan benefit packages within the applicable contract. For example, if hypothetical Organization A operates contract Z0001 under the ADVaNCE MA model; and contract Z0001 contains plan benefit packages Z0001-001 and Z0001-002, then Organization A could not offer LIS-targeted healthy food and produce supplemental benefits only to enrollees in plan Z0001-001. It would be required to offer LIS-targeted healthy food and produce supplemental benefits to enrollees in plan Z0001-001 and Z0001-002.

However, given that bids are submitted at the plan benefit package level, rather than contract-level, we propose at § 516.300(b)(2)(i) that ADVaNCE MA model participants may vary the maximum benefit amounts and delivery methods across plan benefit packages within the applicable contract, so long as the applicable supplemental benefit is offered to all LIS-eligible individuals under the applicable contract. For further clarification, we offer the following hypothetical examples specific to each of the three supplemental benefits proposed for LIS-targeting under the ADVaNCE MA model:

- Organization A could choose to offer each LIS-eligible individual in plan Z0001-001 and Z0001-002 up to $100 of healthy food and produce each month in the contract year. Alternatively, Organization A could choose to offer each LIS-eligible individual in plan Z0001-001 up to $100 of healthy food and produce each month in the contract year while offering each LIS-eligible individual in plan Z0001-002 up to $150 of healthy food and produce each month in the contract year.

- Organization B could choose to offer each LIS-eligible individual in plan Z0002-001 and Z0002-002 up to $150 in TNMN via bus pass each quarter of the contract year. Alternatively, Organization B could choose to offer each LIS-eligible individual in plan Z0002-001 up to $150 in TNMN via bus pass each quarter of the contract year while offering each LIS-eligible individual in plan Z0002-002 up to $200 in TNMN via rideshare voucher each month in the contract year.

- Organization C could choose to offer each LIS-eligible individual in plan Z0003-001 and Z0003-002 up to 90 minutes of caregiving training each month of the contract year. Alternatively, Organization C could choose to offer each LIS-eligible individual in plan Z0003-001 up to 90 minutes of caregiving training each month while offering each LIS-eligible individual in plan Z0003-002 up to 180 minutes of caregiver counseling each quarter of the contract year.

We propose this requirement to align with the contract structure of the ADVaNCE MA model. Additionally, we believe our proposals would be responsive to external comments and responses to prior CMS rulemaking and call letters which have demonstrated a desire for eligibility that is more standardized across MA plans and for MA plans to be permitted to consider financial need as a rationale for directing resources to enrollees most likely to benefit from non-primarily health related supplemental benefits.[268,269,270] Allowing targeting of supplemental benefits to LIS-eligible individuals would directly address both of these external calls. Specifically, MA organizations would be permitted to LIS-target supplemental benefits in the proposed ADVaNCE MA model General Enrollment cohort contracts, proposed ADVaNCE MA model D-SNP cohort contracts, or both. For example, under our supplemental benefit proposals, if an MA organization were to LIS-target healthy food and produce in a D-SNP cohort contract, all enrollees under that contract could have access to some form of healthy food and produce supplemental benefits if all of the D-SNP cohort contract enrollees would be LIS-eligible individuals.

Additionally, related to the proposals at § 516.300 to allow LIS-targeting of healthy food and produce, TNMN, and support for caregivers of enrollees supplemental benefits, we propose at § 516.300(c)(1) that CMS may annually review bid submissions and consider each benefit proposed by ADVaNCE MA model participants for compliance with the supplemental benefit requirements applicable to each benefit.

Finally, we propose to use our authority at 42 CFR 512.150(b) to propose at § 516.300(b)(5) that ADVaNCE MA model participants must submit data annually to CMS on the

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[268] Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program, 85 Fed. Reg. 33,796–33,911 (June 2, 2020), https://www.federalregister.gov/d/2020-11342.

[269] Centers for Medicare & Medicaid Services, Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter (January 30, 2019), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf.

[270] Melony E. Sorbero and Ashley M. Kranz, "Perspectives on Opportunities and Challenges for Medicare Advantage Plans to Address Social Determinants of Health via the CHRONIC Care Act," Inquiry 56 (2019): 1–4, https://doi.org/10.1177/0046958019862120.

utilization and costs of supplemental benefits targeted towards LIS-eligible individuals under the ADVaNCE MA model. This data submission is unique to the ADVaNCE MA model and is separate from the required process outlined in the Part C Reporting Requirements.[271] Given the importance of clearly delineated supplemental benefit data to evaluate the potential cost and quality impacts of our proposed policies, we encourage ADVaNCE MA model participants and their downstream participants (as defined under 42 CFR 512.110) to prepare the capabilities for monitoring and collecting detailed line items for each benefit and reporting such data to CMS, if finalized. We propose to collect these data from ADVaNCE MA model participants because, since VBID benefits were excluded from the Part C Reporting Requirements, we expect ADVaNCE MA supplemental benefits to be excluded from the Part C Reporting Requirements. Therefore, we propose at § 516.600(l)(1) to exclude the reporting of the utilization and costs of supplemental benefits targeted towards LIS-eligible individuals under the ADVaNCE MA model from the Part C Reporting Requirements to follow the precedent set by the exclusion of VBID benefits from the Part C Reporting Requirements for operational simplicity.[272] To minimize reporting burden for MA organizations which may submit supplemental benefit utilizations and costs data under Part C Reporting Requirements for non-ADVaNCE MA model PBPs, we intend to collect supplemental benefit utilization and costs data that align closely in formatting with the existing, annual plan benefit package (PBP)-level Supplemental Benefit Utilization and Costs Section of the Part C Reporting Requirements established under 42 CFR 422.516. Of note, CY 2026 Supplemental Benefit Utilization and Costs data under Part C Reporting Requirements occur at the PBP-level. As proposed at § 516.600(l)(2), all other requirements of 42 CFR 422.516 remain in full force and effect.

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[271] Centers for Medicare & Medicaid Services. 2025, December 1. Medicare Part C Reporting Requirements. https://www.cms.gov/files/document/cy2026-part-c-reporting-requirements-12-01-2025.pdf.

[272] Centers for Medicare & Medicaid Services, Frequently Asked Questions - Contract Year 2025 Part C Reporting Requirements - Supplemental Benefit Utilization and Costs Section, last modified May 2025, https://www.cms.gov/files/document/cy-2025-part-c-supplemental-benefit-utilization-and-costs-faq.pdf.

Additionally, to further evaluate the effects of our supplemental benefit policies, we intend under this proposal to collect beneficiary-level supplemental benefit utilization and costs data reporting from ADVaNCE MA model participants. This beneficiary-level reporting would similarly align with the required data elements under 42 CFR 422.516, to the extent feasible and applicable to beneficiary-level reporting. These new reporting requirements would be limited to collection of supplemental benefit utilization and costs for those supplemental benefits which would be LIS-targeted under the ADVaNCE MA model. We propose to collect these beneficiary-level data, in addition to PBP-level data, since beneficiary-level data would better enable us to evaluate the quality and cost impacts of LIS-targeting supplemental benefits relative to PBP-level data alone. Finally, for the purposes of evaluation, we may also analyze existing supplemental benefit utilization reporting as applicable via the medical loss ratio reporting requirements under 42 CFR 422.2460 and MA encounter data required under 42 CFR 422.310.

b. Administration of Supplemental Benefits

Under proposed § 516.300(b)(4), ADVaNCE MA model participants would remain subject to the requirements at 42 CFR 422.102(g)(2), unless specifically waived for purposes of the ADVaNCE MA model. This would include existing requirements for administering supplemental benefits through debit (sometimes referred to as "flex") cards, including that debit cards be electronically linked to plan-covered items and services through a real-time identification mechanism to verify eligibility of plan-covered benefits at the point of sale, and that debit cards be limited to the specific plan year. As CMS has previously noted, "a plan debit card is not a covered benefit but rather, a mechanism by which an MA plan may provide payment to providers for the covered benefits."[273] Sections 1851(h)(4)(A) and 1854(d)(1) of the

[273] Medicare Program; Contract Year 2027 and Certain Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program, 91 Fed. Reg. 17,384, 17,485 (Apr. 6, 2026), https://www.federalregister.gov/d/2026-06600.

Act expressly prohibit MA plans from offering enrollees cash. That is, supplemental benefits delivered through debit cards are not cash benefits and cannot be considered as such.

We are committed to crushing fraud, waste, and abuse – including in the Medicare Advantage program – and, as such, ADVaNCE MA model participants would remain subject to all existing fraud, waste, and abuse laws and CMS monitoring and compliance requirements, including those at 42 CFR 512.150. Additionally, with respect to the TNMN supplemental benefit, CMS would analyze available MA encounter data and beneficiary-level supplemental benefit utilization and costs data to monitor for potential indicators of program integrity risk (such as consistent utilization of the maximum offered benefit amount, when offerings are substantial). We expect ADVaNCE MA model participants to engage in front-end vetting of transportation providers (including verifying whether any TNMN company employees or drivers are also enrolled as beneficiaries under the ADVaNCE MA model participant's plan. This vetting would be intended to identify and prevent potential billing conflicts of interest, such as self-referred trips (i.e., a driver billing for trips in which they are the beneficiary). This vetting does not bar the employment of MA beneficiaries by TNMN companies. In the case of potential overlap between TNMN employees or drivers and an MA beneficiary under an ADVaNCE MA model participant, the MA organization should establish fraud prevention and deterrence processes through required oversight as outlined in 42 CFR Part 422, Subpart K and OIG compliance guidance on transportation fraud schemes.[274] We also expect ADVaNCE MA model participants to establish fraud prevention and deterrence processes when offering support for caregivers supplemental benefits, consistent with their existing MA program compliance obligations under 42 CFR 422.503(b)(4)(vi) and 422.504. For example, electronic verification that documented caregivers are regularly engaging in typical caregiving activities could help

[274] U.S. Department of Health and Human Services, Office of Inspector General, "Using Targeted Reviews to Reduce Fraud, Waste, and Abuse in Medicaid Nonemergency Medical Transportation," Work Plan Project no. OEI-02-25-00360, October 15, 2025, https://oig.hhs.gov/reports/work-plan/browse-work-plan-projects/using-targeted-reviews-to-reduce-fraud-waste-and-abuse-in-medicaid-nonemergency-medical-transportation/.

protect beneficiaries and safeguard taxpayer funds. As part of our model monitoring activities under § 512.150, CMS may request and review such data, if available, as needed to evaluate or monitor the model.

c. Beneficiary Access

We propose at § 516.300(b)(1) that ADVaNCE MA model participants who choose to target one or more supplemental benefits set forth at § 516.300(a)(1) to LIS-eligible individuals must offer the supplemental benefit(s) as mandatory supplemental benefits. That is, an MA organization offering LIS-target healthy food and produce supplemental benefits, TNMN supplemental benefits (both of which, outside of the ADVaNCE MA model, are permitted only as SSBCI), support for caregivers supplemental benefits, or any combination thereof may only offer such benefits as mandatory supplemental benefits. This requirement, if finalized, would improve access to such supplemental benefits among beneficiaries with low-income, better enable CMS to evaluate the impacts of LIS-targeted supplemental benefits, and ensure alignment with the identical requirement for SSBCI at 42 CFR 422.102(f)(2)(i) in the cases of healthy food and produce and TNMN supplemental benefits.

Likewise, ADVaNCE MA model participants would remain subject to existing requirements that services (including supplemental benefits provided through a contracted provider or vendor) be available and accessible to all eligible enrollees. Specifically, at 42 CFR 422.112(a), an MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. Additionally, we propose at § 516.300(a)(3) that nothing in our proposal for supplemental benefit targeting under the ADVaNCE MA model would preclude an ADVaNCE MA model participant from offering supplemental benefits as otherwise permitted under § 422.102, including SSBCI as outlined in § 422.103(f).

d. Alternatives Considered

In sum, under proposed § 516.300(a), we propose to allow ADVaNCE MA model participants to target certain supplemental benefits to LIS-eligible individuals. Previously cited evidence demonstrates that individuals with low-income collectively comprise a high-needs population. It is our intent that this flexibility would provide ADVaNCE MA model participants of all sizes with an opportunity to focus resources towards identifying and engaging high-needs and high-cost enrollees who could greatly benefit from prevention-oriented supplemental benefits, but who may otherwise not be deemed eligible for such supplemental benefits.

Under the same rationale, we alternatively considered allowing ADVaNCE MA model participants to LIS-target additional supplemental benefits beyond healthy food and produce, TNMN, and support for caregivers of enrollees. This could have included: (1) allowing a limited number of additional supplemental benefits to be LIS-targeted based on the criteria, discussed above, of strong likelihood for improved health outcomes, alignment with our strategic focus on prevention and chronic disease, and potential for cost-savings to Medicare; or (2) broadening LIS-targeting outside of the discussed criteria to maximize ADVaNCE MA model participants' benefit flexibility and innovation and maximize choice of supplemental benefits among LIS-eligible individuals. However, we noted that allowing ADVaNCE MA model participants to LIS-target any primarily or non-primarily health related supplemental benefit could also impact the ADVaNCE MA model's quality improvement and reduction of avoidable health care utilization. We solicit comment on these alternatives allowing supplemental benefits beyond healthy food and produce, TNMN, and caregiver supports to be targeted to LIS-eligible individuals.

Additionally, we considered allowing ADVaNCE MA model participants to LIS-target supplemental benefits based on the LIS eligibility levels operationalized under the VBID model. That is, rather than solely allowing targeting of supplemental benefits to all LIS-eligible individuals, we considered allowing LIS-targeting of supplemental benefits to distinct, further

delineated categories of LIS-eligible individuals based on the LIS eligibility categories and corresponding cost-sharing benefits that, as described in the Advance Notice, are sometimes referred to using category codes as follows:

- **Category Code 1 –** Non-institutionalized Full Benefit Dual Eligible (FBDE) beneficiaries with incomes between 100 percent and 150 percent of FPL and full-subsidy-non-FBDE beneficiaries.
- **Category Code 2 –** Non-institutionalized FBDE beneficiaries with incomes up to 100 percent of the FPL.
- **Category Code 3 –** FBDE beneficiaries who are institutionalized or would be institutionalized if they were not receiving home and community-based services.[275]

Under this alternative approach, an ADVaNCE MA model participant would be allowed to offer certain supplemental benefits to any, or all, of the aforementioned LIS levels/category codes. For example, an ADVaNCE MA model participant could choose to target healthy food and produce supplemental benefits exclusively to LIS-eligible individuals in LIS Category Code One, or to LIS-eligible individuals in LIS Category Codes One and Two but not Three, and so on. However, we believe the proposed approach of targeting supplemental benefits towards all LIS-eligible individuals offers greater simplicity for MA organizations and their enrollees while still allowing for discretion to target towards high-needs and high-cost enrollees who could greatly benefit from prevention-oriented supplemental benefits. We seek comment on this alternative of delineating LIS-eligible individuals for the purpose of offering certain supplemental benefits in a non-uniform manner under the ADVaNCE MA model.

In contrast to allowing further delineation among LIS-eligible individuals, we also alternatively considered allowing ADVaNCE MA model participants to offer the specified supplemental benefits more broadly to their entire enrollee population or to other targeted

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[275] Centers for Medicare & Medicaid Services, "Advance Notice of Methodological Changes for Calendar Year (CY) 2027 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies", (January 2026), https://www.cms.gov/files/document/2027-advance-notice.pdf.

populations other than LIS-eligible individuals or SSBCI-eligible individuals at the MA organization's discretion. However, we again noted that both allowing broad discretion in targeting and allowing provision of the specified benefits to a broader enrollee population, rather than to LIS-eligible individuals, could also impact the ADVaNCE MA model's quality improvement and reduction of avoidable health care utilization.

We solicit comment on these alternative scopes for targeting healthy food and produce, TNMN, and support for caregivers of enrollees' supplemental benefits.

Separate from supplemental benefits but related to the same goal of improving chronic disease prevention, we also considered testing adjustments to Part C rewards and incentives, or R&I, (as described at 42 CFR 422.134) to align with standards applicable to employee wellness programs (as described in the Department of the Treasury, Department of Labor, and Department of Health and Human Services regulations at 26 CFR 54.9802-1(f)), 29 CFR 2590.702(f), and 45 CFR 146.121(f)). Specifically, § 422.134(d)(2)(ii) prohibits the value of a Part C reward item from exceeding the value of the target activity itself. In contrast, 26 CFR 54.9802-1(f)(3)(ii), 29 CFR 2590.702(f)(3)(ii), and 45 CFR 146.136(f)(3)(ii), limits the size of the reward under health-contingent wellness programs to 30 percent of the total cost of the employee-only coverage under the plan. This amount is raised by an additional 20 percent (to 50 percent) to the extent that the additional percentage is in connection with a program designed to prevent or reduce tobacco use. To incentivize chronic disease prevention under the ADVaNCE MA model, CMS considered allowing MA organizations to offer Part C R&I at a size akin to the amount allowed under health-contingent employee wellness programs. However, since evaluators found R&I under the VBID model (which allowed for R&I up to the value of the *expected benefit* of the target activity) may have contributed to increased costs, we have refrained from including any tests of R&I within the ADVaNCE MA model. We also solicit comment on this alternative.

e. Conclusion

We do not propose to test any unique or alternative funding mechanisms for mandatory supplemental benefits. ADVaNCE MA model participants would remain subject to all requirements related to supplemental benefits, unless specifically waived. Additionally, we do not propose to modify which items and services are considered allowable under the healthy food and produce, TNMN, or support for caregivers supplemental benefit categories.

We seek comment on the proposed methods to target healthy food and produce (inclusive of the proposed "healthy food" standard for supplemental benefits), TNMN, and caregiver supports under the ADVaNCE MA model to LIS-eligible individuals, as defined at 42 CFR 423.34(b)(2). Additionally, we seek comment on whether there are other existing MA supplemental benefit categories which may be appropriate for LIS-targeting. That is, supplemental benefits which (1) have strong likelihood to improve or maintain the health outcomes of LIS-eligible individuals, (2) most closely align with the CMS Innovation Center's strategic focus on prevention and HHS's priority of ending the chronic disease epidemic,[276] and (3) have the greatest potential to generate cost-savings for the Medicare program. Next, we seek comment on alternatively allowing ADVaNCE MA model participants to target any primarily or non-primarily health related additional supplemental benefits (that is, supplemental benefits that are not reduced cost-sharing) to LIS-eligible individuals. We also seek comment on alternatively narrowing or broadening the population scope to which ADVaNCE MA model participants may offer the specified supplemental benefits. Finally, we seek comment on how, if at all, the ADVaNCE MA model should test adjustments to Part C rewards and incentives to better align wellness programs with the goal of improving chronic disease prevention.

H. Dialysis Carveout for Beneficiaries with End-Stage Renal Disease

[276] U.S. Department of Health and Human Services, "HHS Priorities" (last reviewed September 30, 2025). https://www.hhs.gov/about/priorities/index.html.

a. Background

As discussed in more detail in section VIII.A.4.d and section VIII.A.2.d, ESRD and its treatment under Medicare payment policy have evolved considerably over the past five years. This section presents data on the consolidation of the dialysis market and summarizes relevant research findings on how that consolidation has affected beneficiary access, quality and cost, for dialysis. We are considering proposing a change to the dialysis coverage structure for beneficiaries who reside in one of the Mandatory States and who are enrolled in a plan subject to an ADVaNCE MA model contract.

The dialysis market is highly concentrated with 70 percent of the market controlled by two large organizations, DaVita and Fresnius. Because of this market concentration, these dialysis organizations have great leverage when negotiating payment rates with MA organizations.[277] A 2026 MedPAC report found that, in 2022, MA plans paid an average of 22 percent more for dialysis than OM, a trend that has continued ever since.[278]

b. Potential Modification to the ADVaNCE MA Model Test

CMS is considering proposing a future modification to the ADVaNCE MA model that would exclude coverage for outpatient maintenance dialysis facility services from MA basic benefits for ADVaNCE MA model beneficiaries and would instead provide coverage for those services through OM, with reimbursement under the ESRD PPS. Beneficiaries would remain enrolled in their MA plan for all other covered Medicare services, consistent with the existing statutory exclusions for hospice services and organ acquisition costs. Under such a potential policy change, CMS would adjust MA benchmarks and capitation payments to reflect the transfer of dialysis payment responsibility to OM and waive other applicable statutory requirements that MA organizations cover dialysis services. Dialysis facilities would submit

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[277] Elaine Lin et al., "Medicare Advantage Plans Pay Large Markups To Consolidated Dialysis Organizations," *Health Affairs* 41, no. 8 (August 2022): 1107–16, https://doi.org/10.1377/hlthaff.2021.02009.

[278] Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, chap. 12, "The Medicare Advantage Program: Status Report" (March 2026), https://www.medpac.gov/wp-content/uploads/2026/03/Mar26_Ch12_MedPAC_Report_To_Congress_SEC.pdf.

claims only to OM for carved-out services and would not be required to submit a separate claim to MA organizations. This potential change would reduce MA dialysis costs without reducing services available to beneficiaries.

We request comment on the potential policy to exclude dialysis coverage from the MA basic benefit and provide coverage though OM as a means for reducing spending, while improving choice and competition.

I. Proposed Waivers of Medicare Program Requirements

1. Background

Section 1115A of the Act authorizes the Secretary to test innovative payment and delivery models that have the potential to reduce Medicare, Medicaid, or CHIP expenditures while preserving or enhancing the quality of care furnished to beneficiaries. Section 1115A(d)(1) further authorizes the Secretary to waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5) of such section) of the Act as may be necessary solely for purposes of carrying out section 1115A with respect to testing models described in section 1115A(b).

This section of the proposed rule details waivers necessary for testing the ADVaNCE MA model under the CMS Innovation Center's section 1115A authority. The ADVaNCE MA model proposes a restructuring of how quality performance is scored and associated payments are determined, how certain supplemental benefits are offered and targeted, how MA contracts are organized within Mandatory States to implement the ADVaNCE MA model test, and shadow testing of a new CMMI Inferred Risk Adjustment Model. These modifications are designed to improve the quality of care furnished to MA beneficiaries and reduce program expenditures.

These proposals require departures from existing statutory and regulatory requirements governing the MA program that would otherwise prohibit or constrain the proposed ADVaNCE

MA model design. Accordingly, we propose the waivers described in this section to the extent necessary to test the ADVaNCE MA model. All waivers described in this section will apply across the model test as described in section VIII.C.2.

We seek comment on all aspects of the proposed waivers described, and on whether additional waivers would be necessary to test the ADVaNCE MA model as proposed.

2. Waivers to Support ADVaNCE MA Model Contract Structure

Sections 1855, 1856, and 1857 of the Act establish organizational, contractual, and compliance requirements that MA organizations must meet to enter and maintain a contract with CMS. These requirements are further implemented through 42 CFR Part 422.

As described earlier in section VIII.D of this proposed rule, the ADVaNCE MA model restructures how eligible MA plans are organized under contracts with CMS, separating D-SNPs and non-D-SNPs operating in Mandatory States into distinct, State-specific ADVaNCE MA model contracts. Specifically, as proposed in § 516.150(c)(2), CMS would split contract numbers of existing MA contracts that meet the criteria proposed at § 516.150(c)(1) and offer one or more eligible plans, as defined at proposed § 516.100(b)(1) within a Mandatory State. Existing MA contract numbers meeting the criteria for determining contract split eligibility would be split in a manner that meets the requirements proposed § 516.150(b)(1):

● General *Enrollment cohort contracts*: State-specific ADVaNCE MA contracts that would contain only eligible plans, as defined in proposed § 516.100(b)(1)(i) through (iv), whose service areas fall entirely within a single Mandatory State; and

● D-*SNP cohort contracts*: State-specific ADVaNCE MA contracts that would contain only D-SNP plans, as defined in proposed § 516.100(b)(1)(v), whose service areas fall entirely within a single Mandatory State, subject to the requirements in proposed § 516.100(c).

As proposed at § 516.150(c)(2), existing MA contracts meeting the criteria proposed at § 516.150(c)(1), would be restructured by CMS rather than through the MA organization's standard application process; meaning applicable MA organizations would not have to submit

any application materials to effectuate these changes. To implement these changes, CMS would carry out a series of administrative operations on behalf of affected MA organizations, including establishing the new contract numbers as applicable and pre-populating with the appropriate contract service area data. Applicable MA organizations are encouraged to review previews of restructured contracts, as proposed at § 516.150(d)(1), prior to the contract application deadline. Following CMS' contract split process, MA organizations remain responsible for creating plan structures and completing and submitting PBP and Bid Pricing Tool information for those plans in accordance with applicable MA and Part D deadlines, including the bid submission deadline. The existing MA contracting framework, including the formal application submission requirements at 42 CFR 422.501 and 423.502, provides for the creation of contracts through MA organization-initiated processes. The waivers proposed in this section are necessary to implement the model's required contract restructuring proposed in § 516.150 and to ensure that the resulting ADVaNCE MA model contracts can be established and operated throughout the ADVaNCE MA model performance period without undue administrative burden for both ADVaNCE MA model participants and CMS.

a. Waivers supporting contract restructure process

(1) Waivers of Notice of Intent to Apply and contract application requirements.

CMS regulations at 42 CFR 422.501(b) and (c), 42 CFR 422.503(b), and 42 CFR 423.502(b) require that MA and Part D contracts complete a Notice of Intent to Apply (NOIA) by the date established by CMS prior to the submission of an application. Since the proposed process for the ADVaNCE MA model at § 516.150(c)(2) would establish new contract numbers that are derived from existing contracts, a waiver of NOIA provisions is necessary for CMS to carry out the restructuring operations on behalf of applicable MA organizations.

At § 516.600(a) we propose to waive 42 CFR 422.501(b) and (c), 42 CFR 422.503(b)(1), 42 CFR 423.502(b), and, to the extent applicable, accompanying Part D regulations under 42 CFR 423, to the extent necessary to permit CMS to carry out the contract

restructuring described in § 516.150 for existing MA contracts without requiring formal completion of a NOIA. MA organizations retain responsibility for completing bid submissions for all new and modified contracts in accordance with applicable deadlines under 42 CFR 422.254. All other requirements of 42 CFR 422.501, 42 CFR 422.503, and 42 CFR 423.502 remain in full force and effect.

(2) Considerations related to D-SNP contract structure – State Medicaid Contracts

If finalized as proposed, the ADVaNCE MA model would require that each existing contract containing eligible D-SNPs and non-D-SNPs with service areas in a Mandatory State be housed in separate ADVaNCE MA model contracts so that each contract can be assigned to the General Enrollment cohort or D-SNP cohort for purposes of the ADVaNCE MA Diamond Ratings system.

Section 42 CFR 422.107(e) provides certain processes by which CMS facilitates the operationalization of establishing D-SNP only contracts for a State Medicaid Agency, that through its SMAC, requires D-SNPs with exclusively aligned enrollment to be offered under contracts that only include one or more D-SNPs and to use required materials that integrate Medicare and Medicaid content. This authority is State-initiated, and its scope is limited to D-SNPs with exclusively aligned enrollment.

The proposed ADVaNCE MA model contract restructuring process would create D-SNP only contracts within Mandatory States, without regard to whether the D-SNPs have exclusively aligned enrollment or whether the State requires such contracts to be offered in D-SNP only contracts or to use integrated materials. Because § 422.107(e) only applies when States elect to invoke it, the processes and requirements of § 422.107(e) would not generally apply to D-SNP only contracts created by CMS under the ADVaNCE MA model contract restructuring process unless a Mandatory State elects to invoke § 422.107(e) for D-SNPs with exclusively aligned enrollment.

(3) Enrollment transitions

If finalized as described in section VIII.D.4.b and proposed in § 516.150(c)(2), CMS would restructure existing MA contracts that meet the criteria proposed at § 516.150(c)(1) in accordance with the requirements proposed in § 516.150(b). The model-specific restructuring is CMS-initiated and does not fall within sections 1851(c)(3)(B) and 1851(e) of the Act or any existing 42 CFR 422.530 crosswalk authority, which governs MA organization-initiated crosswalks in specified circumstances. Therefore, at § 516.600(c), we propose to waive 42 CFR 422.530(a)(1) and (2) and 42 CFR 422.530(b) to the extent necessary to allow MA organizations to crosswalk beneficiaries residing in Mandatory States to eligible plans in new ADVaNCE MA model contracts as part of the restructuring described in section VIII.D.4.b and proposed in § 516.150 of this proposed rule. This waiver only seeks to support the enrollment crosswalk proposed at § 516.150(d)(2) and does not authorize MA organizations to initiate crosswalks outside the scope of existing 42 CFR 422.530 requirements or the underlying statutory authority codified in sections 1851(c)(3)(B), 1856(b)(1), and 1857(e)(1) of the Act. All applicable beneficiary notification and opt-out protections remain in effect, and all other requirements of sections 1851, 1856, and 1857 of the Act and 42 CFR 422.530 remain in full force and effect.

b. Waivers and other considerations supporting operational compliance for new ADVaNCE MA Model Contracts

(1) Total Beneficiary Cost

A plan's Total Beneficiary Cost (TBC) is a metric calculated by summing the plan-specific part B premium, plan premium, and estimated beneficiary out-of-pocket costs. The change in TBC from one year to the next captures the combined financial impact of premium changes and benefit design changes in the PBP on plan enrollees. An increase in TBC is indicative of an increase in beneficiary costs or a reduction in benefits. CMS uses the TBC metric to evaluate whether an MA organization's bid proposes significant increases in cost

sharing or decreases in benefits offered under the plan, in which case CMS has authority to deny the bid under section 1854(a)(5)(C)(ii) of the Act. This approach not only keeps MA plan cost sharing and benefit designs stable, but also ensures enrollees have access to viable and sustainable MA plan offerings.

At § 516.150(e)(1), we propose that MA plans in the ADVaNCE MA model would be treated as new plans for purposes of TBC threshold requirements during bid submission in 2028 for contract year 2029. New plans are excluded from the TBC analysis for their first year of operation to allow the plan to establish a baseline bid. Additionally, plans participating in the ADVaNCE MA model would be subject to the regular TBC evaluation criteria during bid submission in 2029 for contract year 2030, consistent with the process applicable to new plans, which applies TBC evaluation criteria to plans in their second year of operation. TBC is an important tool for CMS to regulate plans and protect beneficiaries. However, due to the significant changes proposed by the ADVaNCE MA model to pilot fundamental reforms in quality and supplemental benefits, we find it appropriate to treat plans in the ADVaNCE MA model like new plans for purposes of the TBC evaluation for CY 2029. This will ease operational burden and benefit design complexity for plans and avoid the intricacies associated with accurately capturing and incorporating the full range of model effects into TBC calculations. We expect that competitive market dynamics would discourage ADVaNCE MA model participants from significantly increasing cost sharing or reducing benefit availability. Furthermore, the TBC evaluation to be applied in CY 2030 of the ADVaNCE MA model provides a strong incentive for ADVaNCE MA model participants to maintain stable cost sharing and benefit design in contract year 2029, serving as a natural guardrail. Notably, D-SNP bids in the ADVaNCE MA model, like other D-SNPs, will continue to be excluded from TBC requirements, as the PBP data used in the TBC calculation does not capture the Medicaid component of a complete D-SNP benefit package.

We considered applying TBC requirements for ADVaNCE MA model participants in contract year 2029 without treating plans in the model as new plans, but, while this has the operational convenience of continuity, it would not incorporate the numerous changes proposed by the ADVaNCE MA model, many of which would likely affect the calculation of TBC. Thus, such an approach would not accurately encapsulate an ADVaNCE MA model benefit configuration. Additionally, we considered incorporating a range of factors relevant to the model into the TBC calculation itself. However, it would be operationally complex to do so accurately and comprehensively.

We propose to treat plans in the ADVaNCE MA model as new plans for purposes of TBC threshold requirements for contract year 2029 only.

We seek comment on our proposal to treat plans in the ADVaNCE MA model as new plans for purposes of TBC threshold requirements in contract year 2029 considering the significant changes expected from implementation of the model. Furthermore, we seek comment on alternative options to address the TBC requirement in the ADVaNCE MA model.

(2) Pre-rulemaking Process

Section 1890A(a) of the Act establishes a pre-rulemaking measure review process for the selection of quality and efficiency measures. At § 516.600(e)(1), we propose to waive section 1890A(a) of the Act to the extent necessary to allow CMS to add new or substantively updated measures that are specific to the Diamond Ratings system as set forth at § 516.205(b)(2)(iv) and § 516.205(b)(3)(ii) without applying the pre-rulemaking measure review process. We believe waiving the pre-rulemaking measure review process codified at section 1890A(a) of the Act is necessary given the ADVaNCE MA model's condensed timeframe. Since the pre-rulemaking process delays the adoption of measures beyond the standard NPRM timeline, and we want to preserve the ability to adopt new measures in the Diamond Ratings system as soon as possible to provide adequate time for impact and evaluation, it is not feasible to include the pre-rulemaking measure review process for new

measures to be added to the Diamond Ratings system. Furthermore, we believe that proposing new measures through notice-and-comment rulemaking alone provides sufficient notice and opportunity for public input. CMS recognizes that the pre-rulemaking process provides an opportunity to solicit and consider stakeholder input on potential measures. However, we also believe that gathering stakeholder input through notice-and-comment rulemaking alone is the right approach to be responsive, allowing us to effectuate new quality measures as quickly as possible and make quality metrics more efficient and applicable. As proposed at § 516.600(e)(2), all other provisions under section 1890A remain in full force and effect.

(3) Minimum Reporting

CMS regulations at 42 CFR 422.152(b)(5) and 423.156 currently require MA organizations to meet a minimum enrollment threshold requirement of 600 or more enrollees in July of the prior year to conduct the CAHPS survey.

At § 516.600(f), we propose to waive the minimum enrollment threshold requirement for conducting the CAHPS survey under 42 CFR 422.152(b)(5) and 423.156 for MA contracts participating in the ADVaNCE MA model for the duration of their participation, beginning with contract year 2029. The ADVaNCE MA model participants would still be required to contract with approved CAHPS survey vendors and conduct the CAHPS survey and submit the survey data to CMS as codified in 42 CFR 422.152(b). To clarify, HOS and HEDIS measures do not have minimum enrollment requirements that are enumerated in the Code of Federal Regulations and so are not included in this proposed waiver. We believe this waiver is necessary as in the ADVaNCE MA model, quality measure scores will be aggregated and reported at the parent organization, State, and cohort levels rather than at the individual contract level. As a result, the minimum enrollment threshold — which exists to ensure statistical reliability of contract-level scores — is no longer applicable under the model's “rolled-up” reporting methodology as proposed in § 516.215(d). Because individual contract-level reporting is replaced by this aggregated approach, applying the threshold would impose an unnecessary and duplicative

burden on participating contracts without producing meaningful quality data. We, therefore, propose to waive the minimum enrollment threshold requirement for conducting the CAHPS survey under 42 CFR 422.152(b)(5) and 423.156 . All other requirements of 42 CFR 422.152 remain in full force and effect unless otherwise specified in this proposed rule.

We seek comment on this proposed waiver, including whether any alternative minimum reporting standards should apply to contracts participating in the ADVaNCE MA model.

(4) Network Adequacy

Consistent with the requirements in section 1852(d)(1) of the Act, 42 CFR 422.116 provides network adequacy rules that MA organizations must adhere to, including specific standards regarding access and a minimum number of available providers. As described in section VIII.D.4.a of this proposed rule, ADVaNCE MA model contracts would be State-bound. This means that CMS assumes that the provider contracts in place will transfer to the new contracts, if applicable. CMS will rely on the most recent provider network adequacy review for the model-specific contracts. CMS will rely on the most recent provider network adequacy review for the model-specific contracts.

At § 516.600(g), we propose to waive 42 CFR 422.116 to the extent necessary to account for possible changes to network adequacy within the model-specific contracts as a result of changes to contract service areas to reflect the State-bound service area requirements of the model. The § 516.600(g) waiver would allow the new model-specific contracts to rely on their predecessor contract’s provider network for purposes of the CY 2029 bid submission, provided that the service area of the new contract consists of the Mandatory State counties drawn from the predecessor contract's service area, and the provider network of the new contract consists of the providers in the predecessor contract's network that serve those counties. CMS will continue to conduct triennial network adequacy reviews and network adequacy reviews after triggering events for new ADVaNCE MA model contracts consistent with existing requirements following the assignment of new contract numbers. While these new contracts

may receive new contract numbers, for the purpose of network adequacy reviews they would be treated operationally as if they are existing contracts, as proposed at § 516.150(e)(2). We note that for both model and non-model contracts, the network adequacy exception provision at 42 CFR 422.116(f) would be available for contracts that qualify. More specifically, an MA plan may request an exception to network adequacy criteria in paragraphs (b) through (e) of 42 CFR 422.116 if it meets the criteria in 42 CFR 422.116(f)(1)(i).

(5) Star Ratings-based Contract Termination

42 CFR 422.510(a)(4)(xi) provides for the termination of MA contracts that achieve a Part C summary rating of less than three stars for three consecutive years. 42 CFR 423.509(a)(4)(x) imposes the same requirement for Part D contracts achieving a Part D summary rating of less than three stars for three consecutive years. The ADVaNCE MA model does not utilize the Star Ratings system as a basis for evaluating or terminating participating contracts.

Therefore, at § 516.600(h) we propose to waive sections 42 CFR 422.510(a)(4)(xi) and 42 CFR 423.509(a)(4)(x) for all contracts participating in the ADVaNCE MA model only to the extent necessary to carry out contract terminations for the Diamond Ratings system rather than for the Star Ratings system. To do so, CMS would apply Diamond Ratings system standards to evaluate participating contracts in lieu of the Star Ratings system. All other grounds for contract termination under 42 CFR 422.510 and 42 CFR 423.509 would remain in full force and effect.

3. Waiver of Quality Bonus Payment Requirements

The ADVaNCE MA model replaces the existing Star Ratings with the Diamond Ratings system, a redesigned quality measurement and payment framework described in section VIII.F of this proposed rule (Quality/Diamond Rating section). Two categories of existing statutory and regulatory provisions would otherwise prevent CMS from implementing the Diamond Ratings system: provisions governing how quality is measured and provisions governing the payment structure tied to that measurement.

a. Quality Rating System and Measurement Methodology

The existing quality framework for MA and Part D plans establishes specific requirements for how quality is measured, how scores are calculated, and how ratings are displayed. Section 1853(o)(4) of the Act requires that quality ratings be determined according to a five-star rating system. Section 1853(o)(1) directs that quality bonus payment increases be applied at the plan or contract level. The implementing regulations at 42 CFR 422.162(b) and 42 CFR 423.182(b) establish contract-level quality ratings for Part C and Part D, respectively. The regulations at 42 CFR 422.164 and 423.184 govern the process for adding, updating, and removing measures. The regulations at 42 CFR 422.166 and 423.186 further govern the full calculation methodology, including the clustering algorithm for non-CAHPS measure scoring, the relative distribution and significance testing methodology for CAHPS measures, domain and summary ratings, measure weighting, the CAI, and the calculation of overall and summary Star Ratings for both Part C and Part D.

The ADVaNCE MA Diamond Ratings system would replace the five-star, contract-level rating framework with a more continuous scoring methodology evaluated at the parent organization level in each applicable State within cohorts defined by plan type, as described in section VIII.F of this proposed rule (Quality/Diamond Rating section). Implementing this framework requires a departure from the existing Star Ratings system, measure management process, and calculation methodology as codified in §§ 422.162, 422.164, 422.166, 423.182, 423.184, and 423.186.

Therefore, at § 516.600(i), we propose to waive sections 1853(o)(4) and 1853(o)(1) of the Act and 42 CFR 422.162(b)(1), 422.162(b)(2), 422.162(b)(4), 422.164(f)(3), 422.164(f)(4)(v)-(vi), 422.166(a)(1)-(a)(2)(ii), 422.166(a)(4), 422.166(b)-(c), 422.166(d)(1), 422.166(d)(2)(i), 422.166(d)(2)(iii)-(d)(2)(vi), 422.166(e)-(h), 423.182, 423.184, 423.186(a)(1)-(a)(2)(ii), 423.186(b)-(c), 423.186(d)(1), 423.186(d)(2)(i), 423.186(d)(2)(iii)-(d)(2)(iv), and 423.186(e)-(h) to the extent necessary to implement the ADVaNCE MA Diamond Ratings

system's continuous scoring methodology, parent organization-level quality assessment, cohort-based comparisons, independent measure management process, and rating of quality based on Diamonds rather than Stars, as described in section VIII.F. of this proposed rule (Quality/Diamond Rating section). All other requirements of the aforementioned statutes and regulations, except as otherwise stated in this proposed rule, remain in full force and effect.

b. Quality Bonus Payment Structure

The existing quality payment structure links financial incentives to discrete Star Ratings thresholds in ways that would constrain the ADVaNCE MA model's ability to implement a more continuous performance payment framework. For ADVaNCE MA model participants in Mandatory States, the ADVaNCE MA Diamond Ratings system replaces the Star Ratings-based quality payment framework. Two specific features of the existing structure are incompatible with this replacement: the binary four-star qualifying threshold and its application to ADVaNCE MA model contracts and the linkage of rebate percentages to specific Star Rating values.

(1) Binary Four-Star Qualifying Threshold for Quality Payment and Treatment of New Contracts

Section 1853(o)(3)(A)(i) of the Act limits quality bonus payment to plans with a quality rating of four stars or higher. This creates a payment threshold that results in large, discontinuous payment changes near that threshold. Therefore, we propose in § 516.600(j), to waive sections 1853(o)(1), 1853(o)(2), 1853(o)(3)(A), and 1854(b)(1)(C)(iii), (v) and (vi) of the Act and 42 CFR 422.258(d)(7) and 422.266(a) to the extent necessary to implement the Diamond Ratings system's payment structure as proposed in § 516.200.

To do so, at § 516.600(j)(1), we propose to replace the binary four-star qualifying plan threshold, codified under sections 1853(o)(1) and 1853(o)(3)(A)(i) of the Act and 42 CFR 422.258(d)(7), the low enrollment exception at 1853(o)(3)(A)(ii) of the Act and §42 CFR 422.258(d)(7)(iv), and the reduced bonus structure for new plans under section

1853(o)(3)(A)(iii) of the Act and 42 CFR 422.258(d)(7)(v), with a continuous scoring scale (as proposed at § 516.215(d)(2)(iii)(B)). The first Diamond Ratings (CY 2031) would be calculated based on the applicable measurement period data and used for payment in CY 2032.

(2) Additional Quality Bonus for Qualifying Counties (the "double bonus")

Additionally, at § 516.600(j)(2), we propose to eliminate the additional bonus for qualifying counties (commonly known as the "double bonus") that would otherwise apply under section 1853(o)(2) of the Act and 42 CFR 422.258(d)(7)(ii)(B) for ADVaNCE MA model participants operating in qualifying counties within the Mandatory States framework as described in section VIII.D starting with CY 2029 QBPs. Research from Health Affairs and the CBO indicates that the double bonus has not produced measurable improvements in clinical or administrative plan quality, functioning instead as a geographic payment differential.[279,280] Additionally, the double bonus is assigned at the county level while the design of the ADVaNCE MA model is at the State level. In the ADVaNCE MA model, parent organizations are directly compared against each other in quality within a State. If a parent organization has more members in a double bonus county, it may unfairly advantage them against other parent organizations in the State when the Diamond Ratings begin. As such, eliminating the double bonus at model implementation provides a more fair on ramp into the Diamond Ratings system. It removes an administratively complex, geographical benchmark adjustment, simplifying the quality bonus framework and more directly aligning payment with quality-driven objectives. Furthermore, the difference in revenue between a five- and three-star plan could be greater than 10 percent after accounting for the benchmark bonus, double bonuses for certain counties, and differences in rebates among other factors. The ADVaNCE MA Diamond Ratings system would remove the double bonus and focus on a continuous, incremental scoring scale that

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[279] Congressional Budget Office, "Reduce Quality Bonus Payments to Medicare Advantage Plans," December 13, 2018. https://www.cbo.gov/budget-options/2018/54737.

[280] Andrew M. Ryan et al., "Association Between Double Bonuses and Clinical and Administrative Performance in Medicare Advantage," *JAMA Health Forum* 3, no. 9 (2022): e223301, https://doi.org/10.1001/jamahealthforum.2022.3301.

rewards all parent organizations of ADVaNCE MA model participants for even marginal quality improvements, promoting robust competition to achieve the highest possible Overall Diamond Rating.

CMS seeks comment on the proposed elimination of the double bonus. Specifically, CMS seeks input on whether elimination could be implemented on a later timeline to align when a plan's Diamond Rating first impacts the benchmark and bidding process (CY 2031), and what operational, contractual, or market considerations should inform that determination.

(3) Rebate Percentages Related to Star Ratings

Sections 1854(b)(1)(C)(iii), (v), and (vi) of the Act link rebate percentages to specific Star Rating values. These provisions would otherwise require that rebate percentages for ADVaNCE MA model participants be determined by Star Rating values rather than Diamond Ratings performance, creating a parallel Star Ratings-based payment structure inconsistent with the model's framework.

At § 516.600(j)(3), we propose to waive sections 1854(b)(1)(C)(iii), (v), and (vi) of Act and 42 CFR 422.266(a)(2) to the extent necessary to permit rebate percentage adjustments for ADVaNCE MA model participants to be based on ADVaNCE MA Diamond Ratings performance rather than Star Ratings values.

Therefore, we propose to waive sections 1853(o)(1), 1853(o)(2), 1853(o)(3)(A)(i), 1853(o)(3)(A)(ii), 1853(o)(3)(A)(iii), 1854(b)(1)(C)(iii), 1854(b)(1)(C)(v), and 1854(b)(1)(C)(vi) of the Act and 42 CFR 422.258(d)(7) and 42 CFR 422.266(a), to the extent necessary to implement the Diamond Ratings system's payment structure as described earlier in section VIII.F. of this proposed rule (Quality/Diamond Rating section). The waiver for 42 CFR 422.166(d)(2)(vi) is addressed in section VIII.H.3.a. of this proposed rule. All other requirements of those aforementioned provisions would remain in full force and effect, unless otherwise specified in this proposal.

(4) Categorical Adjustment Index (CAI)

Currently, one way the MA and Part D Star Ratings system accounts for differences in a contract's enrolled population, such as social risk factors, is by adjusting overall and summary MA and Part D Star Ratings using a Categorical Adjustment Index (CAI). We are instead proposing that the Diamond Ratings system would create group participants within the Mandatory States into either a General Enrollment cohort or a D-SNP cohort based on the contract type, which would serve as the adjustment method. MA organizations offering eligible MA plans in Mandatory States would be required to restructure existing contracts or create new contracts such that all included plan types would either be in a General Enrollment cohort or a D-SNP cohort with service areas limited to the single Mandatory State.

The proposed cohort structure of the performance scoring methodology in the ADVaNCE MA Diamond Ratings system would account for differences in enrollee populations and allow for separate assessment of quality outcomes and comparisons for General Enrollment and D-SNP populations. Our goal in proposing this cohort structure for the Diamond Ratings system is to further incentivize participating parent organizations to exert the full range of their influence and capabilities to deliver the highest quality care possible to their D-SNPs, and to be equally, but separately, accountable for the quality of their General Enrollment contracts.

The Diamond Ratings system aims to reduce disparities within quality bonus payments, improve quality performance among contracts with high-needs populations or those that are near the 4-Star threshold in Star Ratings, and to better account for different populations among D-SNP and General Enrollment contracts. To address these aims and the goals of the ADVaNCE MA model, we are proposing at § 516.600(j)(4) to waive the application of the CAI at 42 CFR 422.166(f) and 42 CFR 423.186(f). We acknowledge the CAI accounts specifically for LIS eligible beneficiaries and disability status where the Diamond Ratings system cohort structure does not. However, we believe the proposed cohort structure more thoroughly accounts for dual eligible beneficiaries who select D-SNP contracts for their care.

4. Other Cross References to Star Ratings

Under § 516.605, we propose that all other requirements for quality ratings and payments for the MA and Part D Star Ratings program, including QBP ratings, continue to apply, except as otherwise waived and where Star Ratings, quality ratings, rating systems, QBP ratings, benchmark increases to the applicable percentage for quality, and final applicable rebate percentages are referenced, the equivalent term for the Diamond Ratings system would be substituted, except as otherwise waived in this part. Under § 516.605(a), for references to Overall Star Ratings, ADVaNCE MA Overall Diamond Ratings would apply instead. For references to QBP ratings, ADVaNCE MA Overall Diamond Ratings would also apply instead. References to increases to the applicable percentage for quality to determine blended benchmark amounts would instead be replaced with increases to the applicable percentage for ADVaNCE MA. References to final applicable rebate percentages would instead be replaced with final applicable rebate percentages for ADVaNCE MA. For purposes of applying these requirements, CMS would convert ADVaNCE MA Overall Diamond Rating values to Star Ratings values using traditional rounding rules. For example, an ADVaNCE MA participant with four Diamonds would be viewed as having the equivalent of four Stars for the purposes of applying other requirements related to the MA and Part D Star Ratings program. An ADVaNCE MA participant with 3.8 Diamonds would be viewed as having the equivalent of four Stars for the purposes of applying other requirements related to the MA and Part D Star Ratings program.

Specifically, CMS would monitor the ongoing quality performance of MA organizations to track and identify those with consistently low performance. To reflect the specifics of the proposed Diamond Ratings system, we are proposing to waive 42 CFR 422.166(h)(1)(ii)(A) and 42 CFR 423.186(h)(1)(ii)(A) at § 516.605(b)(1) and provide instead that Medicare Plan Finder would mark ADVaNCE MA model participating MA organizations that are found to have an Overall Diamond Rating below 3.0 for three consecutive years with a low performing indicator. In the initial years of the model, prior to a contract being assigned three consecutive years of

Overall Diamond Ratings, we propose to use the contract's prior Star Ratings or a combination of the contract's prior Star Ratings and Diamond Ratings, as applicable. For example, in 2031 we would use the 2031 Diamond Rating (based on 2029 performance) and 2029 and 2030 Star Ratings to determine if a contract should be assigned a low performing icon. Notably, 42 CFR 422.166(h)(1)(ii)(B) and 42 CFR 423.186(h)(1)(B) would continue to apply to ADVaNCE MA model participants, which allows CMS to disable online enrollment in Medicare Plan Finder if a contract is labeled with a low performing icon in the ADVaNCE MA model.

Additionally, 42 CFR 422.66(c)(2)(i) establishes the conditions for default enrollment of an individual into an MA D-SNP, with one requirement being that the MA organization must have a minimum overall quality rating from the most recently issued ratings of at least three stars under the rating system described in 42 CFR 422.160 through 422.166 or qualify as a low-enrollment contract or new MA plan under 42 CFR 422.252. For the purposes of applying 42 CFR 422.66(c)(2)(i) to the Diamond Ratings system, under our proposal at § 516.605(b)(2), the requirement would be satisfied if the receiving plan has an ADVaNCE MA Overall Diamond Rating of at least three Diamonds. Where an ADVaNCE MA participant has not yet completed a full performance year, CMS would apply the display ratings as calculated under 516.200(b)(1) as the equivalent Star Ratings for purposes of this paragraph. Where neither an ADVaNCE MA Overall Diamond Rating nor a prior Star Rating is available, the alternative criteria for new MA contracts under 42 CFR 422.66(c)(2)(ii) would apply.

Finally, CMS regulations at 42 CFR 422.162(b)(3) establish how CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each consolidated MA-PD contract, and a Part C summary rating for each consolidated MA-only contract. Specifically, 42 CFR 422.162(b)(3)(i)-(iii) describe how CMS assigns QBP status for the first and second years following a contract consolidation, based on the enrollment-weighted mean of the QBP status of the surviving and consumed contract(s), as provided by 42 CFR 422.162(b)(3)(iv). To account for this during the post-implementation period, we propose to

waive 42 CFR 422.162(b)(3)(i)-(iii) at § 516.605(c)(1) to make it possible to operationalize our proposed § 516.230(d)(1).

This proposal would establish that, throughout the post-implementation period, the QBP related benchmark adjustment and rebate for a newly consolidated contract containing at least one prior model contract would be calculated as an enrollment weighted average of: (1) the QBP related benchmark adjustment and rebate percentage that would have been assigned to model contracts under the Diamond Ratings program; and (2) the QBP related benchmark adjustment and rebate percentage that would have been assigned to the non-model contracts as part of the Star Ratings program.

We believe this waiver is necessary because within the post-implementation period of the ADVaNCE MA model, a parent organization may consolidate previous model contracts with non-model contracts affected by the contract restructuring required under § 516.150. Therefore, because previous model contracts would have been assigned Diamond Ratings instead of Star Ratings in the post-implementation period, the process codified at 42 CFR 422.162(b)(3)(i)-(iii) would not apply to consolidated contracts consisting of model and non-model contracts.

Additionally, 42 CFR 422.162(b)(3)(iv) governs the calculation of the Star Ratings for consolidated contracts which are then posted on Medicare Plan Finder. As such, we propose at § 516.605(c)(2) to waive 42 CFR 422.162(b)(3)(iv) and instead propose at § 516.230(d)(2) to display the enrollment weighted average measure and Overall Star Ratings based on the consolidated contract's non-model contracts only.

We believe a waiver of this provision is necessary because Star Ratings and Diamond Ratings may be based on different measure sets by the end of the ADVaNCE MA model's performance period. Either through combining the Individual Measure Diamonds with Measure Stars, or the Overall Star Rating with the Overall Diamond Rating, using a similar enrollment weighted average would not give beneficiaries an accurate representation of the contract quality

because the underlying contracts may rely on different measure sets. Our proposal would provide a clearer view of a contract's quality performance under the Star Ratings program and would be easier to apply at the contract level.

We seek comment on our proposed waiver to accommodate possible contract consolidation of previous model contracts and non-model contracts by MA organizations in the post-implementation period of the ADVaNCE MA model.

5. Waivers Relating to Supplemental Benefits

Several existing statutory and regulatory provisions limit the availability of supplemental benefits in ways that would otherwise prevent the ADVaNCE MA model from testing the flexibilities described in section VIII.G. of this proposed rule relating to supplemental benefits.

Under current law, supplemental benefits offered within a plan must be provided uniformly to all enrollees. Section 42 CFR 422.100(d)(2)(i) requires that MA organizations offer plans at a uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area. An existing exception to this uniformity requirement is the SSBCI pathway, which is authorized by section 1852(a)(3)(D) of the Act and implemented at 42 CFR 422.102(f). These provisions authorize the Secretary to waive the uniformity requirement but only with respect to supplemental benefits provided to qualifying chronically ill enrollees as SSBCI, consistent with 1852(a)(3)(D)(ii)(II) and 42 CFR 422.102(f)(2)(ii).

Furthermore, consistent with section 1852(a)(3)(D) of the Act, § 422.100(c)(2)(ii)(A) permits MA organizations to offer non-primarily health related supplemental benefits only through SSBCI. To allow ADVaNCE MA model participants to target certain non-primarily health-related supplemental benefits to LIS-eligible individuals outside of SSBCI as described at § 516.300, we propose waiving sections 1852(a)(3)(A), 1852(a)(3)(D)(i) and (D)(ii)(I) of the Act and § 422.100(c)(2)(ii)(A) to the extent necessary to allow the offering of non-primarily health-related supplemental benefits other than as SSBCI.

Additionally, to allow ADVaNCE MA model participants to target the specified primarily and non-primarily health related supplemental benefits to LIS-eligible individuals, we propose waiving the uniformity provisions in sections 1852(a)(3)(D)(ii)(II), 1852(d)(1)(A), and 1854(c) of the Act and 42 CFR 422.2 (uniformity requirements in the definition of "MA plan"), 422.100(d)(2), 422.102(a)(2), 422.102(a)(6)(ii), 422.254(b)(2), 422.262(c)(1) to the extent necessary.

As discussed previously, our internal modeling and external literature[281] have identified the potential for cost savings and quality improvement from utilization of such interventions among low-income populations.

Therefore, as described at § 516.600(k), we propose to waive sections 1852(a)(3)(A), 1852(a)(3)(D)(i), 1852(a)(3)(D)(ii)(I), 1852(a)(3)(D)(ii)(II), 1852(d)(1)(A), and 1854(c) of the Act and §§ 422.2 (uniformity requirement in the definition of "MA plan"), 422.100(d)(2), 422.100(c)(2)(ii)(A), 422.102(a)(2), 422.102(a)(6)(ii), 422.254(b)(2), and 422.262(c)(1) to the extent necessary to permit ADVaNCE MA model participants to offer healthy food and produce, transportation for non-medical needs, and support for caregivers as supplemental benefits to LIS-eligible individuals as described in section VIII.G. of this proposed rule relating to supplemental benefits. These proposed waivers would remove the limitations that restrict non-uniform supplemental benefit targeting and the offering of non-primarily health related supplemental benefits to SSBCI, but do not modify the availability of SSBCI, which would continue to apply on its existing terms. All other requirements of those provisions remain in full force and effect.

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[281] Douglas McCarthy, Corinne Lewis, Celli Horstman, Alexandra Bryan, and Tanya Shah, ROI Calculator for Partnerships to Address the Social Determinants of Health: Guide to Evidence for Health-Related Social Needs Interventions: 2022 Update, The Commonwealth Fund (September 2022). https://www.commonwealthfund.org/sites/default/files/2022-09/ROI_calculator_evidence_review_2022_update_Sept_2022.pdf.

6. Risk Adjustment

As described in section VIII.E. of this proposed rule, the ADVaNCE MA model proposes to shadow test a CMMI inferred risk adjustment methodology in CY 2028. Because the risk scores generated from this new CMMI Inferred Risk Adjustment Model will not be used for payment purposes, the shadow test does not require CMS to depart from any existing statutory or regulatory requirements, and no waivers are necessary at this time. If CMS determines, following testing and validation, to use risk scores generated from this new model for payment or other purposes in future years, additional waivers or regulatory amendments may be necessary and would be proposed through rulemaking at that time.

We seek comment on the proposed waivers with regards to the ADVaNCE MA model and whether additional waivers would be necessary to test the model as proposed.

J. Other Provisions

1. Standard Provisions

a. Proposed beneficiary protections

ADVaNCE MA is designed as a mandatory model subject to the Standard Provisions for mandatory CMS Innovation Center models at 42 CFR Part 512, subpart A. If finalized as proposed, the ADVaNCE MA model would be the first mandatory CMS Innovation Center Model focused on Medicare Advantage. As such, new regulatory text may be necessary to adopt the standard provisions – including beneficiary protections at 42 CFR 512.120 – to be reflective of the unique authorities and requirements of the Medicare Advantage program. Therefore, at §516.610, we propose model-specific provisions governing beneficiary protections to the extent necessary to apply 42 CFR 512.120 to the ADVaNCE MA model.

The standard provisions at § 512.120 establish three core beneficiary protections. First, 42 CFR 512.120(a) requires model participants to preserve beneficiary freedom of choice. Next, 42 CFR 512.120(b) requires that model participants continue to make medically necessary covered services available to all beneficiaries and not selectively target relatively healthy

enrollees or avoid enrollees who are "at-risk," as defined at 42 CFR 425.20. Finally, among other requirements, 42 CFR 512.120(c) prohibits model participants from using or distributing descriptive model materials that are materially inaccurate or misleading.

The first protection at 42 CFR 512.120(a), beneficiary freedom of choice, , prohibits model participants from restricting beneficiaries' ability to receive care from any provider or supplier. To reflect the applicable requirements and flexibilities of the MA program, such as the ability for an MA organization to select the practitioners that participate in its plan provider networks, we propose at § 516.610 that ADVaNCE MA model participants may not restrict beneficiaries' ability to receive care from any provider, except as otherwise allowed under 42 CFR Part 422, which governs plan type, service area, network access, referrals, and coverage of out-of-network services.

Additionally, there are beneficiary freedom of choice protections for specific plan types in the ADVaNCE MA model. For example, under 42 CFR 422.114(b), MA private fee-for-service plans must permit enrollees to obtain services from any entity that is authorized to provide services under Medicare Part A and Part B and that agrees to provide services under the terms of the MA plan. Additionally, 42 CFR 422.112(a) describes how an MA coordinated care plan may specify the networks of providers where enrollees may access covered services; this must include all medically necessary services that are available and accessible under the plan as dictated by 42 CFR 422.116. Additionally, provider networks for special needs plans must meet the needs of the population served as outlined in 42 CF 422.112(a)(1)(i) and 42 CFR 422.101(f). Furthermore, beneficiaries enrolled in a PPO can receive care from any provider, regardless of network status, as mandated by 42 CFR 422.4(a)(1)(v). Given these collective protections, among others, that are applicable to MA organizations, we believe our proposal at § 516.610(b) to broadly apply the Standard Provisions for beneficiary freedom of choice, with some proposed modifications, is sufficient to protect beneficiaries' access to care while maintaining the

flexibilities, such as provider networks, available to MA organizations to meet cost and quality-related goals.

Next, 42 CFR 512.120(b) requires that model participants continue to make medically necessary covered services available to all beneficiaries and not selectively target relatively healthy enrollees or avoid enrollees who are "at-risk" as defined at 42 CFR 425.20. Beyond the protections set forth in 42 CFR 512.120, in order to ensure beneficiary protection specific to MA, we clarify that the broader Part 422 regulatory framework governing MA also continues to apply to participating contracts, except as expressly waived at proposed § 516.600 and further described at section VIII.H. of this proposed rule. Under 42 CFR 422.254(a)(5), an MA organization must offer its approved benefit package throughout the plan year. Accordingly, an MA organization is prohibited from making mid-year reductions in benefits in accordance with 42 CFR 422.254(a)(5). Furthermore, under 42 CFR 422.110, MA organizations are prohibited from denying, limiting, or conditioning the coverage or furnishing of benefits to beneficiaries on the basis of health status. These requirements would apply regardless of an ADVaNCE MA model participant's Diamond Ratings performance and reinforce the protections that 42 CFR 512.120 would provide in the mandatory ADVaNCE MA model context.

In considering the protections set forth in 42 CFR 512.120 and Part 422, proposed § 516.610 establishes a beneficiary protections framework for the ADVaNCE MA model, clarifying how the protections of both established regulations apply to the model. Specifically, § 516.610(b) tailors the application of 42 CFR 512.120(a)(1) to the extent that it is consistent with the requirements of Part 422 regarding governing plan type, service area, network access, referrals, and coverage of out-of-network services. We believe the protections set forth in in 42 CFR 512.120(b) are necessary for the ADVaNCE MA model. The ADVaNCE MA model's proposed payment structure under the Diamond Ratings system could theoretically financially incentivize participants to avoid enrollees who may negatively affect the participant's

ADVaNCE MA Overall Diamond Rating. However, the anti-cherry-picking and availability-of-services provisions at 42 CFR 512.120(b)(3) will directly address this risk by prohibiting such conduct for model participants and ensure beneficiary access. Furthermore, we believe that one technical clarification is warranted regarding appeal rights for MA enrollees, which we proposed in § 516.610(c). 42 CFR 512.120(b)(1) references 42 CFR part 405, subpart I, governing beneficiary appeal rights, which contains the regulations specific to coverage appeals involving OM. However, because beneficiaries enrolled in plans offered by contracts participating in the ADVaNCE MA model are MA enrollees, the applicable grievance and appeal rights are those specified in 42 CFR part 422, subpart M. Accordingly, we propose that, unless otherwise stated in this proposed rule, all rights under 42 CFR part 422, subpart M continue to apply and would not be modified by participation in the ADVaNCE MA model.

Finally, among other requirements, the Standard Provisions at 42 CFR 512.120(c) prohibit model participants from using or distributing descriptive model materials that are materially inaccurate or misleading. Similar protections exist in the MA program 42 CFR part 422, subpart V, among other protections, prohibits MA organizations from misleading, confusing, or providing materially inaccurate information (including model-related marketing and communication materials) to current or potential enrollees.

We believe that the application of 42 CFR 512.120(c) and 42 CFR part 422, subpart V would collectively ensure that ADVaNCE MA model participants operate within the existing protections given to beneficiaries. Therefore, we propose at § 516.610(d) to simply clarify that ADVaNCE MA model participants remain subject to these requirements.

We seek comment on the proposed adoption of 42 CFR 512.120 for the ADVaNCE MA model generally, as applied by the proposals set forth in proposed § 516.610, and on whether any model-specific protections beyond those provided in proposed § 516.610 would be appropriate or necessary given the existing protections at 42 CFR 512.120 and within 42 CFR part 422.

b. Cooperation in ADVaNCE MA Model Evaluation and Monitoring

The ADVaNCE MA model participants and their downstream participants would be required to comply with the requirements of 42 CFR 403.1110(b) and otherwise cooperate with CMS's ADVaNCE MA model evaluation and monitoring activities as may be necessary to enable CMS to evaluate the CMS Innovation Center model in accordance with section 1115A(b)(4) of the Act and to conduct monitoring activities under 42 CFR 512.150, including producing such data as may be required by CMS to evaluate or monitor the model, which may include protected health information as defined in 45 CFR 160.103 and other individually-identifiable data.

We seek comment on the proposed adoption of 42 CFR 512.150 for CMS evaluation of the ADVaNCE MA model.

c. Audits and record retention

We propose to adopt the audit, access, and record retention requirements set forth in 42 CFR 512.135(a), 512.135(b), and 512.135(c) for the ADVaNCE MA model. As applicable to all mandatory CMS Innovation Center models, 42 CFR 512.135(a) states that the Federal Government, including CMS, HHS, the Comptroller General, and their designees, has the right to inspect, investigate, and evaluate any documents and other evidence regarding implementation of an CMS Innovation Center model. As stated in 42 CFR 512.135(b), ADVaNCE MA model participants and downstream participants would be required to maintain and provide to the Federal Government access to any documents and other evidence regarding all items set forth in 42 CFR 512.135(b). As stated in 42 CFR 512.135(c), the ADVaNCE MA model participants and their downstream participants would be required to maintain documents and other evidence described in 42 CFR 512.135(b) for six years from the last payment determination or the date of completion of any audit, evaluation, inspection, or investigation, whichever is later. Furthermore, as stated in 42 CFR 422.504(d) and 422.504(e), ADVaNCE MA model participants would be required to maintain evidence of accounting procedures and

practices, and access to facilities and records. All other requirements described in 42 CFR 422.504 would continue to apply for ADVaNCE MA model participants as well. This retention period may be extended if CMS determines there is a special need to retain particular records, or if there has been a termination, dispute, or allegation of fraud or similar fault against the ADVaNCE MA model participant or a downstream participant. In such cases, the ADVaNCE MA model participant must notify its downstream participants of the need to retain records for an additional period specified by CMS.

We seek comment on the proposed adoption of 42 CFR 512.135(a), 512.135(b), and 512.135(c) dictating audit and record retention requirements, in addition to those applicable under 422.504, for ADVaNCE MA model participants.

d. Rights in Data and Intellectual Property.

We propose to apply 42 CFR 512.140 to the ADVaNCE MA model without modification. We are not proposing to create a separate ADVaNCE MA-specific intellectual property regime. CMS would be able to use and disseminate de-identified ADVaNCE MA model results and techniques consistent with 42 CFR 512.140(a). At the same time, ADVaNCE MA model participants and downstream participants that submit materials they believe to contain proprietary or confidential information, including actuarial memoranda, internal pricing support, or vendor-developed tools, would be required to label or otherwise identify those materials appropriately, subject to CMS review and confirmation under 42 CFR 512.140(b) and (c).

We seek comment on the proposed adoption of 42 CFR 512.140(a), 512.140(b), and 512.140(c) for the ADVaNCE MA model regarding intellectual property and processes for materials containing proprietary or confidential information.

e. Monitoring and compliance

ADVaNCE MA model participants and downstream participants would be subject to the monitoring and remedial action requirements applicable to all CMS Innovation Center models

under 42 CFR 512.150, which establishes the general framework for monitoring and compliance with certain proposed modifications at § 516.615. Under the ADVaNCE MA model, all ADVaNCE MA model participants would be required to comply with applicable law and regulations under 42 CFR 512.150(a). The following describes how CMS would apply and supplement those requirements in the context of the ADVaNCE MA model.

The CMS Innovation Center would conduct robust monitoring of ADVaNCE MA model participants and downstream participants to ensure compliance with ADVaNCE MA model requirements in the proposed ADVaNCE MA model areas of payment adjustments tied to quality performance and supplemental benefits.

ADVaNCE MA model participants and downstream participants would be subject to CMS monitoring with respect to the model-specific risk adjustment policies tested under the model. Under the model, CMS would shadow-test a risk adjustment approach that uses comprehensive data, new technological and statistical methodologies, and a clinical and inferential framework to better assess beneficiary risk. CMS would monitor the development, implementation, and operation of the model-specific risk adjustment methodology to assess whether it is operating consistently within ADVaNCE MA model requirements. CMS would use data submitted by ADVaNCE MA model participants, OM claims data, enrollment data, and other information necessary to administer and evaluate the model.

Additionally, unless otherwise stated in this proposed rule, the existing requirements and enforcement authorities contained in 42 CFR part 422 would be available to CMS and remain applicable to all ADVaNCE MA model participants.

For the monitoring of quality performance, as outlined in 42 CFR 422.164(g), CMS has established data integrity standards that allow for the reduction of measure ratings when data are determined to be inaccurate, incomplete, or biased. This authority extends to various compliance monitoring activities, including validation of submitted data against established

thresholds, with scaled reductions applied when data completeness or accuracy falls below acceptable standards. For example, as specified in 42 CFR 422.164(g)(1)(iii), CMS uses statistical criteria to estimate missing data percentages and applies scaled reductions to Star Ratings for applicable measures to account for data incompleteness. These compliance monitoring activities are crucial for the ADVaNCE MA model test as they ensure the integrity of the evaluation results and protect against inappropriate processing or incorrect practices.

ADVaNCE MA model participants would be subject to CMS monitoring with respect to the model-specific quality bonus payment benchmark adjustment and rebate percentage policies proposed under the model. CMS would adjust the quality bonus payment benchmark and rebate percentage applicable to participating plans based on their Overall Diamond Rating. Pursuant to 42 CFR 422.504(f), MA organizations are required to submit to CMS all information necessary for CMS to administer and evaluate the Medicare Advantage program, including information necessary to support payment calculations, bid review, quality measurement, and ADVaNCE MA model evaluation. This existing authority provides the regulatory basis for CMS to monitor ADVaNCE MA model participants' compliance with model-specific payment adjustment requirements.

If finalized, CMS would monitor ADVaNCE MA model participants' bid submissions, payment-related data, quality data, and rebate calculations to ensure that the applicable quality bonus payment benchmark adjustment and rebate percentage are determined and applied in accordance with the sliding-scale methodology established under the model. CMS would review whether participating plans' Overall Diamond Ratings are accurately reflected in the corresponding quality bonus payment benchmark adjustment and rebate percentage and whether ADVaNCE MA model participants appropriately incorporate those adjustments in bid pricing, rebate allocation, and related submissions.

As specified in 42 CFR 422.164(b), CMS reviews the quality of data on which performance, scoring, and rating are based, including examination of variation in scores among

MA organizations, and assessment of accuracy, reliability, and validity of measures before making final determinations about inclusion of measures in each year's Star Ratings. As such, CMS would also monitor the accuracy, completeness, and reliability of data used to determine Overall Diamond Ratings and associated payment adjustments. This monitoring may include review of bid pricing data and rebate calculations, and assessment of whether ADVaNCE MA model participants have submitted information necessary for CMS to administer and evaluate the model. CMS would exercise its authority under 42 CFR 422.256, 42 CFR 422.310, and 42 CFR 422.504(f) to collect and review the minimum data necessary to monitor compliance with model-specific payment adjustment requirements, while adhering to applicable Federal laws, CMS data sharing procedures, and beneficiary confidentiality protections.

If CMS identifies noncompliance with model-specific requirements for determining or applying quality bonus payment benchmark adjustments, rebate percentages, or related payment calculations, CMS retains the authority to take remedial action under 42 CFR 512.160, including the imposition of sanctions, corrective action plans, or other measures as appropriate.

ADVaNCE MA model participants would also be subject to CMS monitoring with respect to the flexibilities in supplemental benefits available under the model. These flexibilities include: (1) the ability to target healthy food and produce benefits to LIS-eligible individuals; (2) the ability to target transportation benefits for non-medical needs to LIS-eligible individuals; and (3) the ability to target caregiver support supplemental benefits to LIS-eligible individuals. As discussed, we propose to use our authority at 42 CFR 512.150(b) to propose at § 516.300(b)(5) that ADVaNCE MA model participants submit data to CMS annually on the utilization and costs of supplemental benefits targeted to LIS-eligible individuals under the ADVaNCE MA model, waiving the Part C Reporting Requirements at § 516.600(l)(1) to the extent necessary to permit this. We believe that, since VBID benefits were excluded from the Part C Reporting Requirements, it is important to follow that precedent for operational

simplicity.[282] These requirements would be at the plan benefit package level and beneficiary level and align in format with the existing Part C Reporting Requirements set forth in 42 CFR 422.516, to the extent feasible. We propose to collect these beneficiary-level data, in addition to PBP-level data, since beneficiary-level data would better enable us to evaluate the quality and cost impacts of LIS-targeting supplemental benefits relative to PBP-level data alone.

CMS would review the data submitted by ADVaNCE MA model participants relating to the utilization of ADVaNCE MA model flexibilities, including examination of variation in utilization patterns among MA organizations and assess of the accuracy, reliability, and validity of the reported information. This review would allow CMS to monitor whether ADVaNCE MA model participants are offering flexible benefits in accordance with ADVaNCE MA model requirements and to assess the impact of these benefits on beneficiary outcomes and program costs.

CMS would capture data similar to that collected through the Part C Reporting Requirements, and monitor other available data to evaluate to what extent ADVaNCE MA model participants are targeting supplemental benefits to LIS-eligible individuals consistent with the eligibility requirements established under the model.[283,284,285] CMS would additionally monitor to what extent ADVaNCE MA model participants elect to administer caregiver support supplemental benefits only to beneficiaries who meet the model's LIS eligibility criteria, rather than as an SSBCI or uniformly offered primarily health-related supplemental benefit.

CMS would monitor whether ADVaNCE MA model participants are administering these flexibilities in a manner consistent with the model's goals of improving care quality,

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[282] Centers for Medicare & Medicaid Services, Frequently Asked Questions - Contract Year 2025 Part C Reporting Requirements - Supplemental Benefit Utilization and Costs Section, last modified May 2025, https://www.cms.gov/files/document/cy-2025-part-c-supplemental-benefit-utilization-and-costs-faq.pdf.
[283] HPMS Memorandum; Submission of Supplemental Benefits Data on Medicare Advantage Encounter Data Records; February 21, 2024; available at https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly.
[284] HPMS Memorandum; Encounter Data Software Release Updates; February 23, 2024; available at https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly.
[285] HPMS Memorandum; of Supplemental Benefits Data on Medicare Advantage Encounter Data Records – Reminders, Other Supplemental Service Updates, and FAQs; November 12, 2024; available at https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly.

promoting prevention, and enabling beneficiaries to remain in the community. ADVaNCE MA model participants offering supplemental benefits must comply with the model's requirements and with all applicable laws and regulations. Where CMS identifies noncompliance with model-specific flexibility requirements, CMS would retain the authority to take remedial action under 42 CFR 512.160, including the imposition of sanctions, corrective action plans, or other measures as appropriate.

The CMS Innovation Center would be responsible for evaluating each ADVaNCE MA model contract tested under section 1115A of the Act, fulfilling our statutory mandate to assess innovative payment and service delivery models. This evaluation includes comprehensive analysis of the quality of care furnished to beneficiaries and changes in program spending attributable to ADVaNCE MA model implementation. The evaluation would examine multiple dimensions including quality performance and the impact of supplemental benefits on beneficiary outcomes and program costs.

If finalized, ADVaNCE MA model participants must comply with the requirements of 42 CFR 403.1110(b) and cooperate fully with CMS' ADVaNCE MA model evaluation activities. This cooperation would include responding to evaluation surveys, participating in focus groups, and providing requested documentation related to quality improvement initiatives, supplemental benefit offerings, and risk adjustment. Monitoring activities would include obtaining data required by CMS, which may include protected health information as permitted by applicable law. Participation in the evaluation may also include submitting to site visits and interviews with key personnel responsible for ADVaNCE MA model implementation. In conducting monitoring and oversight activities, CMS or its designees would be able to use any relevant data or information including, without limitation, all encounter data for Medicare claims submitted to MA organizations for items or services furnished to beneficiaries.

At § 516.615(a), we propose to apply 42 CFR 512.150 to the ADVaNCE MA model in its entirety with one limited modification. Under 42 CFR 512.150(d)(1), an ADVaNCE MA

model participant may ordinarily request reopening of a model-specific payment determination within four years for good cause. Because we are proposing a separate, narrow, and exclusive error notice and reconsideration review process for identified payment-related issues in **§** 516.622, we do not believe participant-requested reopenings under 42 CFR 512.150(d) are necessary as an alternative review path. We therefore propose at § 516.615(b) that participant-requested reopenings would not be available in the ADVaNCE MA model, except as expressly provided in proposed § 516.622(a), while preserving CMS's authority to reopen payment determinations on its own motion under 42 CFR 512.150(d)(1) and at any time in cases involving fraud or similar fault under 42 CFR 512.150(d)(2), as proposed at § 516.615(c).

We seek comment on the proposed monitoring and compliance framework, including the proposed modifications to 42 CFR 512.150 at § 516.615 and the proposed exclusion of participant-requested reopenings in favor of the reconsideration review process at § 516.622.

f. Remedial Action

At § 516.621(a), we propose that the standard provisions and requirements of the remedial action framework at 42 CFR 512.160 would apply to the ADVaNCE MA model and its participants. We believe that this framework is sufficient for the ADVaNCE MA model and are therefore not proposing a separate model-specific remedial action framework. In the context of the ADVaNCE MA model, remedial action would be appropriate in the case that a participant or downstream entity fails to comply with ADVaNCE MA model requirements, including requirements related to contract restructuring, bid submission and supporting documentation, benchmarks, quality reporting, supplemental benefit flexibilities, data sharing, reconciliation, or otherwise fails to comply with applicable Medicare requirements.

Significantly, removal of a model participant from the ADVaNCE MA model does not occur as a remedial action under 42 CFR 512.160(b), which describes the remedial actions that CMS may take if it is determined that one or more grounds for remedial action occur based on 42 CFR 512.160(a) outside of 42 CFR 512.160(b)(6). Instead, we propose that termination from

participation in the ADVaNCE MA model can occur through two avenues. First, the ADVaNCE MA model could be terminated in its entirety under specified circumstances, as allowed by 42 CFR 512.165. Possible reasons for model termination include, but are not limited to, budget neutrality concerns under section 1115A(b)(3)(B) of the Act, among others. As outlined in 42 CFR 512.165(b), if CMS terminates the ADVaNCE MA model, CMS would provide written notice to the ADVaNCE MA model participant specifying the grounds for model termination and the effective date of such termination.

Second, as proposed at § 516.623, an MA contract under an ADVaNCE MA model participant could be terminated under specified circumstances. The proposed § 516.623(c) through (f) adopts specific provisions of 42 CFR 422.510 regarding corrective action plans, notice of intent to terminate, appeal rights, immediate termination, and immediate sanctions, if applicable. As proposed at § 516.623(b)(1), termination of an ADVaNCE MA contract under § 516.623(a) does not automatically terminate the ADVaNCE MA model participant's participation in the ADVaNCE MA model, except if the ADVaNCE MA model participant holds only one ADVaNCE MA contract.

Therefore, as proposed at § 516.621(b), the existing requirements and enforcement authorities contained in 42 CFR part 422, Subpart K, including application procedures, contract provisions, nonrenewal, and termination, are available to CMS and remain applicable to all ADVaNCE MA model participants unless otherwise specified at § 516.623(a).

We acknowledge that this does not allow CMS to terminate an ADVaNCE MA model participant on any other grounds, but we believe this termination scope aligns with the design and integrity of the model. It would allow the model to avoid disruptions from potential terminable behavior that would trigger other grounds for termination not stated here, preserving the intention of the model to adequately test changes to MA payment, quality incentives, and risk adjustment that are intended to operate across local markets and, therefore, require broad participation within select geographic areas. Considering the mandatory nature of the model,

maximizing participation throughout the entirety of the model is essential for a robust, consistent, and generalizable evaluation, as learned throughout VBID. This ensures maximum consistency and fuels the ability of the model to meet its goals and the mission of the CMS Innovation Center to identify, test, and scale new ways to pay for and deliver better healthcare. Furthermore, if the ADVaNCE MA model were to be expanded into the regular MA program, every MA organization would be included, and their contracts would be subject to the standard MA termination provisions at 42 CFR 422.510. Considering we hope to test changes to MA payment, quality incentives, and risk adjustment as realistically as possible; it stands to reason that our proposed termination provisions would mirror the current program.

We seek comment on the proposed application of the remedial action framework at 42 CFR 512.160 and the availability of 42 CFR part 422, Subpart K to the ADVaNCE MA model.

g. ADVaNCE MA Model Termination by CMS

We propose to apply section 1115A(b)(3)(B) of the Act and 42 CFR 512.165 to the ADVaNCE MA model without modification. If CMS were to terminate the ADVaNCE MA model, participating organizations would remain subject to the otherwise applicable MA framework, and any transition from model-specific payment, reporting, quality display, or supplemental benefit policies back to ordinary MA rules would be implemented through sub-regulatory guidance.

As discussed elsewhere in this preamble, an ADVaNCE MA model participant would be subject to model-wide termination under 42 CFR 512.165, which is distinct from termination or nonrenewal of an MA contract under 42 CFR part 422 (and see related discussion of proposed § 516.623).

We seek comment on the proposed application of 42 CFR 512.165 to the ADVaNCE MA model without modification.

h. CMS Termination of ADVaNCE MA Contract

Under 42 CFR 422.510, CMS may terminate a Medicare Advantage contract that meets any of the criteria detailed in 42 CFR 422.510(a). This authority stems from section 1857 of the Act which established the statutory framework governing MA contracts and CMS's broader responsibility. These termination provisions serve as a critical enforcement mechanism to safeguard the integrity of the MA program.

For the ADVaNCE MA model, we propose at § 516.623(a)(1) that CMS may terminate an ADVaNCE MA contract immediately or upon advance notice under specified circumstances at 42 CFR 422.510(b), if the ADVaNCE MA model participant meets any of the criteria in 422.510(a)(1)-(3), 422.510(a)(4)(i)-(x), or 422.510(a)(4)(xii) through (xvii). In addition, we propose at § 516.623(a)(2)(i) that CMS would be able to terminate an ADVaNCE MA contract immediately or upon advance notice under specified circumstances at 42 CFR 422.510(b) if, for three consecutive performance years, the ADVaNCE MA model participant achieves less than a 2.5 Diamond Ratings score or achieves less than a 2.5 Diamond Ratings score. Additionally, we propose at § 516.623(a)(2)(ii) that CMS would be able to terminate an ADVaNCE MA contract immediately or upon advance notice under specified circumstances at 42 CFR 422.510(b) if, for three consecutive performance years, the ADVaNCE MA model participant achieves a Part C summary plan rating of less than three stars, if three performance years of Diamond Ratings are unavailable. In other words, until CMS has three years of performance data from the Diamond Ratings system, CMS will use Star Ratings or a combination of Star Ratings and Diamond Ratings to determine three years of poor performance. For example, in performance year 2029, CMS will analyze Star Ratings from CY 2029 and CY 2030 plus Diamond Ratings from performance year 2031 to determine whether a contract has received a score of 2.5 or lower for three consecutive years to apply the criteria for termination in proposed 516.623.

Under the proposed ADVaNCE MA model, contracts operating under the same parent organization within the same cohort within a Mandatory State would share identical Overall

Diamond Ratings. Significantly, as proposed at § 516.623(b)(3)(ii), the termination of a contract on the basis of proposed § 516.623(a)(2) could result in the termination of all of the parent organization's contracts in the same cohort within a Mandatory State with identical Overall Diamond Ratings. Furthermore, as proposed at § 516.623(b)(3)(i), CMS could invoke the proposed § 516.623(a)(1) to terminate multiple ADVaNCE MA contracts held by a single ADVaNCE MA model participant, if necessary. If CMS decides to terminate an ADVaNCE MA contract, we propose at § 516.623(b)(4) that CMS would provide notice of termination separately to each affected contract in accordance with 42 CFR 422.510(b). Accordingly, as proposed at § 516.623(c), CMS would notify the ADVaNCE MA model participant in writing at least 45 calendar days before termination in accordance with 42 CFR 422.510(b)(1) except when 42 CFR 422.510(b)(2) is applicable.

Before providing a notice of intent to terminate the contract, we propose at § 516.623(d) that CMS would offer an opportunity to develop and implement a corrective action plan in accordance with 42 CFR 422.510(c), subject to the exceptions in 42 CFR 422.510(c)(2), and provide a written notice of available appeal rights in accordance with 42 CFR 422.510(d) unless CMS chooses to immediately terminate the MA contract under 42 CFR 422.510(b)(2), as proposed at § 516.623(c). This would allow the ADVaNCE MA model participant to demonstrate to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action unless there are grounds for immediate termination under 42 CFR 422.510(b)(2). If CMS makes a determination to terminate an ADVaNCE MA contract, CMS would also impose the intermediate sanctions at 42 CFR 422.750(a)(1) and (3) in accordance with the procedure requirements in 42 CFR 422.510(e).

Once terminated, ADVaNCE MA model participants would have access to the appeals process outlined in 42 CFR 422.660. This proposal establishes a termination framework that

aligns with the ADVaNCE MA model's objective of improving and preserving the quality of care provided to beneficiaries.

Furthermore, as discussed, an MA contract that is part of an Innovation Center model would also be subject to 42 CFR 512.165 in its entirety. As proposed at § 516.623(b), if an ADVaNCE MA contract meets the grounds for termination under § 516.623(a) their parent organization (the ADVaNCE MA model participant) would not automatically be terminated from model participation. Regarding model participation, the termination would solely impact the ADVaNCE MA contract under the greater ADVaNCE MA model participant. The exception would be if an ADVaNCE MA model participant has only one contract, in which case, the termination of said contract based on proposed § 516.623 would trigger ADVaNCE MA model participant termination. Additionally, ADVaNCE MA model termination under 42 CFR 512.165 would not trigger the termination of a non-model contract or an MA contract held by an ADVaNCE MA model participant in accordance with 42 CFR 422.510 as this contract exists separately from the model. In the case of model termination, the previously model participating MA organization could consolidate non-model MA contracts and model MA contracts, and operate as a standard MA contract, subject to 42 CFR 422.510 and the proposed § 516.230(d)(1) as described in section VIII.F.4.c. of this proposed rule.

We seek comment on the proposed termination methodology for ADVaNCE MA contracts and whether additional termination conditions and methods should be included to test the model as proposed.

i. Limitations on Review

Section 1115A(d)(2) of the Act and 42 CFR 512.170 preclude administrative and judicial review of core model-design decisions. For the ADVaNCE MA model, these nonreviewable matters would include, but are not limited to, the selection of Mandatory States; the selection of participating organizations and plan types; the quality program; the cohort structure; and the model's scope, duration, and modifications. We are not codifying a specific

model-specific list of non-reviewable matters because these model-design decisions would already fall within the existing bar on administrative or judicial review.

We seek comment on whether additional model-specific guidance on nonreviewable matters is warranted.

j. Miscellaneous Provisions on Bankruptcy and Other Notifications

We propose to apply 42 CFR 512.180 to the ADVaNCE MA model without modification. We believe the standard CMS Innovation Center notification framework is sufficient for the ADVaNCE MA model because bankruptcy, legal name changes, and changes in control can materially affect CMS's ability to administer model-specific payment and oversight requirements. In the context of the ADVaNCE MA model, these notifications are especially important because the ADVaNCE MA model includes model-specific quality-assessment obligations that may remain financially and operationally significant even in the event that an organization is undergoing corporate transition.

We further clarify that the notification requirements at 42 CFR 512.180 would be cumulative and are in addition to, not in place of, otherwise applicable MA requirements under 42 CFR part 422, including applicable requirements governing changes in ownership. We believe this clarification is appropriate because ADVaNCE MA participants would remain MA organizations subject to part 422, while also being ADVaNCE MA model participants subject to the general standard CMS Innovation Center requirements in 42 CFR part 512, subpart A, with the proposed modifications described in this proposed rule.

We seek comment on the proposed application of 42 CFR 512.180 to the ADVaNCE MA model without modification.

k. Error Notice and Reconsideration Review Process

We recognize that the general reconsideration provisions at 42 CFR 512.190 establish a standard administrative review process for certain CMS Innovation Center models. At § 516.622(a), we propose that 42 CFR 512.190 would apply to the ADVaNCE MA model,

except as provided at § 516.622(b). At § 516.622(b)(1), we propose that with respect to the reconsideration and appeals framework of the Diamond Ratings system only, 42 CFR 512.190 will not apply. We further propose at § 516.622(b)(1) that with respect to the reconsiderations and appeals process for the Diamond Ratings system, 42 CFR 422.260 would apply to the ADVaNCE MA model without modification. This approach ensures that the existing Part 422 appeals and reconsideration procedures relating to QBP ratings also apply to the ADVaNCE MA Diamond Ratings system in place of the general CMS Innovation Center model error and reconsideration review process. Additionally, at § 516.622(b)(2), we propose that with respect to the appeals process governing termination of ADVaNCE MA contracts under § 516.623 only, 42 CFR 512.190 would not apply. We propose that for this process, 42 CFR 422.660 would apply to the ADVaNCE MA model without modification. This approach ensures that ADVaNCE MA model participants retain the same termination appeal rights available to other MA organizations under 42 CFR part 422. At § 516.623(e), we also propose that where CMS imposes an intermediate sanction under 42 CFR 422.750(a)(1) and (3) in accordance with the procedure requirements in 42 CFR 422.510(e), the appeal of that sanction would be heard in the same proceedings as the termination appeal, in accordance with 42 CFR 422.510(e)(2).

As part of 42 CFR 422.260, there is an administrative review process to appeal QBP status determinations based on section 1853(o) of the Act. Through this process, QBP ratings are published for reconsideration and appeal purposes. We propose to retain this reconsideration and appeals process outlined at 42 CFR 422.260. To accompany the Diamond Ratings previews, CMS is considering releasing a similar table in HPMS that reflects each contract's benchmark increase percentage and rebate percentage for reconsideration and appeal during the ADVaNCE MA Overall Diamond Ratings preview period (§ 516.220(f)). ADVaNCE MA model participants would be able to use these specific tables to inform their reconsideration and appeal requests within the Diamond Ratings system.

The additional process described at proposed § 516.622 does not authorize review of any matter otherwise barred by section 1115A(d)(2) of the Act or 42 CFR 512.170.

We emphasize that this model-specific review process set forth in proposed § 516.622(b) is limited in scope and does not permit review of ADVaNCE MA model design, methodology, or other matters precluded by statute or regulation.

We believe these existing review and appeals process appropriately permit MA organizations to bring to CMS specific concerns regarding alleged calculation errors or the use of incorrect data in determining quality payment status, where those alleged errors could affect an individual measure value, the overall Diamond Rating, or the organization's benchmark and rebate amount. The existing regulation at 42 CFR 422.260 further provides a reconsideration process, an informal hearing process, and a CMS reopening authority for credible information showing that an initial determination was incorrect, which collectively provides a sufficient mechanism for addressing the types of discrete errors that may affect payment determinations.

We seek comment on the proposed error notice and reconsideration review framework for the ADVaNCE MA model, including the proposed application of 42 CFR 422.260 to the Diamond Ratings system in place of 42 CFR 512.190 at § 516.622(b).

2. Extreme and Uncontrollable Circumstances

a. Background

Events outside the control of ADVaNCE MA model participants can disrupt the delivery of care, the collection of quality data, and the operation of billing and payment processing systems in ways that would make performance-based assessment inaccurate or unfair to affected contracts and, ultimately, to the beneficiaries they serve. The existing MA regulatory framework addresses these disruptions in three distinct contexts, each of which has implications for the ADVaNCE MA model.

First, 42 CFR 422.100(m) addresses disruptions in the availability of benefits arising from disasters or emergencies declared by the President, the Secretary, or a State Governor.

These provisions require each MA organization to continue making covered benefits available during declared emergencies by waiving requirements for gatekeeper referrals where applicable, ensuring out-of-network access at in-network cost-sharing levels, and making changes that benefit enrollees effective immediately without the standard 30-day notification requirement. We propose to apply the requirements of 42 CFR 422.100(m), governing access to covered benefits during disasters or emergencies, to participating contracts in the ADVaNCE MA model without modification. No feature of the ADVaNCE MA model as proposed would necessitate modifying these requirements.

Second, 42 CFR 422.504(o) requires each MA organization to develop, maintain, and implement a business continuity plan containing policies and procedures to ensure the restoration of essential operational functions following disruptions to business operations. Each MA organization must plan to restore essential functions within 72 hours after any essential function fails or otherwise stops functioning as usual. Section 422.504(o)(2) identifies two specific categories of essential functions subject to this requirement: benefit authorization (if not waived) for services to be immediately furnished and operation of call center customer services.

Third, 42 CFR 422.166(i) addresses disruptions to the collection of quality data through surveys needed for accurate performance measurement under the MA Star Ratings program. These provisions establish a process by which CMS may account for extreme and uncontrollable circumstances in its quality calculations and shield affected contracts from adverse rating consequences attributable to events beyond their control.

Because the ADVaNCE MA model operates within the MA program, each of these provisions is applicable to participating contracts. However, the unique structural features of the model, including the Mandatory State construct and the parent organization-level unit of quality assessment, we are proposing modifications to 42 CFR 422.166(i) and one addition to 42 CFR 422.504(o)(2) to ensure these provisions operate as intended in the ADVaNCE MA

context. We propose those modifications and that addition at § 516.625, as described in detail below.

b. Business Continuity

42 CFR 422.504(o) requires each MA organization to develop, maintain, and implement a business continuity plan containing policies and procedures to plan to restore essential operational functions within 72 hours after any essential function fails or otherwise stops functioning as usual. 42 CFR 422.504(o)(2) identifies two specific categories of essential functions that must be included in the business continuity plan: benefit authorization (if not waived) for services to be immediately furnished and operation of call center customer services.

We propose to apply the business continuity requirements of 42 CFR 422.504(o) to participants in the ADVaNCE MA model without modification. No feature of the ADVaNCE MA model as proposed would necessitate modifying these requirements.

c. Extreme and Uncontrollable Circumstances and Quality Measurement

The ADVaNCE MA Diamond Ratings system differs from the Star Ratings program in two structural aspects that affect how the extreme and uncontrollable circumstances provisions must operate. First, the ADVaNCE MA Diamond Ratings system evaluates quality at the parent organization level within each Mandatory State. Second, because not all enrollees within a selected State are enrolled in participating plan types, the extreme and uncontrollable circumstances threshold calculations under 42 CFR 422.166(i) must be applied to enrollees of participating contracts only. Each of these differences requires a corresponding modification to the requirements in 42 CFR 422.166(i), as applied to the ADVaNCE MA model, to ensure that extreme and uncontrollable circumstances protections function as intended in the ADVaNCE MA model context.

Therefore, we propose at § 516.625(a)(2) to apply to the ADVaNCE MA model the extreme and uncontrollable circumstances regulations at 42 CFR 422.166(i) through (8), with the modifications described later in this section.

(1) Unit of Assessment

42 CFR 422.166(i) applies extreme and uncontrollable circumstances protection at the individual contract level. As one of three criteria, CMS determines whether a sufficient proportion of a given contract enrollees reside in a FEMA-designated Individual Assistance Area at the time of the extreme and uncontrollable circumstances. The ADVaNCE MA Diamond Ratings system, however, evaluates quality at the State level for each parent organization, meaning all contracts affiliated with a given parent organization within the State are assessed together as a single unit for purposes of quality scoring and payment determination. Applying the contract-level threshold without modification would produce results inconsistent with the model's design. We therefore propose that all references to "contract" in 42 CFR 422.166(i)(1) through (8) be read, for purposes of § 516.625(a)(2)(i), as references to "participating parent organization." Parent organizations may operate contracts across multiple States, a disaster occurring in one State is evaluated only for enrollees and contracts within the affected State.

(2) Quality Rating Terminology

The ADVaNCE MA Diamond Ratings system generates ADVaNCE MA Diamond Ratings, which are distinct from MA Star Ratings. We therefore propose that all references to "Star Ratings", "Star Rating," and "Stars" in 42 CFR 422.166(i)(1) through (8) be read, for purposes of § 516.625(a)(2)(ii), as follows: "Star Ratings" is replaced by "ADVaNCE MA Diamond Ratings"; "Star Rating" is replaced by "ADVaNCE MA Diamond Rating"; and "Stars" is replaced by " ADVaNCE MA Measure Diamonds." When the term "Stars" appears in the compound phrases "CAHPS measure stars," "HOS and HEDIS-HOS measure stars," and "HEDIS measure stars" in paragraph (i)(2)(iii), (i)(3)(iii), and (i)(4)(iii) respectively, it is replaced by "ADVaNCE MA Individual Measure Diamonds" to reflect the ADVaNCE MA Diamond Ratings system's terminology.

(3) Minimum Percentage Threshold

42 CFR 422.166(i)(1)(iii) applies the extreme and uncontrollable circumstances provisions when a minimum percentage of enrollees under the contract (either 25 or 60 percent, depending on the provision at issue) reside in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstances, as one of three criteria. The 25 percent threshold governs the core survey-based protections in paragraphs (i)(2) through (8). The 60 percent threshold is operative only in paragraphs (i)(9) and (i)(10), which addressed exclusion of affected contracts from the clustering algorithm used to set cut points and from the Reward Factor variance calculations, respectively. Those provisions applied only "through the 2025 Star Ratings" and do not apply to the ADVaNCE MA model. We therefore propose that the phrase "25 percent or 60 percent" in 42 CFR 422.166(i)(1)(iii) be read, for purposes of § 516.625(c), as "25 percent" only.

We seek comment on all aspects of the proposed extreme and uncontrollable circumstances provisions at § 516.625.

3. ADVaNCE MA Model Overlaps

The ADVaNCE MA model would be a MA-focused CMS Innovation Center model. Because MA operates as a capitated, private managed care framework, whereas existing CMS Innovation Center models rely on OM claims attribution and total cost of care accountability, we do not anticipate substantial overlap between the ADVaNCE MA model and existing CMS Innovation Center models designed around OM. Medicare beneficiaries are generally enrolled either in OM or in MA for purposes of coverage of Medicare Parts A and B services. We recognize, however, that future CMS Innovation Center models or CMS programs may create circumstances in which an ADVaNCE MA model participant, its downstream providers or suppliers, or its enrolled beneficiaries are also affected by another CMS payment, quality, reporting, or benefit policy. In such circumstances, overlap may create operational, payment, or

evaluation questions that CMS would need to address to preserve ADVaNCE MA model integrity, avoid duplicative incentives, and ensure accurate evaluation.

We are not, in this rule, proposing any specific overlap policy with an existing model other than recognizing that overlap with currently operating OM focused models is expected to be limited. We seek comment on our proposed approach to account for overlaps with other CMS programs and models.

4. Data Sharing

a. Background

In the Part C program, CMS provides and/or collects information on quality metrics and supplemental benefit offerings. The data sharing needed for these key operational areas in the MA program requires bidirectional data sharing between CMS and MA organizations to ensure key processes continue and milestones are met.

For purposes of this model, "model-specific data" refers to data elements derived from existing MA data systems, including bid, encounter, quality, and supplemental benefit reporting, as well as any additional data elements determined by CMS to be necessary to monitor and evaluate ADVaNCE MA model performance under section 1115A(b)(4) of the Act. CMS does not intend to establish a new system of records for purposes of the ADVaNCE MA model but would rely on existing authorities and data sharing frameworks to the extent feasible.

Based on CMS's experiences with these efforts and the necessity of data sharing in the Part C Program, we propose to share data consistent with existing Part C data sharing processes when feasible, but we also propose to share with MA organizations model-specific data necessary to support bid development, quality measurement, and ADVaNCE MA model evaluation.

Because existing Part C regulations and systems of record notices (SORNs) establish CMS's authority to share data related to the areas of risk adjustment, quality metrics and supplemental benefits, we propose that ADVaNCE MA model participants would continue to

receive data specific to the ADVaNCE MA model under the existing Part C data sharing mechanisms as discussed more fully below.

All data shared back with MA organizations under the ADVaNCE MA model will follow existing Part C data sharing provisions without modification, including the authorities established under 42 CFR 422.272(d), which authorizes CMS to release MA bid pricing data; 42 CFR 422.250, which authorizes CMS to release MA bid submission data; 42 CFR 422.504(f), where MA organizations are required to submit to CMS all information necessary for CMS to administer and evaluate the MA program, and 42 CFR 422.310(f) which governs how CMS can use and release risk adjustment data submitted by MA organizations.

CMS distinguishes between data used for model evaluation and data used for compliance and enforcement activities. Data collected for evaluation under section 1115A(b)(4), specifically detailing the ADVaNCE MA model's impact on quality of care and cost, would be used to assess ADVaNCE MA model performance and may be aggregated and/or de-identified by CMS where appropriate in accordance with HIPAA standards set forth in 45 CFR 164.514(b). All model data can be used for compliance and enforcement to ensure compliance with applicable statutory, regulatory, and ADVaNCE MA model requirements. According to §422.310(f), when releasing risk adjustment data, CMS may only release the minimum data it determines is necessary in accordance with CMS data sharing procedures and applicable Federal laws (subject to commercially sensitive data limitations). Further, applicable beneficiary confidentiality protections, such as the rules under 42 CFR 422.118 regarding the confidentiality and accuracy of enrollee records, must be observed. As outlined in § 422.504(f), while MA organizations are required to submit comprehensive information to CMS for program administration, this information is subject to applicable data-sharing, privacy, and confidentiality requirements.

To the extent that any data shared with ADVaNCE MA model participants involves protected health information (PHI), such sharing will be conducted in full compliance with the

HIPAA Privacy Rule (45 CFR Parts 160 and 164) and the Privacy Act of 1974 (5 U.S.C. § 552a). As stated previously, CMS would rely on existing SORNs that already cover MA program data and will not share data outside the scope of these existing SORNs. Further the ADVaNCE MA model will incorporate the following standard safeguards with respect to data shared with MA organizations in the ADVaNCE MA model: (1) a minimum necessary standard, whereby CMS will release only the data required to accomplish each stated purpose, consistent with 45 CFR 164.502(b); (2) a prohibition on re-identification of any de-identified data received from CMS; and (3) a prohibition on secondary use of CMS data for any purpose not expressly authorized.

CMS has released MA organization quality data to MA organizations since 2007, as established under section 1851(d) of the Act. 42 CFR 422.504(f)(2) requires MA organizations to provide CMS with quality performance data to help establish and facilitate informed choice for beneficiaries in obtaining Medicare services.

b. Diamond Ratings System

We propose at § 516.205 to establish the Diamond Ratings system as a comprehensive redesign of the Star Ratings system that would measure and reward MA plan performance at the parent organization level within Mandatory States, utilizing cohorts to ensure fair comparisons among organizations serving similar beneficiary populations.

The Diamond Ratings system scores would be viewable on Medicare Plan Finder beginning with the CY 2031 Diamond Ratings and continue throughout the model and would compare entire parent organizations against each other within a Mandatory State and by cohort (one relative score for a parent organization's D-SNP population; another relative score for their General Enrollment population) to allow for meaningful beneficiary comparisons and to promote competition based on quality between plans locally for each parent organization that operates within an ADVaNCE MA Mandatory State. These ratings would be labeled as ADVaNCE MA Overall Diamond Ratings and would be displayed only for plans that are

ADVaNCE MA model participants. The ADVaNCE MA Overall Diamond Ratings would provide usable data to support more informed beneficiary plan selection and to stimulate competition.

The proposed data sharing on Medicare Plan Finder complies with beneficiary confidentiality requirements specified in the regulations at 42 CFR 401.118, which prohibits public disclosure of beneficiary identifying information and limits the release of such information to only when necessary for program purposes, consistent with applicable Federal laws and CMS data sharing procedures.

c. Supplemental Benefit Flexibility Data Sharing

We propose at § 516.300 to allow ADVaNCE MA model participants to engage in a targeting flexibility for offering MA supplemental benefits that is not currently available in the MA program, as well as offer certain non-primarily health related supplemental benefits to LIS-eligible individuals in a manner that would otherwise only be permissible as SSBCI. In the ADVaNCE MA model, CMS proposes to allow ADVaNCE MA model participants to target healthy food and produce, transportation for non-medical needs, or support for caregiver supplemental benefits (or any and all of the aforementioned) to enrollees eligible for Part LIS.

To evaluate the effectiveness of these supplemental benefits, CMS would exercise our authority to collect comprehensive data annually on supplemental benefit utilization and costs through PBP-level reporting as well as beneficiary-level reporting. To minimize reporting burden on MA organizations, these reporting requirements would align as closely as feasible to the established Part C Reporting Requirements in 42 CFR 422.516. CMS would review the quality of this data, including examining variation in utilization patterns among MA organizations and assessing the accuracy, reliability, and validity of the reported information before making determinations about the impact of these benefits on beneficiary outcomes and program costs. As needed, CMS would provide additional sub-regulatory guidance specifying

data reporting formats, definitions, and submission requirements for supplemental benefit utilization to ensure consistency and minimize administrative burden.

The PBP-level data collected for the evaluation and monitoring of these supplemental benefits would be de-identified and aggregated, not including any personally identifiable information that could be used to identify individual beneficiaries. However, the additional beneficiary-level supplemental benefits utilization and costs reporting would include private and sensitive data necessary to allow CMS to effectively monitor supplemental benefit utilization patterns and assess the model's impact on health outcomes and program costs.

5. Evaluation

Pursuant to 42 CFR 403.1110(b) and as described in section VIII.J.1.b of this proposed rule, ADVaNCE MA model participants in Mandatory States would be required to collect and report information to CMS necessary for the purposes of monitoring and evaluating the ADVaNCE MA model as required by statute. We would use such data to conduct an evaluation of the proposed ADVaNCE MA model in accordance with section 1115A(b)(4) of the Act, which requires the Secretary to evaluate each model tested by the CMS Innovation Center.

The evaluation would consider changes in the quality of care and changes in program spending that occurred due to the model. Because one of the goals of the ADVaNCE MA model is to assess market-level competitive effects, we would also consider examining the changes to market competition that occurred due to the model. We would also consider examining changes in utilization patterns, variations in impact, and the likelihood of unintended consequences or other effects.

We would select an independent evaluation contractor to perform this evaluation and would use a multilevel approach to evaluation. We are considering analyses at the State, parent organization, contract, plan, and beneficiary levels. Based on the State groupings method proposed in the section on selection of geographic areas, we believe there are several ways in which we can draw comparison groups and employ scientifically-sound, rigorous methods for

evaluating the effect of the ADVaNCE MA model intervention. The evaluation effort may require participants in the ADVaNCE MA model to provide additional data specifically for evaluation purposes. Such requirements for additional data to carry out ADVaNCE MA model evaluation would be in compliance with 42 CFR 403.1110(b) which, as of January 1, 2015, requires entities participating in the testing of a model under section 1115A of the Act to collect and report such information, including protected health information (as defined at 45 CFR 160.103), as the Secretary determines is necessary to monitor and evaluate the model. We would consider all parent organizations, and their subsidiaries providing plans under eligible contracts within a Mandatory State, to be participating in the testing of the ADVaNCE MA model because they would be receiving payment from CMS under the model.[286]

As discussed in section VIII.C of this proposed rule, the ADVaNCE MA model would have a 10-year performance period. The evaluation period would encompass a baseline period, the entire 10-year performance period, the post-implementation period, and up to 4 years after the performance period to allow for full data availability. We plan to evaluate the ADVaNCE MA model on an annual basis. However, we recognize that interim results are subject to issues such as sample size and random fluctuations in market patterns. Hence, while CMS intends to conduct periodic analyses to offer useful insight during the ADVaNCE MA model test, a final analysis after the end of the 10-year performance and post-implementation period will be important for ultimately synthesizing and validating results.

We seek comment on our proposed evaluation plan.

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[286] Centers for Medicare & Medicaid Services, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015" final rule (79 FR 67751 through 67755) (November 13, 2014), https://www.federalregister.gov/d/2014-26183.

IX. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide notice in the **Federal Register** and solicit public comment before a "collection of information," as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain confirmed or potential collection of information requirements. Comments, if received, will be addressed in the subsequent final rule (CMS-4214-F).

A. Wage Data

To derive average (mean) costs, we are using the most current U.S. Bureau of Labor Statistics (BLS) national Occupational Employment and Wage Statistics estimates for all industries combined (https://data.bls.gov/oes/#/area/0000000/2025), which, at the time of publication of this proposed rule, provide May 2025 wages. In this regard, Table IX.1 presents BLS mean hourly wages, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wages.

TABLE IX.1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE STATISTICS ESTIMATES

Occupational Title	Occupational Code	Mean Hourly Wage ($/hr)	Cost of Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Wage ($/hr)
Business Operations Specialists, All Other	13-1199	45.18	45.18	90.36
Compensation and Benefits Managers	11-3111	78.19	78.19	156.38
Compliance Officers	13-1041	42.50	42.50	85.00
Computer Programmers	15-1251	50.56	50.56	101.12
Computer Support Specialists	15-1230	33.55	33.55	67.10
Computer Systems Analysts	15-1211	55.10	55.10	110.20
Financial Managers	11-3031	89.86	89.86	179.72
General and Operations Managers	11-1021	64.87	64.87	129.74
Human Resources Managers	11-3121	78.96	78.96	157.92
Insurance Claims and Policy Processing Clerks	43-9041	25.44	25.44	50.88
Lawyers	23-1011	89.35	89.35	178.70
Medical and Health Services Managers	11-9111	67.77	67.77	135.54
Software Developers	15-1252	71.20	71.20	142.40

Adjusting our employee hourly wage estimates by a factor of 100 percent is a rough adjustment that is being used since fringe benefits and other indirect costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. In this regard, we believe that doubling the hourly wage to estimate costs is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within this proposed rule.

1. ICRs Regarding Enrollee Notification Requirements for Provider Terminations, Continuity of Care, and SEP Notice Consolidation (§§ 422.111(e), 422.112(b), 422.112(d), and 422.2267(e)(12))

The following proposed changes will be submitted to OMB for review under control number CMS-10981, OMB 0938-TBD (New Collection).

Under proposed § 422.112(d), CMS would codify the criteria used to determine whether a provider termination constitutes a significant change in a plan's provider network, thereby triggering the special enrollment period and requiring MA organizations to notify CMS within 60 days of the termination. This codification formalizes a long-standing reporting process that MA organizations are already expected to follow under sub-regulatory guidance in Chapter 4 of the Medicare Managed Care Manual. Because the proposal reflects existing practice, the incremental burden is expected to be minimal, estimated at 2 hours at $135.54/hr, CMS estimates

a maximum annual burden of 11,066 hours (5,533 MA plans x 2 hr/response) at a cost of $1,499,886 (11,066 hr x $135.54/hr). CMS solicits comment on that estimate as well as on whether codification is expected to increase or decrease reporting volume.

Under proposed §§ 422.111(e) and 422.2267(e)(12), CMS would revise the Provider Termination Model Notice to require MA organizations to include SEP eligibility information when CMS has determined that an affected enrollee qualifies for the special enrollment period at § 422.62(b)(23). CMS is also proposing to consolidate the provider termination notice and the SEP eligibility notice into a single communication and to update the affected enrollee definition to a uniform 1-year lookback period. This is a one-time template revision burden, estimated at 8 hours at $135.54/hr for a Medical and Health Services Manager, reflecting the time needed for legal, compliance, and communications staff to review the revised content requirements, draft updated notice language, conduct internal review, and finalize the updated template. In aggregate, CMS estimates a one-time burden of 3,800 hours (475 MA contracts x 8 hr/response) at a cost of $515,052 (3,800 hr x $135.54/hr). The respondent universe is approximately 475 MA contracts (two thirds of total MA contracts) because CMS estimates that about one third of these updates would be duplicative; contracts under the same MA organization may share Provider Termination Notice templates. CMS solicits comment on this respondent estimation and whether the 8-hour estimate accurately reflects the effort involved and on any additional one-time implementation costs associated with this revision.

Under proposed § 422.111(e)(3), CMS would update the affected enrollee definition to a uniform 1-year lookback period, replacing the current provider-type-specific lookback periods. Under this approach, MA organizations would identify affected enrollees through a single unified query rather than separate queries by provider type and would maintain one consolidated enrollee list per termination event. This change is expected to reduce per-event administrative burden by eliminating the need to run and reconcile separate queries at 1 hour and $135.54/hr for

a Medical and Health Services Manager. In aggregate, CMS estimates a burden reduction of minus 475 hours (475 MA contracts x 1 hr/response) and minus $64,382 (475 hr x $135.54/hr).

TABLE IX.2: COST ESTIMATES FOR Enrollee Notification Requirements

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
422.111(e) and 422.2267(e)(12)	475	N/A	8	NA	135.54	N/A	N/A
422.111(e)(3)	475	N/A	1	NA	135.54	N/A	N/A
422.112(d)	5,533	N/A	2	NA	135.54	N/A	N/A

The respondent universe is approximately 475 MA contracts (two thirds of total MA contracts)—CMS estimates that about one third of these systemic updates would be duplicative because contracts under the same MA organization may share administrative systems. Responses occur on a per-event basis. The total annual burden cost remains to be determined, as the number of provider termination events per year for which MA organizations currently run affected enrollee queries is unknown. CMS solicits comment on that figure, the respondent estimation, as well as on whether the 1-hour per-response estimate accurately reflects the time required under the proposed unified query approach.

2. ICRs Regarding Use of Existing Interoperability API for Prior Authorization Transactions (§ 422.202(c))

If finalized, the following proposed changes would be submitted in an updated version of the existing PRA package OMB control number 0938-1437 (CMS-10843) and submitted to OMB for approval.

Under § 422.202(c)(1), CMS proposes to require that, beginning January 1, 2028, MA organizations include a provision in each provider contract mandating that the provider use the Prior Authorization API to submit prior authorization requests to the MA organization. To comply with this requirement, each MA organization will need to review its existing provider contracts to incorporate the new contractual language. Given that the language is expected to be consistent across contracts, CMS estimates that this review process would take 3 hours at $90.36/hr for a business operations specialist (all other). Applied across all 708 MA

organizations, this yields an estimated one-time burden of 2,124 hours (708 MA organization contracts x 3 hr/response) at a cost of $191,925 (2,124 hr x $90.36/hr).

TABLE IX.3: ESTIMATE FOR PROVIDER CONTRACT REQUIREMENT

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
§ 422.202(c)(1)	708 MA organizations	708	3	2,124	90.36	191,925	N/A

Under § 422.202(c)(2), MA organizations would be required to include a provision in each provider contract obligating both parties to annually test and confirm that the Prior Authorization API functions bidirectionally and remains usable and accessible for both the MA organization and the contracted provider if the provider furnishes non-drug items or services subject to prior authorization.[287] CMS estimates that MA organizations will require approximately 40 hours at $110.20/hr for a computer systems analyst to coordinate, conduct, document, and confirm bi-directional Prior Authorization API testing with contracted providers. This estimate accounts for the time needed to develop a testing protocol, communicate with contracted providers, execute testing procedures, review results, and document confirmation of bi-directional functionality and usability. CMS estimates an annual burden of 28,320 hours (708 MA organization contracts x 40 hr/response) at a cost of $3,120,864 (28,320 hr x $110.20/hr).

TABLE IX.4: ESTIMATE FOR ANNUAL TESTING

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
§ 422.202(c)(2)	708 MA organizations	708	40	28,320	110.20	3,120,864	3,120,864

It is important to note that, because the Prior Authorization API infrastructure is already required to exist under 42 CFR 422.122(b), CMS does not anticipate that MA organizations will incur significant new technical build costs solely attributable to this provision. Rather, the burden associated with this requirement reflects the administrative and operational work of formalizing

[287] If the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule is finalized to include drugs in the Prior Authorization API requirements at § 422.119 before this rule is finalized, CMS proposes to similarly expand the requirements proposed in this rule as needed for consistency with the standards applicable to the Prior Authorization API under § 422.119.

the use of existing infrastructure and ensuring that it operates bidirectionally with contracted providers. In addition, broader use of technology may reduce administrative burden over time. CMS invites public comments on the approach and underlying assumptions used to estimate the burden associated with the Prior Authorization API requirements for contracted providers.

CMS also anticipates that contracted providers will incur burden in connection with their participation in the annual Prior Authorization API functionality test. CMS estimates that each provider will require approximately 1 hour at $135.54/hr for a medical and health services manager to connect to the testing environment, execute the required test transactions, and confirm functionality with the MA organization. CMS recognizes that the actual time needed to complete this testing may vary based on factors such as whether the provider uses an EHR system and the size of the provider organization. CMS solicits public comments on both the estimated cost and the associated time burden. Providers that rely on EHR vendors or contracted technical staff to conduct this testing may incur costs in the form of vendor fees rather than direct staff time. However, for purposes of this burden estimate CMS uses the medical services manager wage rate as a reasonable proxy for the cost of this activity, regardless of whether it is performed by internal staff or an external vendor.

CMS further acknowledges that, due to the absence of reliable data on the total number of contracted providers across all 708 MA organizations who would implement this requirement, it is not currently possible to provide a precise aggregate burden estimate. Therefore, CMS invites public comment on the estimated number of providers subject to this requirement, in order to refine these estimates in the final rule.

3. ICRs Regarding Strengthening Maximum Fair Price Effectuation Policies for Medicare Advantage (§ 422.504)

To facilitate manufacturer effectuation of the MFP for selected drugs payable under Part B and furnished or administered to MFP eligible individuals enrolled in an MA plan under Part

C, the following proposed changes will be submitted to OMB for review under control number 0938-1152 (CMS-10340).

In § 422.504(q), CMS proposes to require MA organizations to collect and submit an 11-digit National Drug Code (NDC-11) on each MA encounter data record for selected drugs payable under Part B for which an MFP is in effect on the claim-from date. Under the current framework, NDC-11s are data elements that can be submitted on MA encounter data records but are not required.

CMS anticipates that this change will not significantly impact the burden on MA organizations as the required submission does not introduce new data elements to the existing MA encounter data record format and includes a data element which many MA organizations already submit to CMS. An internal analysis showed the inclusion of NDC-11s on MA encounter data records in Contract Year 2025 (the most recent year of available data for this analysis) for separately payable drugs payable under Part B and selected for negotiation for initial price applicability year of 2028 approximately 64 percent of the time, a similar rate as Original Medicare claims. We do not anticipate that the addition of this provision would add burden to MA organizations for two reasons. First, many MA organizations already submit NDC-11s for drugs separately payable under Part B on encounter data records, as previously described. Second, as described in CMS Pub. 100-04, Medicare Claims Processing Manual, Transmittal 1401 (CR 5835, December 21, 2007) established processes for reporting NDC-11s on Part B claims for dual-eligible beneficiaries to comport with Medicaid statutory requirements regarding the collection of NDCs for most covered outpatient drugs. *See* Medicare Claims Processing Manual, Chapter 26, § 10.4. Taken together, these existing practices and reporting requirements indicate that some, if not most, MA organizations may already have processes in place to collect NDC-11s from providers and submit them to CMS.

Also in § 422.504(q), CMS proposes to require MA organizations to submit MA encounter data (as described at § 422.310(d)(5)) records involving the furnishing or

administration of a selected drug payable under Part B for which an MFP is in effect on the claim-from date within 30 days of the claim-from date. This proposal does not affect the existing deadline requirements or processes for submission of MA encounter data records for Part B drugs or any other service or item provided to an MA enrollee for the purpose of risk adjustment. We will use data submitted pursuant to § 422.504(q) for risk adjustment purposes unless the MA organization submits risk adjustment data required under § 422.310 by the final risk adjustment submission deadline under § 422.310(g).

There are approximately 922 contracts available nationally covering services otherwise payable under Medicare Part B; this assumption represents CMS' expected number of plans subject to the proposed requirements. However, CMS understands that some MA plans are owned wholly by a larger parent company. Such arrangements may decrease burden associated with updating processes to comply with these proposals. During contract year 2025, approximately 972,500 encounter data records from MA plans for selected drugs for initial price applicability year 2028 and payable under Part B were submitted to CMS. The estimated annual electronic processing cost per encounter data record is $1.85 according to the 2022 Council for Affordable Quality Healthcare (CAQH) Index and the estimated time required to process an electronic record based on the CAQH Index Report is 2 minutes (0.03 hr).

As noted previously, CMS expects these proposed requirements would be subject to 922 contracts, which is the number of active MA contracts for contract year 2026. Since we do not know the number of MA organizations that would need to create new processes to collect and submit NDC-11s for drugs separately payable under Part B on MA encounter data records and the number of MA organizations that would need to modify existing processes for submission of MA encounter data records for selected drugs payable under Part B for which a maximum fair price is in effect within 30 days of the claim-from date, we used the entire expected number of MA contracts for the annual burden estimate. The upper limit of the estimated annual burden to implement the proposed requirements for all MA organizations that are currently submitting

encounter data is 29,175 hours (972,500 data records × 0.03 hr/response) at a cost of $1,799,125 (972,500 data records from MA plans × $1.85 per encounter data record). Given that, as discussed above, many MA organizations already submit encounter data within 30 days and submit NDC-11s on encounter data records, we anticipate that the total realized cost will be significantly lower.

TABLE IX.5: REQUIREMENT FOR MA ORGANIZATIONS TO SUBMIT ENCOUNTER DATA RECORDS INVOLVING SELECTED DRUGS PAYABLE UNDER PART B AND SUBJECT TO AN MFP AND TO COLLECT AND SUBMIT NDC-11 CODES ON EACH SUCH MA ENCOUNTER DATA RECORD WITHIN 30 DAYS OF THE CLAIM-FROM DATE

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
§ 422.504(q)	708 MA organizations	972,500	0.03	29,175	$67.10	$1,799,125	$1,799,125

The following proposed changes will be submitted to OMB for review under control number 0938-1483 (CMS-10912). We note that the burden estimates discussed below were incorporated into this ICR package (0938-1483 (CMS-10912)) and CMS solicited comments on initial revisions to which the comment period closed on September 22, 2026. CMS is currently reviewing comments and intends to issue a revised ICR for a 30-day comment period later in calendar year 2026.

CMS proposes at § 422.504(p) to require any contract between an MA organization and a provider (as defined in § 422.2), or between a first tier, downstream, or related entity and a provider on the MA organization's behalf, for participation in one or more of the MA organization's networks include a provision that if the provider furnishes or administers selected drugs payable under Part B during the period when such drugs are subject to an MFP, the provider must 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. This proposal is similar to the current requirement at § 423.505(q) for Part D plan sponsors to include in their pharmacy agreements provisions requiring the pharmacy to be enrolled in the MTF DM. Similar to dispensing entities of selected drugs covered under Part D, provider enrollment in the MTF

DM is needed for necessary operations related to administration of the Part C program.

CMS expects approximately up to 16,000 providers, including both institutional organizations and sole practitioners, to enroll in the MTF DM; this assumption represents CMS' maximum expectation for participation. CMS expects institutional providers to enroll associated individual providers through a central office. CMS believes collection of these data will be a one-time cost for each submitting provider enrolling in the MTF DM and that a significant majority of providers will enroll before January 1, 2028. The MTF DM will not charge providers any fees to use the system.

We estimate enrollment in the MTF DM will be performed by a financial manager (2 hr at $179.72/hr); a business operations specialist, (2 hr at $90.36/hr); a general and operations manager (2 hr at $129.74/hr); and a lawyer (2 hr at $178.70/hr). Across all 16,000 providers, we estimate an annual burden of 128,000 hours (16,000 respondents x 8 hr/response) at a cost of $18,512,640 (16,000 respondents x [(2 hr x $179.72/hr) + (2 hr x $90.36/hr) + (2 hr x $129.74/hr) + (2 hr x $178.70/hr)]).

TABLE IX.6: REQUIREMENT FOR PROVIDERS THAT FURNISH OR ADMINISTER SELECTED DRUGS PAYABLE UNDER PART B SUBJECT TO AN MFP TO ENROLL IN THE MTF DM

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost[288] ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
§ 422.504(p)	Providers that furnish or administer drugs selected for the Medicare Drug Price Negotiation Program	16,000	8	128,000	578.52	18,512,640	18,512,640

CMS also proposes to require that any out-of-network cost sharing for selected drugs payable under Part B and subject to an MFP is calculated based on a price that does not exceed the MFP. The provision we are proposing does not impose any new or revised collection of information requirements and/or burden. In making this assertion we note that the proposed

[288] The labor cost of $578.52 represents a total of 4 hours of work (4 types of workers, each working 1 hour). Therefore, the time per response at the aggregated $578.52/ hour rate is 2 hours, rather than 8 hours.

provision may require updates to current guidance governing MA organization bid requirements, which is currently approved by OMB under control number 0938-0763 (CMS-R-262), but it would not change how CMS evaluates compliance with cost sharing limits as part of bid review. If finalized, CMS intends to continue providing annual instructions on bid documentation through subregulatory guidance.

4. ICRs Regarding the Low Performing Icon (LPI) Notice (§§ 422.2267(e)(13)(vi) and 423.2267(e)(17)(vi))

The following proposed changes will be submitted to OMB for review under control number 0938–TBD (CMS–XXXX). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request.

As described in section IV.J of this proposed rule, we are proposing to codify a requirement that MA organizations and Part D sponsors that meet the LPI threshold furnish the CMS-approved LPI notice directly to their enrollees, rather than CMS mailing the notice on plans' behalf. This proposal would establish a new burden for MA organizations and Part D sponsors who meet the LPI threshold.

Since 2012, CMS has mailed the LPI notice (CMS Product No. 11627) to beneficiaries enrolled in MA, MA-PD, and standalone Part D plans that have received an overall Star Rating of less than 3 stars for 3 or more consecutive contract years. Under this proposal, MA organizations and Part D sponsors meeting the LPI threshold would be required to mail the CMS-approved standardized notice to each enrolled beneficiary no later than November 15th of each contract year.

To inform our burden estimates, we reviewed historical LPI mailing data from contract years 2021 through 2025, as summarized in table IX.7:

TABLE IX.7: BURDEN ESTIMATES

Contract Year	Number of Organizations	Number of Notices Sent
2021	0	0
2022	0	0
2023	1	1,714
2024	3	24,610
2025	4	45,000
Average	2 (8/5 yr= 1.6)	14,265 (71,324/5 yr)

The number of affected plans and notices sent may vary significantly from year to year based on plan performance. To account for this variability, we based our burden estimates on a 5-year average derived from historical LPI mailing data, which results in an average of approximately two plans and 14,265 notices per contract year.

We note that MA organizations and Part D sponsors already maintain mailing infrastructure for other required beneficiary communications, including the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC), which is expected to reduce the marginal cost of compliance with this requirement. Because the notice content is CMS-standardized with a few variable fields, plans are not required to develop or draft notice language.

We estimate it would take 2 hours at $50.88/hr for an Insurance Claims and Policy Processing Clerk to receive and review the CMS-approved notice, populate any variable fields, compile a list of beneficiaries, and arrange for printing and distribution with a print vendor. In aggregate, we estimate an annual burden of 4 hours (2 plans × 2 hr/response) at a cost of $204 (4 hr × $50.88/hr).

We also believe that the primary burden associated with this requirement is a non-labor cost—specifically, the printing and postage costs associated with mailing the CMS-approved notice to enrolled beneficiaries. Utilizing the average of historical data, each plan would be required to send notices to approximately 7,133 beneficiaries (14,265 notices/2 plans). Paper, envelopes, and toner for printing from a typical office supply store will be approximately $2,235 for 14,265 notices ($1,595 for envelopes, $191 for paper, and $450 for toner). The United States Postal Service website (https://www.uspsdelivers.com/direct-mail-cost-calculator/) states that the

cost of mailing individual notices via First-Class mail would be $0.67 each, which equates to a total mailing cost of $9,558 (14,265 total notices x $0.67) for all plans. The total of materials and postage would be $11,793 ($2,235 + $9,558) and the total cost, including labor, would be $11,997 ($11,793 + $204).

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
§§ 422.2267(e)(vi) and 423.2267(e)(vi)	2	2	2	4	50.88	11,997	11,997

TABLE IX.8: COST ESTIMATES FOR LPI NOTICE

5. ICRs Regarding Reducing Model of Care (MOC) Burden, Improving Special Needs (Plans (SNP) Care Coordination Requirements, and Updating HRA Outreach Requirements (§ 422.101(f))

The following proposed changes will be submitted to OMB for review under control number 0938-1296 (CMS-10565).

In section V.A of this proposed rule, CMS proposes amendments to § 422.101(f) to: address gaps in care management by Special Needs Plans (SNPs) identified through the CMS SNP audit process; reduce unnecessary burden on plans and providers associated with SNP Model of Care (MOC) training requirements; and amend current health risk assessment requirements to account for technological advancements employed by MA organizations when communicating with enrollees. Specifically, these proposals would:

- Amend § 422.101(f)(1)(vii) to require that person-centered goals and objectives in ICPs be specific to all active needs and diagnoses as prioritized by the enrollee; address supplemental benefits available to the enrollee under the plan; and ensure that the ICP is shared amongst a designated group;
- Amend ICT regulations at § 422.101(f)(1)(ix) to better suit the unique populations served by SNPs; and
- Remove MOC training requirements at § 422.101(f)(2)(ii) to alleviate SNP and provider burden, and

Because SNPs are already required to conduct ICPs, facilitate ICTs, and ensure access to care under current regulations, CMS does not anticipate that the proposed amendments to §§ 422.101(f)(1)(vii), 422.101(f)(1)(ix), and 422.101(f)(2)(vii) would impose any new information collection burden on MA organizations offering SNPs. These proposals either clarify existing requirements or codify practices already operationally required of SNPs.

The proposed removal of the MOC training requirement at § 422.101(f)(2)(ii), however, would result in a reduction of existing information collection burden, as described later in the preamble of this proposed rule.

Under current § 422.101(f)(2)(ii), SNPs are required to ensure that all appropriate staff — whether employed, contracted, or non-contracted — are trained on the SNP's MOC in order to coordinate and/or deliver all covered services and benefits. Operationally, CMS requires that each SNP type, and certain subtypes, maintain separate approved MOCs. Specifically, MA organizations are not required to submit a separate MOC for a new Plan Benefit Package (PBP) if it is the same SNP type and subtype operating under an existing contract with an already-approved MOC. For example, an MA organization with an existing D-SNP and an approved MOC does not need to submit a separate MOC for a new D-SNP PBP under the same contract number. However, exceptions apply: C-SNPs covering different chronic conditions must maintain separate MOCs. For instance, an MA organization operating both a C-SNP for diabetes and a C-SNP for cancer under the same contract would be required to maintain two separate MOCs. Similarly, an I-SNP contract with one PBP serving institutionalized individuals and a separate PBP serving institutionalized-equivalent members in the community would require separate MOCs. CMS estimates that this proposed change would affect approximately 840 currently approved MOCs.

The burden associated with the current MOC training requirement consists of the time SNP sponsors spend preparing and submitting MOC training materials through an internal

communication platform, which contracted and non-contracted providers then access to complete plan-specific MOC training. CMS estimates the following annual burden per plan:

- A compliance officer spends 3 hours at $85.00/hr preparing a slide deck summarizing the SNP's MOC, for a burden of 2,520 hours (840 MOCs x 3 hr/response) at a cost of $214,200 (2,520 hr × $85.00/hr);
- A computer programmer spends 1 hour at $101.12/hr uploading the training materials to the plan's internal communication platform, for a burden of 840 hours (840 MOCs x 1 hr/response) at a cost of $84,941 (840 hr × $101.12/hr); and
- A compliance officer spends 5 hours at $85.00/hr verifying provider training completion through the platform's tracking capabilities and distributing training awareness materials to providers who have not yet completed the required training, for a burden of 4,200 hours (840 MOCs x 5 hr/response) at a cost of $357,000 (4,200 hr × $85.00/hr).

By removing the MOC training requirement at § 422.101(f)(2)(ii), CMS estimates a total annual burden reduction of minus 7,560 hours and minus $656,141.

TABLE IX.9: ANNUAL BURDEN REDUCTION

Respondent Type	Number of Respondents	Time per Response/Respondent	Total Time (hr)	Hourly Wage ($/hr)	Total Cost ($)
Compliance Officer (slide deck preparation)	840	(3)	(2,520)	85.00	(214,200)
IT Specialist (material upload)	840	(1)	(840)	101.12	(84,941)
Compliance Officer (training verification)	840	(5)	(4,200)	85.00	(357,000)
Total	840	varies	(7,560)	varies	(656,141)

CMS also anticipates that removing this requirement would reduce burden for SNP contracted and non-contracted providers. CMS estimates that each provider subject to the MOC training requirement currently spends approximately 1 hour annually completing MOC training for C-SNPs, or every 2 to 3 years for I-SNPs and D-SNPs, depending on the applicable MOC approval period. However, because CMS does not have reliable data on the total number of contracted and non-contracted providers subject to this requirement across all 840 approved

MOCs, CMS is unable to provide a precise aggregate burden estimate for the provider population. CMS invites public comment on the estimated number of providers subject to this requirement and the associated time burden, which would allow us to refine this estimate in any final rule.

6. ICRs Related to Network Adequacy (§ 422.116(a)(2)(ii), (b)(1)(xxviii), (b)(1)(xxix), (b)(2)(xiv), and (d)(7))

The following proposed changes will be submitted to OMB for review under control number 0938-1346 (CMS-10636).

CMS proposes to remove the network adequacy submission and review requirements for initial applicants and service area expansion (SAE) applicants under the MA application process. Under the current framework, prospective MA organizations are required to submit provider network data as part of the MA application, which is reviewed by CMS prior to contract approval.

Under this proposal, provider network submissions would no longer be required at the application stage. Instead, MA organizations would be required to submit provider network data during the first year the contract is operational, at which point CMS would conduct its network adequacy review.

This change does not eliminate the overall burden associated with network adequacy submissions; rather, it redistributes that burden from the pre-contract application period to the first operational contract year. The total number of full network adequacy reviews conducted by CMS is expected to remain consistent with current levels.

CMS also proposes to consolidate the existing separate network adequacy standards for Clinical Psychology and Clinical Social Work provider types into a single, unified Outpatient Behavioral Health (OBH) facility-specialty type standard. This consolidation is intended to streamline the network adequacy review process, reduce administrative complexity, and align the standards with current care delivery models.

Under the current framework, MA organizations are required to separately document and demonstrate network adequacy for Clinical Psychology and Clinical Social Work as distinct specialty categories. Under the proposed change, these two categories would be merged into the existing OBH standard, resulting in a single submission and review process for outpatient behavioral health network adequacy.

This consolidation is expected to result in a measurable reduction in respondent burden, as MA organizations will no longer be required to separately contract with, compile, document, and submit network data for two additional distinct behavioral health specialty categories. The total scope of network adequacy review remains substantively the same; however, the administrative effort required to prepare and submit the data is reduced.

Estimated Burden Impact compiled from the 2025 formal network adequacy reviews:

- Total exception requests (ER) received in 2025 formal review for Clinical Social Work: 55

++ Total ER provider validations for 2025 formal review for Clinical Social Work: 101

- Total ERs received in 2025 formal review for Clinical Psychology: 80

++ Total ER provider validations for 2025 formal review for Clinical Psychology: 253

- Estimated Time per ER, including provider validations: 1 hour at $85.00/hr. for a Compliance Officer

- Estimated Time per ER, including provider validations (Proposed, consolidated): 1 hour at $85.00/hr. for a Compliance Officer

- Estimated total ERs for OBH (proposed, consolidated) based on 2025 Formal Review: 25

- Estimated Net Reduction in Annual Time based on estimated time for completion outlined in CMS-10636: 131 hours

- Estimated Net Reduction in Annual Cost: $11,135.00 (131 hr. x $85.00/hr.)

Furthermore, this consolidation is anticipated to yield meaningful reductions in CMS operational workloads. By streamlining the behavioral health network adequacy standards into a single OBH category, MA organizations are expected to submit more complete and accurate network data from the outset, resulting in fewer submission deficiencies and exception requests. This, in turn, is projected to reduce the frequency and volume of follow-up communications between CMS and MA organizations, including requests for corrected or supplemental data. Additionally, with a simplified and unified standard, CMS anticipates a reduction in the scope of data analysis required to assess network adequacy compliance across behavioral health specialties. Fewer submission failures and clearer compliance expectations are also expected to result in a decrease in the number of compliance actions, corrective action plans, and associated administrative proceedings that CMS would otherwise need to initiate and manage. Collectively, these efficiencies are estimated to reduce CMS staff time dedicated to behavioral health network adequacy oversight by approximately 131 hours annually, representing an estimated cost savings to the Federal Government of approximately $11,135 per year (based on an hourly loaded labor rate of $85.00.

7. Updating Agent and Broker Compensation and Oversight (§§ 422.2272, 422.2274, 423.2272, and 423.2274)

a. ICRs Regarding Reporting of Agent and Broker Terminations (§§ 422.2271(b)(1)(ii) and 423.2271(b)(1)(ii)).

The following proposed changes will be submitted to OMB under control number 0938-TBD (CMS-10991).

The proposed rule requires MA organizations and Part D sponsors to provide CMS, within 15 calendar days, all agent and broker terminations due to violations of Federal law, CMS regulations, or relevant State laws and the reasons for termination. CMS does not expect a significant number of agents and brokers to be terminated. In plan year 2024 the Federally-facilitated Exchange (FFE) terminated 1,615 agents and in plan year 2025 the FFE terminated

1,544 agents[289]. With the FFE averaging 1,580 agents being terminated each year this amounts to an average of two agent terminations each year per contract (1,580 terminations / 761 contracts). CMS does not plan on requiring detailed reports, just a notification of the agents the MA organization or Part D sponsor is terminating and the reason for such termination, resulting in a minimal amount of reporting and burden. Reporting would only be based on an actual termination for a violation of Federal laws, CMS regulations, or relevant State laws. Based on these assumptions CMS believes the burden will be negligible. Based on the requirement to submit each termination, as proposed, MA organizations and Part D sponsors would incur a burden estimated increase of 2 hours per year. With 761 contracts using a business operations specialist, all other at $90.36/hr CMS estimates a burden of 1,522 hours (2 hr/year x 761 contracts) at a cost of $137,528 (1,522 hr x $90.36/hr). The collection of information requirements would be based on the number of agent and broker terminations by each MA organization or Part D sponsor.

TABLE IX.10: COST ESTIMATES FOR REPORTING OF AGENT AND BROKER TERMINATIONS

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
§§ 422.2271(b)(1)(ii) and 423.2271(b)(1)(ii)	761 MA/Part D Plan Contracts	761	2	1,522	90.36	$137,528	$137,528

b. ICRs Regarding Compensation Submission of Documentation, Including, Contracts (§§ 422.2271(b)(3)(iv) and 423.2271(b)(3)(iv)).

The following proposed changes will be submitted to OMB under control number 0938-TBD (CMS-10991).

The proposed rule requires MA organizations and Part D sponsors to provide documentation, including contracts, regarding compensation. Documentation would only need to be submitted as requested by CMS. CMS anticipates that the Agency will only request 100 contracts or less for review. Based on this, CMS will only be requesting contracts or other

[289] https://data.healthcare.gov/ab-suspension-and-termination-list

documentation from 100 or fewer MA organizations and/or Part D sponsors. CMS expects that such a limited request would result in negligible burden overall for the MA and Part D programs. CMS estimates that it will take MA organizations and Part D sponsors one (1) hour to gather and provide CMS with each contract. Using a business operations specialist, all other, CMS estimates the total cost for gathering and providing 100 contracts to CMS would be $9,036 (100 contracts x 1 hr x $90.36/hr) for each year.

TABLE IX.11: COST ESTIMATES FOR COMPENSATION SUBMISSION OF DOCUMENTATION

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
§§ 422.2271(b)(3)(iv) and 423.2271(b)(3)(iv)	100 MA/Part D Plan Contracts	100	1	100	90.36	$9,036	$9,036

c. ICRs Regarding Collecting Supplemental Compensation (§§ 422.2271(b)(3)(iii)(A)-(C) and 423.2271(b)(3)(iii)(A)-(C))

The following proposed changes will be submitted to OMB under control number 0938-TBD (CMS-10991).

In this rule, CMS is also proposing at new §§ 422.2271(b)(3)(iii)(A) through (C) and 423.2271(b)(3)(iii)(A) through (C), that MA organizations and Part D sponsors, by the last Friday in July, report to CMS the supplemental compensation (if any) that the MA organization or Part D sponsor will pay independent agents and brokers for each plan, including the specific type, monetary amounts or retail value of non-monetary compensation, and a detailed explanation of supplemental compensation programs, including payment schedules. CMS notes that plans have no requirement or obligation to pay supplemental compensation to agents and brokers. The supplemental compensation reporting would be an annual submission to CMS and the initial year of reported supplemental compensation would be contract year 2028. The collection of supplemental compensation data will allow CMS to better understand the types of supplemental compensation agents and brokers receive, the frequency and monetary value of

such compensation, the metrics or conditions used to determine supplemental compensation, and variation in compensation arrangements across MA organizations and Part D sponsors.

CMS estimates that a subset of 60 percent of MA organizations and Part D sponsors will utilize supplemental compensation and hence be required to annually submit supplemental compensation data. For those MA organizations and Part D sponsors who will be submitting supplemental compensation data, at this time, CMS does not have sufficient information regarding supplemental compensation arrangements and therefore makes a general estimate that plans will have on average two supplemental compensation arrangements per contract that they would submit to CMS annually. Since this would be a new requirement, CMS is unclear whether there would be more than two supplemental benefit arrangements on average and solicits comments from stakeholders on whether more or less per contract would be more appropriate, and any estimates on how many supplemental arrangements commenters might expect to submit to CMS annually.

Given these assumptions, for 457 contracts (761 contracts x 0.6), CMS estimates that submitting supplemental compensation amounts for two (2) supplemental compensation arrangements will take a business operations specialist, all other 2 hours at $90.36/hr. Therefore, the total annual burden for the 457 MA organization and Part D sponsors to submit supplemental compensation each year would be 914 hours (457 contracts x 2 hr/contract) at a cost of $82,589 (914 hr x $90.36/hr).

TABLE IX.12: COST ESTIMATES FOR COLLECTING SUPPLEMENTAL COMPENSATION

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
(§§ 422.2271(b)(3)(iii)(A)-(C) and 423.2271(b)(3)(iii)(A)-(C)	761 MA/Part D Plan Contracts	457	2	914	90.36	$82,589	$82,589

d. ICRs Regarding Change Made to Compensation Amounts (§§ 422.2274(a)(5) and 423.2274(a)(5)).

The following proposed changes will be submitted to OMB under control number 0938-TBD (CMS-10991).

This proposed rule would permit MA organizations and Part D sponsors to change their compensation throughout the plan year, and that those changes would go into effect 30 days after the change is made in the form and manner prescribed by CMS. CMS notes that, as currently required under §§ 422.2274(c)(5) and 423.2274(c)(5), plans may change their compensation amounts at any time throughout the plan year, provided it falls within CMS' Fair Market Value range (min/max) submitted. The burden under this proposed rule would involve plans submitting updated data to CMS with new compensation amounts should an MA organization or Part D sponsor decide to change compensation during the plan year. Above, CMS calculated the burden of the new proposal to collect supplemental compensation. For both base and supplemental compensation, CMS only expects a small number of organizations to change their compensation during the plan year, especially since CMS's understanding is that it is typical for contracts between MA organizations or Part D sponsors and agents and brokers to generally span an entire year. Given these assumptions, CMS estimates that 10 percent of contracts will change their base compensation during the contract year, resulting in approximately 10 percent of the 761 contracts or 76 contracts (761 contracts x 0.10) having to resubmit compensation amounts. CMS estimates that resubmitting compensation amounts will take one (1) hour at $90.36/hr using a business operations specialist, all other. Therefore, the total burden for the 76 MA organization and Part D sponsors that change their compensation each year would be 76 hours (76 contracts x 1 hr/contract) at a cost of $6,867 (76 hr x $90.36/hr).

CMS also estimates that 10 percent of contracts will change their supplemental compensation during the contract year. With 761 contracts, approximately 76 will have to resubmit compensation amounts. CMS estimates that resubmitting compensation amounts will take 1 hour at $90.36/hr for a business operations specialist, all other. Therefore, the total annual

burden for the 76 MA organization and Part D sponsors that change their compensation each year would be 76 hours (76 contracts x 1 hr/contract) at a cost of $6,867 (76 hr x $90.36/hr).

Combining the burden for changing both base and supplemental compensation, CMS estimates that the total annual burden for the 152 MA organizations and Part D sponsors that change their base and supplemental compensation each year would be $13,735 (152 x 1 hr x $90.36).

TABLE IX.13: COST ESTIMATES FOR CHANGING COMPENSATION AMOUNTS

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
§§ 422.2274(a)(5) and 423.2274(a)(5)	152 MA/Part D Plan Contracts	152	1	152	90.36	$13,735	$13,735

8. ICRs Regarding Cost Sharing Standards for Ground Ambulance and Emergency Services (§§ 422.100 and 422.113)

As discussed in section III.D of this proposed rule, this proposal requires MA plans (including employer group waiver plans [EGWPs]) in-network cost sharing for ground ambulance and emergency services to be subject to the following cost sharing standards, beginning in contract year 2028:

- Ground ambulance – the range of cost sharing limits at § 422.100(f)(6)(iii).
- Emergency services – dollar limits that are actuarially equivalent to 15 to 20 percent of the most recent Medicare FFS data projections.

Specifically, this proposal: (1) changes the current in-network service category cost-sharing limits for ground ambulance and emergency services; and (2) updates current policies governing organization bid requirements about how benefits must be provided by plans, which are currently approved by OMB under control number 0938-0763 (CMS-R-262).

As CMS confirms in annual bid reviews, MA organizations already comply with CMS actuarial guidelines as required by § 422.254(b)(5), (c)(5), and (c)(6). Following these guidelines

requires use of generally accepted actuarial principles, the actuarial bases of the bid, a description of cost sharing applicable under the plan and the actuarial value of the cost sharing. CMS relies on its oversight and monitoring authority and longstanding bid review policy (and the compliance program, recordkeeping, audit and access requirements at §§ 422.503 and 422.504) to request any additional information and necessary documentation from organizations to investigate plan compliance with the program and benefit requirements.

Consequently, CMS asserts that that this proposal does not impose any new or revised collection of information requirements or related burden and is not subject to the requirements of the PRA because: (1) this proposal does not change how CMS evaluates compliance with cost-sharing limits as part of bid review; (2) plans comply with CMS's current practice; and (3) this proposal does not change any bid documentation requirements in the CMS issued, annual bid instructions.

C. Summary of Proposed Information Collection Requirements and Associated Burden

TABLE IX.14: SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN

Regulatory Section in Title 42 of the CFR	Brief Description	OMB Control No. (CMS ID No.)	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
§ 422.112(d)	Enrollee Notification Requirements for Provider Terminations, Continuity of Care, and SEP Notice Consolidation	0938-INSERT (CMS-10981)	5,533 MA plans	NA	2	N/A	135.54	N/A	N/A
§§ 422.111(e) and 422.2267(e)(12)	Enrollee Notification Requirements for Provider Terminations, Continuity of Care, and SEP Notice Consolidation	0938-INSERT (CMS-10981)	708 MA organizations	475	8	N/A	135.54	N/A	N/A
§ 422.111(e)(3)	Enrollee Notification Requirements for Provider Terminations, Continuity of Care, and SEP Notice Consolidation	0938-INSERT (CMS-10981)	708 MA organizations	475	1	N/A	135.54	N/A	N/A
§ 422.202(c)(1)	Use of Existing Interoperability API for Prior Authorization Transactions	0938-1437 (CMS-10843)	708 MA organizations	708	3	2,124	90.36	191,925	N/A
§ 422.202(c)(2)	Use of Existing Interoperability API for Prior Authorization Transactions	0938-1437 (CMS-10843)	708 MA organizations	708	40	28,320	110.20	3,120,864	3,120,864
§ 422.504(p)	Medicare Transaction Facilitator: Providers	0938-1483 (CMS-10912)	Providers that furnish or administer drugs selected for the Medicare Drug Price Negotiation Program	16,000	8	128,000	578.52	18,512,640	18,512,640
§ 422.504(q)(1)-(2)	Submission of Encounter Data Records for Selected Drugs	0938-1152 (CMS-10340)	708 MA organizations	972,500	0.03	29,175	67.10	1,799,125	1,799,125
§§ 422.2267(e)(vi) and 423.2267(e)(vi)	Low Performer Icon (LPI) Notice	0938-NEW (CMS-TBD)	2 MA organizations and Part D sponsors	2	2	4	50.88	11,997	11,997
§ 422.101(f)	Reducing Model of Care (MOC) Burden, Improving Special Needs Plans (SNP) Care Coordination Requirements, and Updating HRA Outreach Requirements	0938-1296 (CMS-10565)	565 Model of Care submissions from SNPs	840	(9)	(7,560)	Varies	(656,141)	N/A
§ 422.116	Changes to the MA Application and Network Adequacy	0938-1346 (CMS-10636)	708 MA organizations	512	N/A	N/A	85.00.50	N/A	N/A
§ 422.116(b)	Changes to the MA Application and Network Adequacy	0938-1346 (CMS-10636)	708 MA organizations	512	8	4,096	85.00	348,160	348,160
§§ 422.2271(b)(1)(ii) and 423.2271(b)(1)(ii)	Updating Agent and Broker Compensation and Oversight	0938-INSERT (CMS-10991)	761 MA/Part D Plan Contracts	761	2	1,522	90.36	137,528	137,528
§§ 422.2271(b)(3)(iv) and 423.2271(b)(3)(iv)	Updating Agent and Broker Compensation and Oversight	0938-INSERT (CMS-10991)	100 MA/Part D Plan Contracts	100	1	100	90.36	9,036	9,036

Regulatory Section in Title 42 of the CFR	Brief Description	OMB Control No. (CMS ID No.)	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost 1st Year ($)	Total Cost Subsequent Years ($)
§§ 422.2271(b)(3)(iii)(A)-(C) and 423.2271(b)(3)(iii)(A)-(C)	Updating Agent and Broker Compensation and Oversight	0938-INSERT (CMS-10991)	761 MA/Part D Plan Contracts	457	2	914	90.36	82,589	82,589
§§ 422.2274(a)(5) and 423.2274(a)(5)	Updating Agent and Broker Compensation and Oversight	0938-INSERT (CMS-10991)	152 MA/Part D Plan Contracts	152	1	152	90.36	13,735	13,735
§§ 422.100 and 422.113	Cost Sharing Standards for Ground Ambulance and Emergency Services	0938-0763 (CMS-R-262)	708 MA organizations	708	N/A	N/A	N/A	N/A	N/A
Total				994,910	Varies	186,847	Varies	23,571,458	24,035,674

X. Regulatory Impact Analysis

A. Statement of Need

This proposed rule addresses several critical needs in the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), PACE organizations, and Medicare cost plans that require regulatory action to ensure program integrity, beneficiary protection, and statutory compliance. This rule also includes proposals intended to implement new requirements, codify existing subregulatory guidance, and provide greater clarity and operational consistency for plans operating in the MA and Part D spaces for contract year 2028.

This proposed rule includes a wide range of provisions to strengthen the MA and Part D programs for contract year 2028. Key proposals address beneficiary protections – including standardized healthy food definitions for supplemental benefits, improved provider termination notifications, continuity of care guarantees, and better-aligned cost-sharing for ambulance and emergency services. The rule also targets program integrity through tighter controls on the Disaster/Emergency SEP and enrollment capacity limits, while modernizing operations via mandatory use of a FHIR-based Prior Authorization API, policies to facilitate manufacturer effectuation of maximum fair prices for selected drugs administered or furnished to Medicare Advantage enrollees, and a streamlined agent and broker compensation framework. Additional provisions would update MA application and network adequacy requirements, and improve Medicaid coordination for Special Needs Plans serving dually eligible individuals.

This rule proposes to establish the Aligning Data and Value to Nurture Competition and Efficiency in Medicare Advantage (ADVaNCE MA) model under section 1115A of the Act to test whether alternative quality programs, targeted supplemental benefits, and an alternative risk adjustment methodology can improve care quality for MA enrollees without increasing costs to the Medicare program. The absence of a rigorous, mandatory testing mechanism limits CMS' ability to generate the evidence needed to drive data-informed improvements to MA payment and care delivery in future rulemaking.

The absence of regulatory action would result in ongoing operational inefficiencies and missed opportunities for program improvement and innovation. Therefore, this rulemaking is necessary to ensure the Medicare program operates effectively, efficiently, and in compliance with Federal law while serving the best interests of Medicare beneficiaries.

B. Overall Impact Analysis

We have examined the impacts of this proposed rule as required by Executive Order 12866, "Regulatory Planning and Review"; Executive Order 13132, "Federalism"; Executive Order 13563, "Improving Regulation and Regulatory Review"; Executive Order 14192, "Unleashing Prosperity Through Deregulation"; the Regulatory Flexibility Act (RFA) (Pub. L. 96-354); section 1102(b) of the Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as 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 the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant under section

3(f)(1) of E.O. 12866.

C. Detailed Economic Analysis

Many provisions of this proposed rule have negligible impact either because they are technical provisions or because they are clarifications. Throughout the preamble we have noted when we estimated that provisions have no impact. Additionally, this RIA discusses several provisions with either zero impact or impact that cannot be quantified. The remaining provisions' effects are estimated in section IX of this proposed rule, which estimates costs associated with paperwork burden resulting from this rule. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this RIA cross-references impacts from section IX of this proposed rule in order to arrive at the total impact. Table X.1 summarizes the estimated transfers and costs associated with the various provisions in this proposed rule over a 10-year period. Further details are provided later in this RIA.

TABLE X.C-1: SUMMARY OF THE TRANSFERS AND COSTS OF THE PROPOSED RULE BY PROVISION FOR YEARS 2028-2037 (In $ Millions)

Category of Provisions	Year(s)										
Transfers	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**	**2035**	**2036**	**2037**	**2028-2037**
Effects of Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System	N/A	N/A	N/A	(11,500.0)	(12,740.0)	(13,980.0)	(15,370.0)	(16,610.0)	(17,880.0)	(18,880.0)	(106,960.0)
Improvements for Special Needs Plans - Amend definition of FIDE SNP	42.0	46.0	50.0	54.0	58.0	64.0	68.0	72.0	75.0	79.0	608.0
Improvements for Special Needs Plans - Update to default enrollment for states transitioning from Medicaid FFS to Medicaid managed care	(5.0)	6.0	11.0	11.0	12.0	13.0	14.0	15.0	16.0	17.0	110.0
Improvements for Special Needs Plans -Expanding the Definition of HIDE SNP	(4.0)	(8.0)	(14.0)	(19.0)	(24.0)	(31.0)	(37.0)	(45.0)	(53.0)	(61.0)	(296.0)
TOTAL TRANSFERS	33.0	64.0	47.0	(11,454.0)	(12,694.0)	(13,934.0)	(15,325.0)	(16,568.0)	(17,842.0)	(18,845.0)	(106,268.0)
From the Medicare Trust Funds to MA Organizations and Part D Sponsors											
COSTS*	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**	**2035**	**2036**	**2037**	**2028-2037**
Use of Existing Interoperability API for Prior Authorization Transactions	3.3	3.1	3.1	3.1	3.1	3.1	3.1	3.1	3.1	3.1	31.4
Strengthening Maximum Fair Price Effectuation Policies for Medicare Advantage	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.8	18.0
Updating Agent and Broker Compensation and Oversight	(82.0)	(82.3)	(82.3)	(82.3)	(82.3)	(82.3)	(82.3)	(82.3)	(82.3)	(82.3)	(822.5)
Expanding Electronic Delivery of Required Enrollee Communications	(187.2)	(187.2)	(187.2)	(187.2)	(187.2)	(187.2)	(187.2)	(187.2)	(187.2)	(187.2)	(1,872.0)
Other Provisions†	23.6	24.0	24.0	24.0	24.0	24.0	24.0	24.0	24.0	24.0	239.9
TOTAL COSTS	(240.5)	(240.1)	(240.1)	(240.1)	(240.1)	(240.1)	(240.1)	(240.1)	(240.1)	(240.1)	(2,424.6)

* Figures in the Costs section of Table X.1 have been rounded to the nearest tenth of one million. For that reason, numbers in the 2028-2037 column may not equal the sum of columns 2028 through 2037.

†The Other Provisions row includes estimates for first year and annually recurring impacts for the provision Removing the Requirement for the TPMO Disclaimer and the Information Collection Requirements of the following provisions: Reducing Model of Care (MOC) Burden, Improving Special Needs Plans (SNP) Care Coordination Requirements, and Updating HRA Outreach Requirements; Updating Agent and Broker Compensation and Oversight; Changes to the MA Application and Network Adequacy; Enrollee Notification Requirements for Provider Terminations, Continuity of Care, and SEP Notice Consolidation; Low Performer Icon (LPI) Notice; and Strengthening Maximum Fair Price Effectuation Policies for Medicare Advantage.

1. Cost Sharing Standards for Ground Ambulance and Emergency Services (§ 422.100 and 422.113)

As discussed in section III.D. of this proposed rule, this proposal requires MA plans (including employer group waiver plans (EGWPs)) in-network cost sharing for ground ambulance and emergency services to be subject to the following cost sharing standards, beginning in contract year 2028: (1) ground ambulance—the range of cost sharing limits at § 422.100(f)(6)(iii); and (2) emergency services—dollar limits that are actuarially equivalent to 15-20 percent of the most recent Medicare FFS data projections. CMS expects that this proposal to update the cost sharing standards for ground ambulance and emergency services will result in MA plans changing cost sharing amounts across service categories and MOOP limits.

From an aggregate perspective, CMS assumes that this proposal will not result in: (1) additional out of pocket costs for MA enrollees compared to beneficiaries in Original Medicare; or (2) significant losses for MA organizations. This is because there is a statutory requirement for MA organizations to submit bids that are at least actuarially equivalent to coverage in Original Medicare. This statutory requirement is operationalized through an actuarial equivalence test based on a projection of MA cost sharing under each plan. At the time that the actuarially equivalent cost sharing amounts are calculated, the expectation is that there will be no costs or savings for the policy year in question. As a result, the plan will cover—and MA enrollees would receive—the same level of total benefits on average in each contract year prior to and after implementation.

If this proposal is finalized, CMS would not experience additional burden because adjustments to the plan benefit package could be made as part of normal business operations as needed. In addition, CMS expects this proposal would prompt some organizations to adjust their plan benefit designs, primarily to come into compliance with this proposal, if: (1) any of their

contract year 2027 plan benefits are not compliant with the proposed ground ambulance[290] cost-sharing standards for contract year 2028 and (2) they submit a bid to continue that plan offering for contract year 2028. Further, enrollees who remain in those continuing plans are expected to experience changes in cost that will change over time based on their health status and service utilization (for example, ground ambulance services or other service categories).

These potential impacts to organizations and enrollees are discussed in greater detail in the following section. In brief, CMS expects this proposal will result in:

- Non-significant changes to total plan costs; as such MA plans will likely shift cost sharing by service category and MOOP limits to maintain benefits that are actuarially equivalent to current benefit packages.

- Enrollees utilizing emergency services less often while increasing utilization of other services (for example, urgent care); which is likely to result in:

++ Neutral financial impacts given that that change in utilization may create savings or additional costs, depending on whether the forgone emergency services were necessary or not.

++ Negligible impacts on hospitalization rates given that most MA plans waive emergency services cost sharing when the enrollee is admitted as an inpatient to the same hospital within a 3-day window from an emergency department visit (the expectation being that an enrollee needing emergency services at an urgent care clinic would be transferred to an emergency department and then admitted as an inpatient with zero emergency department cost sharing).

a. Potential Impacts of Ground Ambulance and Emergency Services Cost-Sharing Standard Changes on MA Organizations and Enrollees

CMS expects in the first applicable contract year when the proposed ground ambulance and emergency services cost-sharing limits would apply (contract year 2028), MA organizations

[290] As this proposal for emergency services cost sharing standards would result in increases to the dollar limits (based on the most recent Medicare FFS data projections), all MA plans are already compliant and changes to their emergency services cost sharing amounts would be at the plan's discretion.

may or may not have increased costs to provide these services. This is because plans incorporate varying cost sharing arrangements for these services—with amounts less than, greater than, or equal to the proposed ground ambulance and emergency services cost sharing standards.

First, for ground ambulance services, continuing plans that previously established cost sharing for these services at amounts that are equal to or less than the proposed cost sharing standard (a range of cost sharing limits based on MOOP type), may not have any cost impacts as a direct result of this proposal. In contrast, CMS expects MA organizations offering plans with previously established cost sharing for ground ambulance services at amounts that exceed the proposed cost sharing standard will: (1) reduce their ground ambulance cost sharing amounts to come into compliance with this proposal and (2) have increased costs to provide ground ambulance services. Based on contract year 2026 plan data, as shown in Tables X.9 and III.D-7, 65 percent of MA plans have ground ambulance cost sharing amounts that exceed the proposed standard by $75 on average. As a result, CMS believes if this proposal is finalized, then roughly 65 percent of MA plans may lower their ground ambulance cost sharing amounts by $75 on average to come into compliance. However, this is only a rough estimate based on contract year 2026 plan data with the following limitations:

- Those figures do not account for the percentage of plans that may choose to non-renew or change their MOOP type (and thus their applicable cost sharing standard).
- The $75 average cost sharing change assumes that MA organizations will only lower their ground ambulance cost sharing amounts by the minimum necessary amount to come into compliance.

Second, for emergency services, MA plans are currently subject to dollar limits that are less than the proposed cost sharing standard based on the most recent Medicare FFS data projections. Based on contract year 2026 and prior year plan data, it is possible the existing dollar limits have incentivized some MA organizations to switch their plans from mandatory to a lower or intermediate MOOP types. For example, as shown in Table X.C-2, of the MA plans that

switched from a mandatory MOOP type to a lower or intermediate MOOP type in contract year 2026, the percent of plans that utilized[291] cost-sharing flexibilities was about 89 percent for emergency services; 63 percent for urgently needed services; 31 percent for occupational therapy; and less than 30 percent for all other service categories.

CMS takes these percentages of utilization as evidence that the current cost-sharing flexibilities for emergency services and urgently needed services may be influential on lower MOOP type adoption.[292] As a result, this aspect of CMS's proposal—updating emergency services dollar limits annually based on the most recent Medicare FFS data projections—may decrease the incentive for MA plans to offer lower MOOP types in future years. This is because the most recent Medicare FFS data projections have shown a trending increase in emergency services costs. As a result, dollar limits based on the most recent Medicare FFS projections would provide more flexibility within each MOOP type compared to the current limits. However, the other aspect of CMS's proposal—making ground ambulance services subject to a range of cost sharing limits—would increase the incentive for lower MOOP types in comparison to the existing 50 percent coinsurance standard (that applies to all MOOP types). At this time, CMS cannot predict the extent to which the proposed cost sharing standard changes in combination may influence MA plans to adopt lower MOOP types. The percentage of plans offering the various MOOP types is provided in Table III.D-8. As shown in Table III.D-8, 29 percent of contract year 2026 plans offer a lower MOOP type. If this proposal is finalized, CMS will monitor the trend of MOOP type adoption and may consider proposing additional changes to cost sharing or MOOP limit standards if lower MOOP type adoption decreases in future years and CMS has determined that adoption of lower MOOP types by MA plans is a priority of the agency.

TABLE X.C-2: MA PLANS THAT SWITCHED TO LOWER MOOP TYPES IN

[291] In this context utilizing a cost sharing flexibility means the plan established a cost sharing amount for a service category that is greater than the applicable cost-sharing limit set for the mandatory MOOP type.
[292] The number and percentage of plans that utilized each service category cost sharing flexibility do not total to 100 percent as most plans that switched utilized cost-sharing flexibilities from multiple service categories.

CONTRACT YEAR 2026 AND UTILIZED* COST-SHARING FLEXIBILITIES BY SERVICE CATEGORY

Service Category	Number of Plans that Switched MOOP Types and Utilized Cost-Sharing Flexibility	Percent of Plans that Utilized the Cost-Sharing Flexibility Out of the Total Number of Plans that Switched MOOP Types
Emergency Services	31	88.6%
Urgently Needed Services	22	62.9%
Occupational Therapy	11	31.4%
Skilled Nursing Facility 1-20	10	28.6%
SET for PAD Services	10	28.6%
Inpatient Hospital Acute – 10 Days	9	25.7%
Inpatient Hospital Psychiatric – 8 Days	9	25.7%
Cardiac Rehabilitation Services	9	25.7%
Pulmonary Rehabilitation Services	9	25.7%
Inpatient Hospital Acute – 6 Days	8	22.9%
Partial Hospitalization	8	22.9%
Inpatient Hospital Psychiatric – 15 Days	3	8.6%
Physician Specialist Services	3	8.6%
Physical Therapy and Speech-Language Pathology Services	1	2.9%
All Other Service Categories	0	0%
Total Number of Plans that Switched MOOP Types**	**35**	**100%**

*Notes: In this context, utilizing a cost sharing flexibility means the plan established a cost sharing amount for a service category that is greater than the applicable cost-sharing limit set for the mandatory MOOP type.
**Notes: The number and percentage of plans that utilized each service category cost sharing flexibility do not total to 100 percent as most plans that switched utilized cost-sharing flexibilities from multiple service categories.

Overall, if this proposal is finalized, then CMS expects MA organizations will consider:

- Raising their emergency services cost sharing amount to take advantage of the higher dollar limits.
- Lowering their ground ambulance services cost sharing amount to, at a minimum, come into compliance with the new standard.
- Changing the plan's MOOP type, to access the cost sharing flexibilities for these, and perhaps additional, service categories.

However, MA plan bids must: (1) remain at least actuarially equivalent to Original Medicare; and (2) satisfy Original Medicare coverage requirements. As a result, CMS expects the total change experienced by enrollees on a per member per month (PMPM) basis will be minimal.

MA enrollee out-of-pocket costs change each year based on: (1) how organizations update their plan benefit designs (within the cost sharing limits and standards set by CMS), (2)

enrollees' health conditions and use of services, and (3) enrollment switching patterns, if applicable. As a result, the specific adjustments organizations make in response to this proposal would in turn determine the varying individual financial impacts enrollees would experience. As an illustrative example, in response to this proposal, a continuing MA plan for contract year 2028 may: (1) reduce cost sharing for ground ambulance services; and (2) increase cost sharing for emergency services. The extent to which CMS expects these changes is shown and discussed in section III.D of this proposed rule: Tables III.D-5 and III.D-6 compare average MA plan cost sharing and the illustrative limits of this proposal for ground ambulance and emergency services and Table III.D-7 compares the illustrative ground ambulance cost sharing limits posed by this proposal against contract year 2026 MA plan cost sharing (of MA plans with cost sharing that exceeds the proposed limits) to assess the expected average change to MA ground ambulance cost sharing amounts if this proposal is finalized.

Based on the allowable increases to average emergency services cost sharing amounts shown in Table III.D-6, CMS expects that if this proposal is finalized that some MA enrollees may consider seeking care at an urgent care center over the emergency room because this proposal is expected to increase the differential of average cost sharing between urgently needed services and emergency services. Currently urgently needed services are subject to a range of cost sharing limits (between $40 to $65 based on MOOP type for contract year 2026), which CMS is not proposing to change. MA plans have on average a $39 copayment limit for these services. As a result, CMS expects this proposal has the potential to produce changes in MA enrollee utilization of services – this utilization change in turn may result in additional costs or a cost savings for the MA plan—based on whether emergency services were necessary at the time:

- If the emergency services were necessary and the enrollee went to urgent care instead—the urgent care centers would be expected to refer those patients to the ER, resulting in an overall extra cost for the MA plan.
- If the emergency services were not necessary and the enrollee went to urgent care

instead of the emergency room, there would be cost savings for the MA plan.

A discussion of possible quantification of these potential effects follows.

b. Impact Analysis: Proposed Ground Ambulance and Emergency Services Cost-Sharing Standards

The aggregate, short term impact of this proposal on MA organizations and enrollees should be minimal due to the statutory requirement that plans remain actuarially equivalent to Original Medicare. However, as noted previously and shown in Tables III.D-5 – III.D-7, MA plan cost sharing amounts for – and thus potential enrollee utilization of – emergency and ground ambulance and other service categories may change as a direct result of this proposal. Given this, there are possible impacts on similarly situated organizations (for example, those that experience decreased enrollee utilization of emergency services) and on enrollees (for example, those with or without conditions that require emergency and transport services). CMS cannot currently project these impacts because MA plans are not required to retain a particular MOOP type from one contract year to the next — which determines the applicable ground ambulance and emergency services cost sharing limits under this proposal — or to redistribute cost sharing in any particular manner. Instead, plans may design benefits in any way that maintains compliance with the dollar limits tied to their chosen MOOP type and with actuarial equivalence requirements. If this proposal is finalized, CMS will assess its actual impact on plan cost sharing by reviewing MA plan MOOP type and service category cost sharing changes for contract year 2028, once available after the bid submission deadline.

2. Enrollee Notification Requirements for Provider Terminations, Continuity of Care, and SEP Notice Consolidation (§§ 422.111(e), 422.112(b), and 422.2267(e)(12))

CMS is proposing several changes to regulations governing provider network terminations in MA. These proposals include: (1) revising the timing and content of required enrollee notices for provider terminations; (2) establishing new minimum continuity of care standards requiring MA organizations to cover services from a terminated provider for at least 90

days at in-network cost-sharing rates; (3) requiring MA organizations to include special election period (SEP) eligibility information in the provider termination notice when CMS has determined that the affected enrollee qualifies for the SEP at § 422.62(b)(23); (4) updating the affected enrollee definition to a uniform 1-year lookback period; and (5) codifying longstanding criteria used to identify whether a provider termination constitutes a significant change in a plan provider network at § 422.112(d).

a. Savings from Simplified and Streamlined Notice Requirements

CMS anticipates that the proposed revisions to the provider termination notice requirements will generate administrative savings for MA organizations. Most notably, the proposal to eliminate the telephonic notice requirement at § 422.111(e)(1)(i) removes a distinct and operationally burdensome notification pathway that currently requires MA organizations to maintain separate telephonic outreach processes in addition to written notice. The elimination of this requirement is expected to reduce per-termination administrative costs for MA organizations.

Additionally, the proposed update to the affected enrollee definition at § 422.111(e)(3) and § 422.62(b)(23)(ii) to a uniform 1-year lookback period is expected to reduce net administrative costs by eliminating the need for MA organizations to run separate queries and maintain separate enrollee populations by provider type. Under the proposed rule, MA organizations would identify affected enrollees through a single query, maintain one list, and issue one consolidated notice—rather than managing two separate enrollee populations for what is, in effect, a single network disruption event.

CMS is unable to quantify these savings at this time because the per-notice cost of telephonic outreach and the administrative cost of maintaining dual enrollee populations vary across MA organizations and are not available to CMS.

CMS solicits comment on the estimated per-notice cost savings associated with eliminating the telephonic notice requirement, the estimated administrative savings associated

with consolidating the affected enrollee query and list maintenance process, and the number of provider termination events per year for which MA organizations currently issue notices.

b. Financial Burden on MA Organizations from 90-Day Continuity of Care Requirement

The proposed continuity of care requirement at § 422.112(b)(9), which would require MA organizations to cover services from a terminated provider for a minimum of 90 days at in-network cost-sharing rates, may impose financial costs on MA organizations. However, CMS is unable to quantify the financial burden of this requirement at this time because the costs depend on variables that are not available to CMS.

CMS solicits comment on the estimated number of provider terminations per year that would trigger the continuity of care requirement, the estimated number of affected enrollees who would utilize continuity of care services during the 90-day period, the types of services most commonly utilized during continuity of care periods, and the estimated differential between in-network and out-of-network rates for those services.

c. Net Effect of Codifying Significance Determination Criteria (§ 422.112(d))

The proposed codification of significance determination criteria at new § 422.112(d) formalizes a process that MA organizations are already expected to follow under sub-regulatory guidance in Chapter 4 of the Medicare Managed Care Manual. The proposed 60-day notification requirement is consistent with the existing § 422.202(d)(4) provider notification timeframe. Because this proposal codifies existing sub-regulatory practice rather than imposing an entirely new obligation, CMS does not anticipate a significant net increase in administrative burden attributable to this provision.

CMS solicits comment on the current frequency with which MA organizations submit significant provider termination notifications to CMS under the existing sub-regulatory guidance, whether the proposed codified criteria align with the standards MA organizations currently apply internally, and whether codification is expected to increase or decrease reporting volume relative to current practice.

3. Use of Existing Interoperability API for Prior Authorization Transactions

The provision requiring MA organizations and their contracted providers to utilize the Prior Authorization API for prior authorization transactions is projected to increase costs for the 708 affected MA organizations by approximately $3,312,789 million in contract year 2028, with $3,120,864 in annual costs expected to continue in subsequent years. This cost estimate reflects the ongoing administrative burden associated with coordinating, conducting, and documenting the required annual bidirectional API testing with contracted providers. Because the underlying API infrastructure is already mandated under existing regulations, these costs are attributable primarily to operational compliance activities rather than new technical infrastructure investment.

4. Strengthening Maximum Fair Price Effectuation Policies for Medicare Advantage (§ 422.100 and § 422.504)

CMS is proposing to require that any out-of-network cost sharing for selected drugs payable under Part B subject to an MFP is calculated based on a price that does not exceed the MFP (as defined in proposed § 422.2). CMS is also proposing four changes to facilitate manufacturer effectuation of the MFP for selected drugs payable under Part B for which an MFP is in effect that are furnished or administered to MA enrollees. These proposals include: (1) at proposed § 422.504(p) requiring any contract between an MA organization and a provider, or between a first tier, downstream, or related entity and a provider on the MA organization's behalf, for participation in one or more of the MA organization's networks include a provision that if the provider furnishes or administers selected drugs payable under Part B during the period when such drugs are subject to an MFP, the provider must be enrolled in the Medicare Transaction Facilitator Data Module (MTF DM) and 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, in a form and manner determined by CMS; (2) at proposed § 422.504(q)(1)(i)) requiring MA organizations to submit MA encounter data records

involving the furnishing or administration of selected drugs payable under Part B for which an MFP is in effect on the claim-from date within 30 days of the claim-from date; (3) at proposed § 422.504(q)(1)(ii) requiring MA organizations to collect and submit NDC-11s on MA encounter data records for selected drugs payable under Part B for which an MFP is in effect on the claim-from date; and (4) at proposed § 422.504(q)(2) requiring MA organizations to certify, in a form and manner specified by CMS, that the data submitted under § 429.504(q)(1) is complete, accurate, and truthful.

a. Medicare Advantage Out-Of-Network Cost Sharing for Selected Drugs Payable Under Part B

Under this proposal, coinsurance for selected drugs subject to an MFP furnished or administered by an out-of-network provider would be calculated based on a price no greater than the MFP. We expect this policy to have no impact on overall MA expenditures.

MA plan sponsors are required to establish cost sharing for basic benefits specified by CMS that do not exceed levels annually determined by CMS to be discriminatory, as set forth at § 422.100(f)(6). MA plan sponsors that establish out-of-network cost sharing for Part B drugs are required to include this cost sharing in their prospective bid calculation. As a result, any plan-level cost changes arising from this proposal, including adjustments to beneficiary cost-sharing obligations, must be fully reflected in prospective bid calculations. Per § 422.100(j)(2), an MA plan's total cost sharing for all basic benefits must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis. Therefore, to the extent that this policy reduces cost-sharing on the selected drugs with an MFP below total financial liability, MA plan bids will likely respond by raising cost-sharing for other benefits (such as other Part B drugs) in order to maintain compliance with the requirements from paragraph (j)(2). These potential cost sharing adjustments must consider the projected utilization, so any changes in utilization resulting from changes to cost-sharing will be accounted for. Actuarial equivalence standards and cost-sharing adjustments neutralize any net effect on bids.

Under the proposed regulation, coinsurance for selected drugs payable under Part B with

an MFP below the total financial liability furnished or administered by an out-of-network provider must be calculated based on a price that is equal to or less than the MFP, thereby potentially reducing beneficiary out-of-pocket costs for those selected drugs (not in aggregate from an actuarial perspective). However, given that drugs payable under Part B will have MFPs in effect for the first time in 2028, we are uncertain at this time the extent to which this proposed regulation would impact beneficiary cost sharing. Given that selected drugs furnished or administered by out-of-network providers and payable under Part B represent a minority of total spending by MA plans, we do not expect broader impacts resulting from the lower cost sharing.

b. Medicare Transaction Facilitator Requirements for Network Providers

The proposal of the "Medicare Transaction Facilitator Requirements for Providers" provision applies to MA organizations. The proposal would require any contract between an MA organization and a provider, or between a first tier, downstream, or related entity and a provider on the MA organization's behalf, for participation in one or more of the MA organization's networks include a provision that if the provider furnishes or administers selected drugs payable under Part B during the period when such drugs are subject to an MFP, the provider must be enrolled in the MTF DM. CMS notes that this provision in the proposed rule would have a negligible direct economic impact on MA organizations (associated with adding language to their contracts with providers) and will not have a direct significant economic impact on a substantial number of small entities. CMS recognizes that providers (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 contracts with MA organizations and enroll in the MTF DM. This one-time enrollment activity among providers 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).[293]

As discussed in section II.I.1 of this proposed rule, we believe that enrollment in the MTF DM by providers that furnish or administer selected drugs payable under Part B for which an MFP is in effect would facilitate continued beneficiary and provider access under the MA program to selected drugs that are payable under Part B. As discussed in this proposed rule, the MTF is designed to provide efficient, timely, and unified data exchange and payment flow where none currently exists between Primary Manufacturers and providers. Further, by enrolling in the MTF DM, providers can self-identify whether they are a provider 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. CMS will provide information about providers' self-identification in the MTF DM to Primary Manufacturers to assist in development of Primary Manufacturers' mitigation approaches for provider material cashflow concerns as part of their MFP Effectuation Plans, consistent with section 1193(a)(5) of the Act and as mentioned in this proposed rule.

c. Submission of Encounter Data Records for Selected Drugs Payable under Part B

CMS is proposing to require MA organizations to submit MA encounter data records involving the furnishing or administration of selected drugs payable under Part B for which an MFP is in effect on the claim-from date within 30 days of the claim-from date. This proposal would not affect the existing deadline requirements or processes for submission of MA encounter data records for Part B drugs or any other service or item provided to an MA enrollee for the purpose of risk adjustment. However, MA encounter data for selected drugs payable under Part B and submitted to CMS under the proposal will be used for risk adjustment purposes unless the MA organization submits risk adjustment data required under § 422.310 by the final risk adjustment submission deadline under § 422.310(g).

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[293] Available at: https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10912.

This proposed requirement is necessary to ensure MA beneficiaries' access to selected drugs payable under Part B. Absent a requirement for MA organizations to submit encounter data for selected drugs payable under Part B for which an MFP is in effect within 30 days, providers could wait up to approximately 26 months to receive an MFP refund from the manufacturer. As such, providers could be inadvertently disincentivized from furnishing or administering selected drugs payable under Part B for which an MFP is in effect, thereby potentially impacting MA enrollee access to selected drugs payable under Part B. This proposed requirement will help facilitate manufacturer effectuation of the MFP for selected drugs payable under Part B and furnished or administered to MFP-eligible individuals enrolled in an MA plan under Part C and help ensure that providers furnishing or administering selected drugs payable under Part B receive MFP refund payments from manufacturers promptly, thereby enabling them to continue furnishing or administering to MA beneficiaries selected drugs payable under Part B. Following solicitation of public comment on the 30-day timeline in the Draft Guidance on Manufacturer Effectuation of the Maximum Fair Price in 2028 under the Medicare Drug Price Negotiation Program, we believe that a 30-day timeline appropriately balances increased burden on MA organizations with the need for prompt manufacturer MFP refund payments to providers.

d. Collection and Submission of NDC-11s for Selected Drugs Payable under Part B

As discussed in the preamble, we anticipate that this proposed requirement at § 422.504(q)(1) would have no significant impact on burden for MA organizations as the required submission does not introduce a new data element to the existing MA encounter data record format and includes a data element that MA organizations may already submit to CMS. Given that many MA organizations already require providers to submit NDC-11s and MA organizations are accustomed to collecting NDC-11s from providers on claims for dually eligible beneficiaries, we anticipate that little to no change in burden associated with this proposal will be required for MA organizations.

e. Certification of Submission of Encounter Data Records for Selected Drugs Payable under Part

B

As discussed in the preamble, we anticipate that this proposed requirement at § 422.504(q)(2) would have no impact on burden for MA organizations, as there is no associated collection of information related to this change. MA organizations submitting encounter data records are already required to attest to a certification through HPMS for encounter data records submitted under § 422.504(l) that the data submitted under § 422.504(l) are accurate, complete, and truthful. Given that MA organizations are already required to submit attestations for encounter data records, we anticipate that little to no change in burden associated with this proposal will be required for MA organizations.

5. Specialty Tier Eligibility with Respect to Selected Drugs and Technical Correction (§ 423.104)

In this rule, consistent with existing policy, we propose to revise our specialty-tier regulations to expressly state that, for selected drugs with an MFP in effect for the applicable contract year, CMS will use the MFP rather than the PDE claims history to determine specialty-tier placement eligibility. If a selected drug's maximum fair price for a 30-day equivalent supply is below the annually determined specialty threshold, which is set at $1,080 for 2027, it will be ineligible for the specialty tier. As this policy is already in effect, we do not expect an impact on Medicare Part D expenditures. The requirements for actuarial equivalence in Part D bid submissions prevent a change in tiering from changing the overall value of the Part D plan sponsor's benefit. While cost sharing may be lower for the drugs impacted by this policy, any specific utilization effects will be counterbalanced by increased cost sharing on other drugs to maintain equivalence.

When the maximum fair price for a selected drug is below the specialty tier threshold, such drugs would be ineligible for the specialty tier and would be required to be placed on non-specialty tiers. Part D plan sponsors are also required to submit actuarially sound bids that satisfy the actuarial equivalence standards set forth under 42 CFR 423.265. As a result, any plan-level

cost changes arising from this proposal—including adjustments to beneficiary cost-sharing obligations—must be fully reflected in prospective bid calculations. To the extent that this policy reduces cost-sharing on the selected drugs with a maximum fair price below the specialty tier threshold, the bids must respond by raising cost-sharing on other drugs. This adjustment must consider the projected utilization on all drugs, so any changes in utilization resulting from changes to cost-sharing will be accounted for. Actuarial equivalence standards and cost-sharing adjustments neutralize any net effect on bids and payments from CMS to Part D plan sponsors.

Finally, this policy may produce changes in utilization patterns for affected drugs. Under the proposed regulations, selected drugs with a maximum fair price below the specialty tier threshold are not eligible for the specialty tier. Selected drugs that may have had negotiated prices above the specialty tier threshold in previous years prior to their maximum fair price taking effect will instead be placed on a preferred tier, reducing the beneficiary cost-sharing. However, given that drugs with prices in the range to be impacted by this policy represent a minority of selected drugs for initial price applicability years 2026 and 2027, we do not expect broader impacts on population health from lower cost-sharing. We expect that Part D plan sponsors will continue to adjust their formularies to promote cost-effective drugs for their members.

6. Updating Agent and Broker Compensation and Oversight

CMS has proposed to eliminate the requirement for TPMOs to report staff disciplinary actions or violations to MA Organizations and Part D sponsors, currently required at §§ 422.2274(g)(2)(iii) and 423.2274(g)(2)(iii). As CMS discussed in the preamble, CMS believes MA organizations and Part D sponsors are in the best position to monitor their TPMOs and make the determination themselves regarding reporting of TPMOs' disciplinary actions and violations. This proposal will require a one-time burden to change policies and procedures. With 761 contracts requiring 15 minutes (0.25 hr.) to modify each policy and procedure at $90.36/hr for a business operations specialist, all other, CMS estimates 190.25 hours (761 contracts × 0.25

hr) resulting in a cost of $17,190.99 (190.25 hrs × $90.36/hr), or at the contract level, a cost of $22.59 per contract ($17,190.99 total cost / 761 contracts).

CMS also proposed a new requirement at new §§ 422.2271(b)(3)(iii)(A) through (C) and 423.2271(b)(3)(iii)(A) through (C), that MA organizations and Part D sponsors, by the last Friday in July, report to CMS the supplemental compensation that the plan will pay independent agents and brokers for each plan, including the specific type, monetary amounts or retail value of non-monetary compensation and a detailed explanation of supplemental compensation programs, including payment schedules. CMS estimates that a subset of 60 percent of MA organizations and Part D sponsors (457 contracts) will utilize supplemental compensation and hence be required to annually submit supplemental compensation data. CMS does not have sufficient information regarding supplemental compensation arrangements and therefore makes a general estimate that plans will have on average two supplemental compensation arrangements per contract that they would submit to CMS annually. Since this would be a new requirement, CMS is unclear whether there would be more than two supplemental compensation arrangements on average and solicits comments from stakeholders on whether more or less per contract would be more appropriate, and any estimates of how many supplemental compensation arrangements commenters might expect to submit to CMS annually. CMS discussed the cost burden to this proposal in the Collection of Information section.

Given the uncertainty regarding supplemental compensation amounts and types (for example, bonuses, gifts, etc.), CMS discussed reviewing supplemental compensation for contract year 2028 to gain further insight into if and how MA organizations and Part D plans implement supplemental compensation prior to determining if supplemental compensation should be subject to an outlier analysis. CMS estimates that 457 contracts will submit supplemental compensation submissions (where CMS estimates two submissions per contract).

CMS estimates that it will take 0.5 hours for CMS to review each submission, with an average of two submissions per contract. Therefore, CMS estimates it will take a total of 457

hours (457 contracts x (2 submissions x 0.5 hour)) to review all supplemental compensation submissions annually. Using a business operations specialist, all other, at a cost of $90.36 per hour, CMS estimates that the total cost for CMS annually to review this data would be $41,294.52 ($90.36 per hour x 457 hours). Additionally, CMS discussed and requested comments on whether an outlier review of supplemental compensation was necessary, feasible, and requested suggestions on how best to review supplemental compensation.

CMS also proposed a new requirement at §§ 422.2271(b)(3)(iv) and 423.2271(b)(3)(iv) which requires MA organizations and Part D sponsors to provide documentation, including contracts, regarding compensation. CMS' estimates requesting 100 contracts per year from MA organizations and Part D sponsors. Assuming an MA organization or Part D sponsor spends one (1) hour obtaining each contract, CMS estimates that the total cost would be $9,036 (100 contracts × $90.36/hr.) for a business operations specialist, all other. With 761 contracts the average price for each contract would be $11.87 ($9,036 / 761).

CMS has proposed to eliminate the duplicative requirements at §§ 422.2272(b), 423.2272(b), 422.2274(c)(9)(i) and 423.2274(c)(9)(i) for MA organizations and Part D sponsors to establish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the MA plan, and understand the rules applicable under the plan. For these requirements, there is a one-time burden to change the MA organization or Part D sponsor policies and procedures. With 761 contracts at 15 minutes per contract (0.25 hr.) At $90.36/hr. for a business operations specialist, all other, we estimate a total of 190.25 hours (761 contracts × 0.25 hr) resulting in a one-time cost of $17,190.99 (190.25 hrs × $90.36/hr) or $22.59 per contract ($17,190.99/761). However, there is also cost savings associated with this proposed provision. Current enrollment verification requirements necessitate plan outreach to new enrollees, documentation of contact attempts, maintenance of tracking systems, and issuance of written communications when direct contact is unsuccessful. Eliminating §§ 422.2272(b) and

423.2272(b) would remove these requirements, resulting in reduced labor, mailing, and administrative costs for MA organizations and Part D sponsors.

Based on 2023 enrollment data, there were 11,085,209 enrollments made by agents. These include new to Medicare, Original Medicare to MA or Part D, and changes between MA and Part D plans. CMS's current regulations require MA organizations and Part D plans confirm that enrolled beneficiaries have, in fact, enrolled in the MA or Part D plan, and understand the rules applicable under the plan. CMS estimates that each enrollment requires 5 minutes of outreach and documentation, at a labor cost of $90.36 an hour, using a business operations specialist, all other. If the proposed rule is finalized, MA organizations and Part D sponsors will no longer be required to provide outreach and documentation resulting in cost savings. CMS estimates the time for the outreach is 886,816.72 hours (0.08 hrs x 11,085,209 enrollments). Multiplying the time for outreach by the cost of labor at $90.36, CMS estimates a cost savings of $80,132,758.82 (886,816.72 hrs x $90.36/hr). CMS estimates that MA organizations and Part D sponsors will be unable to reach 20 percent for these enrollments by phone and will send information to 2,217,042 enrollees (11,085,209 enrollments x 0.20). Assuming a cost of $0.65 for printing and postage, CMS estimates this will result in an additional savings of $1,441,077 (2,217,042 enrollees x $0.65 printing and postage). Combining the cost of the initial outreach and follow-up mailings, CMS estimates a total estimated savings of $81,573,835.80 per year ($80,132,758.82 + $1,441,077) or $107,192.95 ($81,573,835.80 / 761 contracts) per contract per year.

We propose a new requirement at new paragraphs §§ 422.2274(b) and 423.2267(b), which states that CMS must review base compensation submissions to ensure the amounts are within the fair market value. We are also proposing to have the authority to deny base compensation if the compensation is considered an outlier as defined in §§ 422.2260 or 423.2260. However, CMS estimates that if this provision is finalized as proposed, there may be some additional cost for MA organizations and Part D sponsors whose base compensation is

denied as an outlier. For contract year 2026, there are 761 contracts with 5,076 plan benefit packages (PBP). While CMS is unsure of how many base compensation submissions will be denied based on being an outlier, CMS is using the assumption that 5 percent of PBP base compensation rates will be considered outliers; this would result in 254 PBPs (5,076 PBPs x 0.05) needing to review and resubmit their base compensation rates. To review their compensation rates, we estimate that for each PBP that needs to resubmit their base compensation rates, it would take 2.5 hours at $90.36/hour, using a business operations specialist, all other to calculate and determine new base compensation rate amounts, totaling $225.90 (2.5 hr. x $890.36/hr.) for each PBP. With 254 PBPs, we estimate this step to be a cost of $57,378.60 ($225.90 x 254 PBPs). Next, plans will have to resubmit their new base compensation rates to CMS. We estimate it will take organizations 30 minutes at $90.36/hour using a business operations specialist, all other, totaling $45.18 (0.5 hr. x $90.36/hr.) for each PBP. With 254 PBPs, we estimate data entry to cost $11,475.72 ($45.18 x 254 PBPs). Combining the two estimates, the total cost burden for MA organizations and Part D sponsors will be $68,854.32 ($57,378.60 + $11,475.72). This averages out to $90.48 per contract ($68,854.32 / 761).

CMS is proposing a new requirement at new paragraph §§ 422.2271(c)(4) and 423.2271(c)(4), which prohibits MA organizations and Part D sponsors from entering into contracts with agents and brokers that have been terminated from participation in the Federally Facilitated Exchange (FFE). MA organizations and Part D sponsors would be required to monitor, on a monthly basis, the FFE terminations of agents and brokers with whom they have existing contracts, and terminate within 15 calendar days, any existing contract with an agent or broker, upon determining that the agent or broker has been terminated from the FFE. CMS anticipates new costs for MA organizations and Part D sponsors if this proposal is finalized. For this analysis, CMS assumes that MA organizations and Part D sponsors have existing electronic records containing identifiable information for their contracted agents and brokers (for example,

name, National Producer Number (NPN), etc.), such that comparing those internal records to the Agent Broker Suspension and Termination List would not involve a manual process. CMS further assumes that MA organizations and Part D sponsors have existing contract termination documents that have been vetted by contract administrators or legal counsel. Thus, executing these terminations would not require continuous action by an MA organization or Part D sponsor's legal counsel. Based on those assumptions, CMS estimates it would take in-house counsel one (1) hour to update existing documents. This accounts for MA organizations and Part D sponsors that have multiple contracts, reducing the overall cost per contract. The cost to update legal documents would be a one-time cost, resulting in a cost for each MA organization or Part D sponsor, using the wage for a lawyer, of $178.70 (1 hr x $178.70/hr.) and a total industry cost of $135,990.70 (761 contracts x $178.70). CMS estimates a business operations specialist would need one (1) hour per month to identify agents and brokers suspended from participation in the FFE and execute terminations at a cost of $90.36/hr., and an annual cost for each plan of $1,084.32 ($90.36/hr x 12 hrs). In total, to identify agents and brokers and modify documents, the cost for each MA organization or Part D sponsor for the first year would be $1,263.02 ($1,084.32+ $178.70) and $1,084.32 for each subsequent year. The first year will cost $961,158.22 ($1,263.02 x 761). Following the first year, the total estimated cost for all MA organizations and Part D sponsors would be $825,167.52 ($1,084.32 x 761 contracts) per year.

CMS is proposing to remove the provisions §§ 422.2274(g)(2)(i) and 423.2271(g)(2)(i), which require first tier, downstream or related entities (FDRs) and TPMOs to disclose subcontracted relationships used for marketing, lead generation, and enrollment to MA organizations and Part D sponsors. MA organizations and Part D sponsors are responsible for overseeing their FDRs and are in the best position to determine what documents are necessary for proper oversight. What documents are collected are business decisions for which the MA organizations and Part D sponsors are in the best position to determine, not CMS. If finalized as proposed, CMS anticipates that MA organizations and Part D sponsors would need to modify

existing contracts. For contract year 2026, there are 761 contracts. CMS estimates it would take legal counsel 1 hour at $178.70 per hour to modify the contracts. The total one-time cost is expected to be $178.70 per contract, for a total industry cost of $135,990.70 ($178.70 * 761). MA organizations and Part D sponsors would also see a decrease in costs for not having to request and receive the subcontracted relationships. MA organizations and Part D sponsors may contract with a large number of FDRs and TPMOs, which then in turn may contract with other entities. CMS assumes that an MA organization or Part D sponsor currently has a business operations specialist, all other, spend, at $90.36/hr, 2 hours per month ensuring information is collected for an annual total of 24 hours (2 hrs x 12 months). Therefore, CMS estimates that eliminating this requirement will save plans annually, per contract, $2,168.64 ($90.36/hr * 24 hrs). This results in an overall industry savings of $1,650,335.04 ($2,168.64 * 761) per year.

7. Removing the Requirement for the TPMO Disclaimer

CMS is proposing to eliminate the TPMO Disclaimer requirements at §§ 422.2267(e)(41) and 423.2267(e)(41), and thus, the related provisions at §§ 422.2274(g)(2)(iv) and 423.2274(g)(2)(iv). MA organizations and Part D sponsors are not required to eliminate the disclaimer from already printed materials, meaning they can use existing stock, disclaimer included, until their stock runs out. This proposal will require a one-time burden to change policies and procedures and to notify TPMOs of the change. With 761 contracts requiring 30 minutes (0.5 hr) per response at $90.36/hr. for a business operations specialist, CMS estimates a total reduction of 380.5 hours (761 contracts × 0.5 hr) and a cost reduction of $34,381.98 (380.5/hrs × $90.36/hr). This is a cost savings of $45.18 per contract ($34,381.98/761). The reduction of the disclaimer from sales calls would have a negligible impact to the total length of the call and thus CMS estimates that it would not change the cost associated with such calls.

8. Expanding Electronic Delivery of Required Enrollee Communications (§§ 422.2267(d)(2)(ii) and 423.2267(d)(2)(ii))

CMS is proposing to default to electronic delivery of all required materials for MA

organization and Part D sponsors. CMS does not anticipate any costs associated with the notification to enrollees since MA organizations and Part D sponsors already notify enrollees about electronic delivery of the Evidence of Coverage (EOC), the Provider Directory, and the Formulary. However, CMS does anticipate the proposal to allow sending all required documents under §§ 422.2267(e) and 423.2267(e) electronically, will result in a significant decrease in the costs incurred by MA organizations and Part D sponsors. These changes will not require any submission to OMB for updated PRA documentation.

Currently there are approximately 36 million MA organization and Part D enrollees. CMS assumes 80 percent of enrollees, 28,800,000 (36,000,000 enrollees x .8) will receive required documents electronically. CMS assumes the other 20 percent will request hard copies. Not including the documents already provided electronically, there are approximately 20 additional required documents. Some of these documents (for example, excluded provider notice, provider termination notice, etc.) are not sent to all enrollees while other documents are sent multiple times to enrollees who use services (for example, Explanation of Benefits). For the purpose of the proposal, CMS assumes each member receives 50 pages of documents in eight separate mailings. The total number of pages would be 1,440,000,000 pages (28,800,000 enrollees x 50 pages) and the total number of mailings would be 230,400,000 (28,800,000 enrollees x 8 mailings per year). Using an average cost of $ .05 per page, the total cost to print 1,440,000,000 pages would be $72,000,000. Using bulk mail, with an average cost of $ .50 to mail each document, the estimated cost to send eight documents a year would be $115,200,000 (230,400,000 x .50). The total cost of printing and mailing results in an outlay of $187,200,000 ($72,000,000 + $115,200,000) per year, industry-wide. With 761 contracts that is an average savings of $245,992 per year, per contract. Over a 10-year period the total savings would be $1,872,000,000.

9. Effects of Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.166 and 423.186)

We are proposing to remove 19 Star Ratings measures to continue to simplify and refocus the areas included in the Star Ratings and to simplify the Star Ratings methodology by removing the reward factor and modifying the improvement measure hold harmless. These proposed changes would sharpen the focus of the Star Ratings on outcomes and further incentivize quality improvement by raising the bar for contract performance required to achieve high ratings. We are also proposing a small number of technical updates that would not have an impact on the ratings distribution. We have estimated the impact of the Star Ratings changes on the Medicare Trust Fund in this proposed rule. Beyond the Medicare Trust Fund, there may be effects on supplemental benefits, premiums, and plan profits. These impacts will likely vary significantly from plan to plan (or contract to contract) based on the business strategies and the competitive landscape for each plan and contract.

We simulated the cumulative impact of the proposed changes on MA contracts using the 2027 Star Ratings data (2025 measurement year) but updating the measure set to remove the 11 measures finalized for removal in the Contract Year 2027 final rule. We calculated the net impacts summarized in Table X.3 due to the proposed Star Ratings updates by quantifying the difference in an MA organization's final Star Rating with and without the proposed changes. We assume Medicare Trust Fund impacts due to the Star Ratings changes associated with these proposed revisions to the methodology would be effective for the 2030 Star Ratings and would impact the 2031 Quality Bonus Payments (QBPs).

All impacts are considered transfers, but we request comments on the extent to which provision of goods or services would increase or decrease in association with the payment changes. The impact analysis for the proposed Star Ratings updates takes into consideration the final quality ratings for those MA contracts that would have Star Ratings changes under this proposed rule (excluding the 11 measures that were finalized for removal in the Contract Year 2027 final rule).

There are two ways that Star Ratings changes will impact the Medicare Trust Fund:

- A Star Rating of 4.0 or higher will result in a QBP for the MA contract, which, in turn, leads to a higher benchmark for the MA plans offered by the MA organization under that contract. MA organizations that achieve an overall Star Rating of at least 4.0 qualify for a QBP that is capped at 5 percent (or 10 percent for certain counties).

- The rebate share of the savings will be higher for those MA organizations that achieve a higher Star Rating. The rebate share of savings amounts to 50 percent for plans with a rating of 3.0 or fewer stars, 65 percent for plans with a rating of 3.5 or 4.0 stars, and 70 percent for plans with a rating of 4.5 or 5.0 stars.

In order to estimate the impact of the Star Ratings updates, baseline assumptions are updated with the assumed Star Ratings changes described in this proposed rule. We estimated the cumulative impact of the proposed changes to the Star Ratings calculations since there are interactions between the changes. The impacts are shown in Table X.3. For the Star Ratings updates, the net impact is estimated to be between -$11.50 billion in 2031 and -$18.88 billion in 2037, resulting in a 10-year net impact estimate of -$106.96 billion, which equates to 1.17 percent of the Medicare payments to private health plans for the years 2028 through 2037.

TABLE X.3: NET IMPACTS ($ MILLIONS) PER YEAR TO THE MEDICARE TRUST FUND FOR STAR RATINGS UPDATES

Calendar Year	Net Impact Star Ratings Updates	Percent of Medicare Payments to Private Health Plans
2028	0	0.00%
2029	0	0.00%
2030	0	0.00%
2031	-11,500	-1.45%
2032	-12,740	-1.48%
2033	-13,980	-1.49%
2034	-15,370	-1.50%
2035	-16,610	-1.51%
2036	-17,880	-1.51%
2037	-18,880	-1.51%
Total (2028-2037)	**-106,960**	**-1.17%**

10. Improvements for Special Needs Plans (§§ 422.2, 422.66(c), 422.101(f), and 422.514(h))

a. Amend definition of FIDE SNP

In this proposed rule, we are proposing to amend the definition of FIDE SNP at § 422.2 to remove the requirement that the D-SNP provide access to Medicare and Medicaid under a single entity that holds both an MA contract with CMS and a Medicaid MCO and replace it with the same requirement currently applicable to HIDE SNPs under § 422.2: the requirement that the plan provides coverage of Medicaid benefits under a capitated contract that is between the State Medicaid agency and the MA organization, the MA organization's parent organization or another entity that is owned and controlled by its parent organization, or 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.

Over the 10-year period from 2028 to 2037, we estimate that this proposal would result in total net transfers from the Medicare Trust Fund to MA organizations of approximately $609 million. The projected transfers are driven by the possibility that a subset of HIDE SNPs newly qualifying for FIDE SNP designation could become eligible for frailty-adjusted MA payments. The proposal does not change MA payment methodology, beneficiary eligibility, or enrollment requirements. Instead, it broadens the organizational structures that may qualify for FIDE SNP designation by allowing the Medicaid managed care contract to be held by the MA organization, its parent organization, or an affiliated entity under the same parent organization

The analysis assumes that several existing HIDE SNPs could become eligible for FIDE SNP status under the revised definition. Because plan-level qualification for the frailty adjustment is not publicly available, we assume that 30 percent of the potentially affected enrollment qualifies for frailty-adjusted payments. Approximately 60 percent of current FIDE SNP enrollment is in plans that qualify for the frailty adjustment. To account for uncertainty

regarding whether the affected HIDE SNP populations would meet CMS's frailty criteria, we conservatively apply one-half of the observed FIDE qualification rate.

Estimated payment impacts were developed using the average frailty adjustment currently observed for existing FIDE SNPs and projected forward using MA payment trends from the 2025 Medicare Trustees Report. The proposal does not affect MA enrollment, benchmarks, or bid submission requirements, and therefore estimated transfers reflect only the potential increase in risk-adjusted payments associated with expanded eligibility for FIDE SNP designation.

While greater organizational alignment between Medicare and Medicaid may improve care coordination, we did not estimate any offsetting Medicare savings. The proposal does not require changes in enrollment alignment or care delivery, and we are not aware of sufficient evidence demonstrating measurable reductions in Medicare expenditures associated solely with the expanded FIDE SNP eligibility criteria.

Under these assumptions, estimated gross transfers from the Medicare Trust Fund to MA organizations increase from approximately $41 million in 2026 to $95 million in 2037, for a total gross cost of approximately $727 million over the 2028 – 2037 projection period. Because beneficiary premiums finance approximately 25 percent of Medicare Part B costs, the estimated net transfers from the Medicare Trust Funds to MA organizations and general revenues is approximately $609 million over the same period.

TABLE X.4: AMEND DEFINITION OF FIDE SNP – PLANS MAY BE ELIGIBLE FOR FRAILTY ADD ONS TO ENROLLEE RISK SCORES

	2026	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**	**2035**	**2036**	**2037**	**Total (2028-2037)**
Gross Cost ($Millions)	41	45	50	55	60	64	69	76	82	86	90	95	727
Net of Pt B Premium	84.5%	84.4%	84.4%	84.3%	84.2%	84.1%	84.0%	83.9%	83.7%	83.6%	83.5%	83.3%	
Net Cost ($Millions)	35	38	42	46	50	54	58	64	68	72	75	79	609

b. Update to default enrollment for States transitioning from Medicaid FFS to Medicaid managed care

We are proposing allow default enrollment into a D-SNP for individuals who are eligible for Medicare and who are in the process of transitioning from Medicaid FFS into a Medicaid managed care plan affiliated with the D-SNP, as part of a State-initiated transition to Medicaid managed care.

This analysis estimates the impact of the proposed revision to § 422.66(c), which would allow default enrollment into an affiliated D-SNP for individuals transitioning from Medicaid FFS into Medicaid managed care at the time they become Medicare eligible. The analysis focuses on States where meaningful Medicaid FFS-to-managed care transition pathways remain for full-benefit dually eligibles.

States were grouped into three tiers based on the likelihood that newly Medicare-eligible duals would be in Medicaid FFS and subsequently transition into an aligned Medicaid managed care and D-SNP arrangement. Tier 1 States (Alabama, Georgia, Missouri, Mississippi) represent the highest-impact States due to greater reliance on FFS pathways for aged, blind, disabled, and LTSS populations. Tier 2 States (IN, NC, OK) have established managed care programs but retain some transition pathways. Tier 3 States (Arizona, New Jersey, Pennsylvania, Tennessee, Virgina) have mature managed care and MLTSS programs and are expected to experience only limited impacts.

Enrollment estimates were developed using beneficiary-level Medicare-Medicaid enrollment data, focusing on new full-benefit dual eligibles currently enrolled in Original Medicare. For 2028, the model projects approximately 3,300 additional MA enrollees attributable to the proposal, growing to approximately 14,300 active enrollees by 2037. Enrollment impacts were estimated using State-specific assumptions regarding: (1) the percentage of newly Medicare-eligible duals in Medicaid FFS at Medicare eligibility, (2) the percentage transitioning into Medicaid managed care, and (3) the percentage entering an

affiliated/aligned D-SNP pathway. Tier 1 States were assumed to have the highest pathway rates (30 percent FFS at eligibility, 60 percent MCO transition, 60 percent aligned pathway), with lower assumptions applied to Tier 2 and Tier 3 States. A 25 percent annual cohort decay factor was applied to reflect mortality and other enrollment attrition among a high-need dual-eligible population.

Per-capita Original Medicare transfers were based on a projected-enrollment-weighted average of KFF's 2021 estimates for full-benefit dual eligibles under age 65 enrolled in Original Medicare, resulting in a baseline transfer of $23,511 from the Medicare Trust Funds to MA organizations. These transfers were then trended forward using the 2025 Medicare Trustees Report USPCC growth factors.

To estimate the Medicare Advantage cost differential, the analysis used observed experience from a cohort of beneficiaries who became newly Medicare eligible and full-benefit dual eligible in 2022. County-level Medicare Advantage and Original Medicare expenditures were compared for this cohort through 2025, and the resulting duration pattern was used to develop MA-to-Original Medicare transfer factors for newly enrolled beneficiaries. This approach recognizes that expenditures for newly Medicare-eligible duals differ materially from expenditures observed after several years of enrollment and avoids applying payment relationships derived from mature Medicare populations.

Under these assumptions, estimated gross transfers from the Medicare Trust Funds to MA organizations increase gradually over the projection period as additional cohorts are default enrolled into MA. Total gross transfers from the Medicare Trust Funds to MA organizations over the 2028–2037 period are estimated at approximately $133 million. Because beneficiary premiums finance approximately 25 percent of Part B transfers, only the remaining share is borne by the Medicare Trust Funds and general revenues. After applying the projected net-of-Part-B-premium factors (84.5 percent in 2028 declining to 83.5 percent by 2037), the estimated net transfers from the Medicare Trust Funds and general revenues to MA organizations is

approximately $112 million.

TABLE X.5: COST IMPACT TO ALLOW DEFAULT ENROLLMENT INTO A D-SNP OF INDIVIDUALS ELIGIBLE FOR MEDICARE WHO ARE TRANSITIONING FROM MEDICAID FFS INTO A MEDICAID MANAGED CARE PLAN AFFILIATED WITH THE D-SNP

	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2028-2027
Additional Full Dually Eligible Enrollment in MA (average enrollees):	3,300	6,000	8,000	9,600	10,900	11,900	12,700	13,400	13,900	14,300	104,000
Per Capital Costs Above Baseline:	($1,815)	$1,135	$1,559	$1,420	$1,357	$1,334	$1,340	$1,364	$1,403	$1,456	
Gross Cost ($ millions):	(6)	7	12	14	15	16	17	18	20	21	133
Net of Part B Premium:	84.5%	84.5%	84.3%	84.2%	84.1%	84.0%	83.9%	83.7%	83.6%	83.5%	
Net Cost ($ Millions):	(5)	6	11	11	12	13	14	15	16	17	112

c. Expanding the Definition of HIDE SNP

We are proposing to broaden the HIDE SNP definition at § 422.2 to allow for more flexible and innovative arrangements between D-SNPs and Medicaid MCOs.

We developed savings estimates for expanding the HIDE SNP definition to allow certain CO D-SNPs to qualify as HIDE SNPs through arrangements with Medicaid managed care organizations that are not under the same parent organization. We assume that this change would allow some CO D-SNPs to become more integrated with the Medicaid delivery system and could generate efficiencies in the provision of Medicare-covered benefits.

The analysis is limited to CO D-SNP enrollment in States where HIDE or FIDE SNPs already operate, providing evidence that the State's Medicaid delivery system can support integrated D-SNP arrangements. We apply State-specific assumptions regarding the share of CO D-SNP enrollment for which greater integration is feasible and assume that potentially affected enrollment transitions gradually over the 2028 through 2037 projection period. Lower transition rates are assumed where the same D-SNP contract already operates an integrated D-SNP because the current organizational requirements are less likely to be the primary barrier to additional integration.

Savings are estimated using observed differences in Medicare Advantage bids and rebates between CO D-SNPs and more integrated D-SNPs. Consistent with previous estimates of

increased D-SNP integration, lower bid-to-benchmark ratios among more integrated D-SNPs are assumed to reflect, in part, greater efficiency in providing Medicare-covered benefits. The per capita savings and affected enrollment are projected forward using Medicare enrollment and expenditure trends.

We similarly estimate Part D savings using observed differences in combined Part D bid and reinsurance amounts between CO and more integrated D-SNPs. As with Part C, the estimate assumes that a portion of the observed difference would be realized as CO D-SNPs transition to more integrated arrangements. This approach is generally consistent with previous estimates of D-SNP integration, which projected Part D impacts using differences in bid and reinsurance amounts and the enrollment expected to become more integrated.

Under these assumptions, affected enrollment increases from approximately 27,000 in 2028 to 320,000 in 2037. Estimated net Part C savings are approximately $123 million over the 2028–2037 projection period, and estimated Part D savings are approximately $173 million. Total estimated Medicare savings are approximately $296 million over 2028 through 2037.

TABLE X.6: ESTIMATED COSTS (SAVINGS) PER YEAR (MILLIONS) TO MEDICARE TRUST FUND FOR ALLOWING MORE FLEXIBLE AND INNOVATIVE ARRANGEMENTS BETWEEN D-SNPs AND MEDICAID MCOs

Part C											
Calendar Year	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**	**2035**	**2036**	**2037**	**Total**
BID + REBATE PMPM Difference	(6.58)	(6.51)	(6.44)	(6.47)	(6.52)	(6.69)	(6.97)	(7.25)	(7.53)	(7.83)	
PROJECTED CO D-SNP Enrollment	27,452	56,637	87,148	118,547	150,642	183,354	216,797	250,938	285,541	320,206	
Gross Cost ($ millions)	(2)	(4)	(7)	(9)	(12)	(15)	(18)	(22)	(26)	(30)	(145)
Net of Part B Premium:	84.8%	84.8%	84.7%	84.7%	84.6%	84.6%	84.6%	84.6%	84.6%	84.6%	
Net Cost ($ millions):	(2)	(3)	(6)	(8)	(10)	(13)	(15)	(19)	(22)	(25)	(123)
Part D											
Calendar Year	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	Total
BID + REINSURANCE PMPM Difference	(7.13)	(7.34)	(7.50)	(7.65)	(7.93)	(8.23)	(8.49)	(8.74)	(9.01)	(9.28)	
Gross Cost ($ millions)	(2)	(5)	(8)	(11)	(14)	(18)	(22)	(26)	(31)	(36)	(173)
Net of Part D Premium:	-	-	-	-	-	-	-	-	-	-	-
Net Cost ($ millions):	(2)	(5)	(8)	(11)	(14)	(18)	(22)	(26)	(31)	(36)	(173)

Overall, we examined the potential impacts of the three proposed provisions related to Improvements for Special Needs Plans on the Medicaid program. Changes in the level of Medicare-Medicaid integration could affect Medicaid expenditures, particularly through changes in the coordination and utilization of long-term services and supports and behavioral health services. For example, greater integration could reduce or delay institutional long-term care while increasing the use of home- and community-based services. Changes in enrollment in Medicaid managed care arrangements could also affect Medicaid service utilization and expenditures. However, available evidence does not provide a sufficient basis for estimating the net Medicaid impact of these provisions. Because many Medicaid services are provided through capitated managed care arrangements, changes in service utilization may not immediately affect Medicaid program expenditures but could affect future capitation rates. The timing and magnitude of these effects would depend on State-specific utilization experience, rate-setting methodologies, and other factors. Accordingly, we do not estimate Medicaid costs or savings associated with these proposals and welcome public comments that could inform such an estimate.

11. Aligning Data and Value to Nurture Competition and Efficiency in Medicare Advantage (ADVaNCE MA) Model

The proposed ADVaNCE MA model tests certain changes to MA program structure in the model geographies for the individual and D-SNP markets. The model would adjust quality bonus payments to plans in model geographies and allow plans to offer certain supplemental benefits targeted based on beneficiaries' Part D Low Income Subsidy (LIS) status. The model would also consider alternatives to the current risk adjustment methodology and ESRD payments; as these adjustments are either informational or not proposed in this rule, we do not opine on the potential savings/costs associated with those adjustments. Below we discuss the potential impacts associated with the modifications proposed in this rule.

a. Changes to Market Geographies

To construct a control group for evaluation, the ADVaNCE MA model would be isolated to a subset of States. Currently, MA parent organizations may have contracts that can span over State lines. For the purposes of conducting the model test, these contracts would need to be split so that they do not contain both ADVaNCE MA and non-ADVaNCE MA geographies. This change alone would result in parent organizations submitting more contracts and bids and, therefore, may result in additional administrative costs for parent organizations, although we expect these additional costs to be small. The contract splitting process would affect contracts that currently span mandatory and non-mandatory state boundaries. I-SNPs (including IE-SNPs and HI-SNPs) are excluded from model participation and, therefore, would be unaffected by the contract restructuring requirements.

Additionally, CMS is proposing Star Ratings in non-model areas be adjusted for the impact of excluding model area contracts from Star Ratings. We would need to consider how the exclusion of model area contracts from the Star Ratings program may affect national cut points, clustering algorithms, and CAI calculations used to determine Star Ratings for non-model area contracts. If finalized, CMS will monitor these potential spillover effects and make further adjustments as necessary to minimize unintended impacts on non-model area plans. Therefore, we expect no savings/costs impact for non-model plans.

Further, our payments to EGWPs are made based on calculations from bids submitted in the individual non-D-SNP market. CMS is proposing to exclude EGWPs from the ADVaNCE MA model. If finalized, we will make considerations on how to adjust EGWPs' payment calculations, including any future rulemaking, to keep EGWP disruption minimal. Our payments to EGWPs are based on the average bid-to-benchmark ratio for individual MA plans in their service area. The restructuring of model area contracts and the introduction of Diamond Ratings-based benchmark adjustments could affect both the bid-to-benchmark ratio and the implicit rebate calculation for EGWPs — potentially disrupting EGWP payment rates in mandatory geographic areas and, indirectly, in non-Mandatory States as well. If finalized, we will monitor

these potential effects and make adjustments as necessary to minimize unintended impacts on EGWP payment rates, including through future rulemaking.

b. Changes to Quality Bonus Payments

The ADVaNCE MA model would make the following changes to how MA quality scores affect MA payments:

- Testing an alternative to the Star Ratings program with a new Diamond Rating system (determined at the parent organization level for each state) with two distinct Diamond Ratings per parent organization — one for the D-SNP cohort and one for the General Enrollment cohort.

- The applicable benchmark adjustment would be based on a linear interpolation of a particular parent organization's rating versus the range of the market. Specifically, the highest-rated plan in a given market would receive the maximum benchmark adjustment (proposed at up to five percent, though the final percentage is illustrative and subject to change based on forthcoming analytics, public comment, and budget review), and the lowest-rated plan would receive no additional benchmark adjustment (that is, zero percent), with all other plans receiving an adjustment between these two, based on the proposed formula. Also, the "double bonus counties" framework would not apply and there would be no additional adjustment for these counties.

- The rebate percentage would be based on a linear interpolation of a particular parent organization's rating versus the range of the market (that is, the highest Diamond Rating plan would receive a rebate percentage of 70 percent and the lowest Diamond Rating plan would receive a rebate percentage of 50 percent with all other plans receiving a rebate percentage between these two, based on the proposed formula).

- If finalized, CMS would retain the flexibility to make budget adjustments in future rulemaking, so that the other payment revisions do not result in costs to the MA program. Such adjustments would need to be regularly updated and could have different market implications depending on their structure (for example, changing the benchmark adjustment for the highest

rated plan vs changes to benchmarks for all plans). Also, the adjustments to achieve this goal will likely be based on model experience, but will impact prospective payments. These adjustments may not fully offset past savings or losses.

The ADVaNCE MA model aims for budget savings at the overall model level, relative to the existing MA Quality Bonus Payment system. This may be challenging, as the determination of counterfactual costs to the model will be increasingly hard to determine over time. For example, if a parent organization leaves one of the Mandatory States due to revenue reductions, that would have an impact on payments beyond the proposed model changes to benchmark and rebate levels. It is possible that the model impact will be either higher or lower costs.

We note that the removal of the "double bonus counties" framework on its own would generate savings absent the other tests currently proposed in the model. We estimate this change could reduce a particular Mandatory State's total benchmarks anywhere from zero to 3.0 percent, with an average reduction of 0.6 percent across all States. The total payment reductions from any benchmark reduction would depend on reactions from market participants, for example, the amount of savings from rebate-based payments versus bid-based payments would depend on the change in plan bids and the resulting bid to benchmark ratio.

In addition to the cost/savings implications of the model, there are also implications for beneficiaries in the model geographies. Plans may leave certain ADVaNCE MA markets based on their forecasted revenue reductions, forcing currently enrolled beneficiaries to choose new MA plans or revert to Original Medicare. We have reviewed data on forecasted revenue changes to inform scenario analysis of potential market changes. In one hypothetical scenario, where MA organizations facing material revenue reductions pull out of ADVaNCE MA States representing less than 10 percent of their enrollment, approximately 400,000 enrollees would have to find a new plan. This is just one of many hypothetical scenarios. For example, it's also possible that new plans could enter markets due to new competitive considerations or more beneficiaries switching to MA from Original Medicare due to the new benefit offerings.

c. Changes to Supplemental Benefit Offerings

ADVaNCE MA model participants would also be allowed to offer certain supplemental benefits (including food and produce, transportation for non-medical needs, and caregiver support) to beneficiaries based on their LIS eligibility. There is some evidence in literature to support such benefits producing medical cost savings. However, such an impact would need to be weighed against the reduction of other supplemental benefits and their relative value. Increased use of targeted benefits may put upward pressure on risk scores. MA organizations offering these model supplemental benefits may have additional interactions with their enrollees, leading to more opportunities for new diagnoses. MA organizations' revenue is still tied to risk scores within the model, so new diagnoses could lead to higher payments to plans. This pattern was observed in the discontinued CMS Innovation Center Value-Based Insurance Design (VBID) model, although the additional benefits in that model targeted specific conditions, unlike in the ADVaNCE MA model.

Offering these supplemental benefits is optional for MA organizations. ADVaNCE MA model participants retain full discretion to use rebate dollars for other purposes (premium reductions, cost-sharing reductions, or other supplemental benefits). The ADVaNCE MA model creates a new pathway that gives plans the option to target food, transportation, and caregiver support specifically to LIS-eligible enrollees — something not available under current law.

d. Conclusion

The ADVaNCE MA model includes multiple tests of the MA program, and it is difficult to anticipate exactly how these tests will impact all interested parties. As it relates to assessing the regulatory impact, CMS could propose future policy adjustments to avoid unfavorable impacts to trust fund expenditures and to achieve model savings. For example, if the overall payments inside the model exceeded estimates of what they would have been absent the model, CMS could propose to modify ADVaNCE payments to reduce model payments in future years.

The payment and incentive structures may have other impacts to enrollees or administrative costs. The impact of the supplemental benefit offerings is unclear.

D. Alternatives Considered

In this section, we include discussions of alternatives considered for the MA Ground Ambulance and Emergency Services Cost-Sharing Standards provision. CMS did not develop an alternatives considered section for the other provisions in this proposed rule as they generally are direct implementations of Federal laws or codifications of existing policy for MA and Part D.

1. Alternatives Considered for MA Ground Ambulance and Emergency Services Cost-Sharing Standards (§ 422.113(a) and 422.113(b)(2)(v))

CMS considered several alternatives when developing this proposal. CMS discusses the alternatives considered for each service category (ground ambulance and emergency services) in detail within the subsequent sections of this proposed rule. In brief, CMS evaluates these alternatives on how well they:

- Address potential financial incentives MA organizations may have under the current cost sharing standards to raise cost sharing for benefit categories that are not emergency services, such as ground ambulance services, to make up for the current cost sharing limit for emergency services.

- Address ground ambulance affordability concerns raised by interested parties (including ground ambulance providers).

- Maintain or improve upon the existing cost sharing incentives for MA organizations to adopt lower MOOP amounts.[294]

- Align copayment and dollar limits for ground ambulance and emergency services with industry trends for that benefit.

However, CMS does not include alternatives for all aspects of this proposal. Specifically,

[294] As discussed in section X.D.1.c.(2). of this proposed rule, based on contract year 2026 and prior year plan data, CMS believes the existing emergency services dollar limits have incentivized some MA organizations to switch their plans from mandatory to a lower or intermediate MOOP types.

under any of the alternatives discussed for this proposal, CMS would do the following:

- Apply the $5 rounding rule when calculating the ground ambulance and emergency services dollar limits, calculate and annually update those dollar limits based on the most recent Medicare FFS data projections, and issue the updated dollar limits through sub-regulatory guidance—to ensure the calculation approach of these dollar limits is consistent with how CMS calculates other professional service cost sharing limits (including maintaining actuarial equivalence to the considered methodology for future contract years).

- Remove the "lower of" clause in § 422.113(b)(2)(v) (which requires MA plans to establish emergency services cost sharing amounts that are the lower of: (A) CMS dollar limits or (B) the cost sharing established by the MA plan if the emergency services were provided by the organization)—to simplify the standard, since CMS evaluated each alternative based on whether its resulting dollar limit — standing alone, without a fallback comparison — would sufficiently protect beneficiaries' access to these services.

a. Cost Estimation

As noted in sections III.D. and X.C.1 of this proposed rule, because of multiple factors affecting bids and the longstanding actuarially equivalent MA plan bid requirements, CMS acknowledges this proposal may result in a possible combination of savings and costs for individual organizations and enrollees but in aggregate neutral financial effects. In brief, as the actuarial equivalence tests are applied to MA plans for each alternative presented in this section, in aggregate the plans would continue to be required to be actuarially equivalent to Original Medicare and the expected total enrollee cost-sharing expense for the plan year would remain the same for those enrollees in MA and for beneficiaries in Original Medicare. Consequently, CMS expects no material changes to the Medicare Trust Fund expenditures since aggregate enrollee cost sharing would remain unchanged or minimally affected under the proposed or alternative methodologies considered.

b. Evaluation Approach of Alternatives Considered

In sections X.D.1.c.(1) through (3) and X.D.1.d.(1) through (3) of this proposed rule CMS: (1) summarizes the MA ground ambulance and emergency services cost-sharing standards considered by each alternative; (2) evaluates the potential and definitive consequences of each alternative in comparison to the other alternatives; and (3) provides rationale for the decision to propose the cost-sharing standards considered under Alternative 3. The tables referenced in discussing these topics are included primarily to indicate potential consequences to the ground ambulance and emergency cost-sharing limits and plan cost-sharing amounts for these categories. To develop the illustrative dollar values in these tables, CMS used: (1) analyses of the most recent and relevant data sources CMS had at the time of developing this proposal: contract year 2027 Medicare FFS data projections (based on 2024 Medicare FFS data and the OACT's cost and utilization projections between 2024 and 2027, respectively) and contract year 2026 MA Plan data and (2) application of the existing rounding rules in current regulation (§ 422.100(f)(6)(ii)) that apply to certain MA copayment limits (including the range of cost sharing limits proposed to apply to ground ambulance services) and are proposed to apply to emergency services copayment limits per § 422.113(b)(2)(v).

The consequences discussed and shown in the tables in sections III.D and X.D.1.c.(1) through (3) and X.D.1.d.(1). through (3). of this proposed rule are uncertain because:

- Final ground ambulance and emergency services copayment and dollar limits set in future contract years (under the existing cost-sharing standards in current regulations, the proposed cost-sharing standard, or the other alternative cost-sharing standards considered) would likely be different than the illustrative copayment and dollar limits in this proposed rule based on using updated Original Medicare FFS data projections and coverage rules to calculate the limits.
- CMS cannot predict what cost-sharing amounts MA organizations will establish in future contract years because: (1) MA organizations may establish plan cost sharing amounts up to the applicable final limit set by CMS, regardless of any prior trend in establishing cost sharing for that service category; (2) MA organizations establish plan cost sharing amounts based on

many variables that may change annually (including provider contracting arrangements, managed care practices, and scope of supplemental benefit offerings); and (3) if CMS does not set an actuarially equivalent copayment or dollar limit for a future contract year then the plan's copayment amount may be actuarially equivalent to, or less than, the applicable cost-sharing standard based on data specified in the regulation which may include their total financial liability for that benefit (which may be greater or less than the illustrative copayment limits referenced in sections III.D. and X.D.1.c.(1) through (3) and X.D.1.d.(1). through (3). of this proposed rule).

c. Alternatives Considered for Emergency Services Cost Sharing Limits

In this section, CMS discusses alternatives considered when developing this proposal (alternative 3) to set emergency services cost sharing limits based on 15–20 percent of the most recent Medicare FFS weighted average allowed amount for these services from the OACT, beginning in contract year 2028. The impact of each of the alternatives on the copayment and dollar limits, based on contract year 2027 Medicare FFS data projections, is shown in Table X.D-1.

TABLE X.D-1: COMPARISON OF BASELINE AND ALTERNATIVE 1–3 ILLUSTRATIVE CONTRACT YEAR 2027 MA "EMERGENCY SERVICES" SERVICE CATEGORY COST SHARING LIMITS

Description	Lower MOOP	Intermediate MOOP	Mandatory MOOP
Baseline*	$150	$130	$115
Alternative 1**	$195	$170	$145
Alternative 2**	$240	$180	$120
Alternative 3**	$240	$210	$180

*Notes: Baseline cost sharing limits are currently codified in § 422.113(b)(2)(v)(B).
**Notes: Alternative 1-3 cost sharing limits are projected contract year 2027 values (based on the most recent Medicare FFS data projections from the OACT) that are actuarially equivalent to the percentages described in the discussions of each alternative (see sections X.D.1.c.(1). through (3). of this proposed rule). This includes the specific contract year 2027 projection (weighted average or median) used to reach these values. The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (per § 422.100(f)(7)).

(1) Alternative 1

In this alternative, CMS considered using the most recent Medicare FFS median projection to update the existing emergency services dollar cost sharing limits based on the same percentage basis that those limits were based upon. As discussed in the proposed rule, "Medicare

and Medicaid Programs; Contract Year 2021 and 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" issued February 18, 2020 (the February 2020 proposed rule),[295] the proposal for the current emergency services cost sharing limits for an MA plan with a mandatory MOOP limit and an MA plan with a lower MOOP limit were tied to the dollar figures that are 15 percent and 20 percent of the most recent (at the time) Medicare FFS median cost, rounded to the nearest or lower whole $5 increment. In addition, the emergency services dollar limit for MA plans with an intermediate MOOP limit was based on the numeric midpoint of the related cost sharing limits for MA plans with mandatory and lower MOOP limits, rounded to the nearest or lower whole $5 increment.

As this alternative uses the same approach with updated Medicare FFS data projections, CMS would set the MA emergency services category dollar limits for contract year 2028 and future years based on MOOP type as follows:

- Lower MOOP type: actuarially equivalent dollar value to 20% of the most recent median Medicare FFS data projection.
- Intermediate MOOP type: numeric midpoint between the dollar limits for the lower and mandatory MOOP types.
- Mandatory MOOP type: actuarially equivalent dollar value to 15 percent of the most recent median Medicare FFS data projection.

All dollar limits would be rounded to the nearest, or lower, whole $5 increment.

As shown in Table X.D-1, in comparison to the other alternatives in this section, this alternative results in the lowest dollar limits for emergency services—with one exception. Alternative 2 results in a lower dollar limit for the mandatory MOOP type. However, all the illustrative dollar limits considered under this alternative are less than the average emergency

[295] The February 2020 proposed rule is available at: https://www.federalregister.gov/documents/2020/02/18/2020-02085/medicare-and-medicaid-programs-contract-year-2021-and-2022-policy-and-technical-changes-to-the

services cost sharing of employer plans ($217, as shown in Table III.D-3). For example, as shown in Table III.D-8, approximately 71 percent of contract year 2026 MA plans have a mandatory or intermediate MOOP type. Under this alternative, those 71 percent of MA plans would be subject to emergency services dollar limits that are about $47 to $72 less than average employer plan cost sharing for the same benefit. CMS believes the dollar limits for most MA plans should be closer to the employer plan average because CMS expects providing flexibility up to comparable trends in the industry would better address the potential financial incentive MA organizations have to raise cost sharing for other service categories (such as, ground ambulance services).

While the proposal (alternative 3) retains the ability for CMS to switch to using the median Medicare FFS projection to set the emergency services dollar limits in future years (as this alternative considers), as shown in Table X.D-2, the median has been consistently lower than the projected weighted average in recent years) and thus is expected to consistently result in lower dollar limits (compared to alternative 3). Therefore, at this time, CMS is not proposing this alternative.

TABLE X.D-2: EMERGENCY SERVICES TOTAL MEDICARE FFS PROJECTIONS*

Projected Contract Year	Median Per Visit	Weighted Average Per Visit
2021	$755.00	$998.00
2022	$811.00	$1,042.00
2023	$861.00	$1,106.00
2024	$879.00	$1,112.00
2025	$880.00	$1,105.00
2026	$908.00	$1,142.00
2027	$973.00	$1,193.00

*Notes: Includes all part B services including the hospital facility charges, the professional provider fees, procedures, tests, images, DME, lab, and Part B drugs. Excludes those with an inpatient admission in the 3-day Medicare FFS hospital window.

(2) Alternative 2

Under this alternative, CMS considered the following approach to set the emergency services dollar limits for contract year 2028 and future years, based on MOOP type:

- Lower MOOP type: actuarially equivalent dollar value to 20 percent of the most recent

weighted average Medicare FFS data projection.

- Intermediate MOOP type: numeric midpoint between the dollar limits for the lower and mandatory MOOP types.
- Mandatory MOOP type: actuarially equivalent dollar value to 10 percent of the most recent weighted average Medicare FFS data projection.

All dollar limits would be rounded to the nearest, or lower, whole $5 increment.

In brief, this approach results in two primary changes in comparison to alternative 1:

- Using the weighted average Medicare FFS data projection as the basis for all emergency services dollar limits.
- Reducing the percentage basis for which the dollar limit for the mandatory MOOP type is based upon—from 15 percent to 10 percent.

These changes aim to result in dollar limits that are closer to the average employer plan cost sharing for emergency services for the lower and intermediate MOOP types while retaining a low dollar limit for the mandatory MOOP type (to incentive adoption of lower MOOP limits). CMS believes this alternative achieves this goal because for the approximate 74 percent of contract year 2026 MA plans with a lower or intermediate MOOP type, those plans would be subject to emergency services dollar limits that are close (within $23-$37) to the average employer plan cost sharing for the same benefit ($217). For example, the dollar limit for MA plans with a lower MOOP under this alternative is $240 (based on contract year 2027 Medicare FFS data projections); this is $23 more than the average employer plan emergency services cost sharing.

In addition, as shown in Table X.D-1, this alternative results in the largest range between the dollar limits for emergency services of the various MOOP types (between $120 and $240). CMS believes limiting the increase to the cost sharing limit applicable to the mandatory MOOP type (based on contract year 2027 Medicare FFS weighted average data projections) from $115 to $120 while simultaneously increasing the dollar limit for the lower MOOP type from $150 to

$240 will increase the cost sharing incentive for MA plans to adopt the lower MOOP type. This is because, as shown in Table X.C-2, about 89 percent of MA plans that switched from a mandatory to a lower or intermediate MOOP type in contract year 2026 utilized the current ER cost sharing flexibilities offered to lower MOOP types (the most of any service category). As a result, CMS believes the ability to access ER cost sharing flexibilities greater than the current dollar limit for MA plans with a mandatory MOOP type would be a strong incentive for MA organizations to consider switching their plans to lower MOOP types.

However, CMS is concerned that a $5 increase to the emergency services dollar limit for the mandatory MOOP type is insufficient to address the potential financial incentive those MA plans (representing 26 percent of all MA plans) have to raise cost sharing for other service categories (such as, ground ambulance services). As a result, CMS is not proposing this alternative.

(3) Alternative 3 (Proposed)

In this alternative, CMS considered updating the MA emergency services category cost-sharing standards for contract year 2028 and future years by setting the dollar limits based on the same percentages and approach that the existing emergency services cost sharing limits are originally based on, only updated to reflect the most recent Medicare FFS data projections available annually. As discussed in the final rule titled, "Medicare Program; Maximum Out-of-Pocket (MOOP) Limits and Service Category Cost Sharing Standards" and issued April 14, 2022 (the April 2022 final rule),[296] CMS set a 4-year transition from the prior emergency services dollar limits ($90–$120, based on MOOP type) to values that were actuarially equivalent to 15–20 percent of contract year 2021 weighted average Medicare FFS data projections (resulting in the current dollar limits of: $115–$150). Specifically, under this alternative, CMS would annually set emergency services dollar limits based on MOOP type as follows:

[296] The April 2022 final rule is available at: https://www.federalregister.gov/documents/2022/04/14/2022-07642/medicare-program-maximum-out-of-pocket-moop-limits-and-service-category-cost-sharing-standards.

- Lower MOOP type: actuarially equivalent dollar value to 20 percent of the most recent weighted average Medicare FFS data projection.
- Intermediate MOOP type: numeric midpoint between the dollar limits for the lower and mandatory MOOP types.
- Mandatory MOOP type: actuarially equivalent dollar value to 15% of the most recent weighted average Medicare FFS data projection.

For each of these dollar limits CMS would apply the existing $5 increment rounding rule from § 422.100(f)(6)(ii). As shown in Table X.D-1, in comparison to the existing cost-sharing standards in current regulations and the other alternatives in this section, this alternative results in the highest emergency services cost sharing limits based on the contract year 2027 weighted average Medicare FFS data projection from the OACT ($1,193.00, as shown in Table X.D-2). For example, as shown in Table X.D-1, this alternative results in an illustrative $180 emergency services cost sharing limit for the mandatory MOOP type because 15 percent of $1,193.00 (the contract year 2027 weighted average Medicare FFS data projection) is $178.95, which rounds to $180 (the nearest or lower $5 increment). A $180 emergency services cost sharing limit for the mandatory MOOP type is $35 to $65 more than the cost sharing limits that would result for that service category and MOOP type if the existing MA cost-sharing standard ($115) or other alternatives in this section ($145 or $120) were used. As a result, CMS believes this alternative by itself could result in fewer MA plans choosing to establish lower MOOP amounts in future years. This is because MA plans would have more flexibility in establishing emergency services cost sharing amounts under the mandatory MOOP type compared to the existing $115 limit (per § 422.113(b)(2)(v)). However, this proposal also:

- Retains unique dollar limits for emergency services across MOOP types (with the lower MOOP types retaining the most flexibility).
- Creates a new cost-sharing incentive for the lower MOOP type: a range of cost sharing limits for ground ambulance services.

As a result, from a general perspective this proposal may maintain or improve upon the existing cost sharing incentives for MA organizations to adopt lower MOOP amounts. However, as discussed in section X.C.1. of this proposed rule, at this time CMS is unable to predict the extent to which these proposed ground ambulance and emergency services cost sharing standard changes in combination may change MOOP type allocation across MA plans.

If this alternative were to be finalized, CMS would monitor adoption of lower MOOP types and will consider if additional changes to the emergency services cost sharing standards are appropriate for future rulemaking or sub-regulatory guidance. For example, changes to the percentage basis for emergency services cost sharing standards would be proposed through rulemaking while potential changes to the actuarial basis (such as use of weighted average or median measures of central tendency) could be completed through the subregulatory guidance process outlined at § 422.100(f)(7)(iii).

In summary, this alternative (in combination with the proposal for ground ambulance services) best addresses the following goals:

- Address potential financial incentives MA organizations may have under the current cost sharing standards to raise cost sharing for non-emergency benefit categories, such as ground ambulance services, to make up for the reduced cost sharing received for emergency services.
- Address ground ambulance affordability concerns raised by interested parties, specifically the imbalance of cost sharing between original Medicare and MA for ground ambulance services, to better protect MA enrollees from excessive cost sharing and ground ambulance providers from uncollectable bad debt.
- Maintain or improve upon the existing cost sharing incentives for MA organizations to adopt lower MOOP amounts.
- Use the most recent Medicare FFS data projections to set copayment and dollar limits for ground ambulance and emergency services that align with industry trends for that benefit.

d. Alternatives Considered for Ground Ambulance Services Cost Sharing Limits

In this section, CMS discusses alternatives considered when developing the proposal (alternative 3) to set ground ambulance services cost sharing limits based on the range of cost sharing limits codified at § 422.100(f)(6)(iii), beginning in contract year 2028. The impact of each of the alternatives on the ground ambulance cost sharing limits, based on contract year 2027 weighted average Medicare FFS data projections, is shown in Table X.D-3.

TABLE X.D-3: COMPARISON OF BASELINE[1] AND ALTERNATIVE 1-3[2] ILLUSTRATIVE MA "GROUND AMBULANCE SERVICES" SERVICE CATEGORY COST SHARING LIMITS BASED ON CONTRACT YEAR 2027 MEDICARE FFS DATA PROJECTIONS

Description	Lower MOOP	Intermediate MOOP	Mandatory MOOP
Baseline	50%	50%	50%
Alternative 1	50% / $300	50% / $300	50% / $300
Alternative 2	20% / $120	20% / $120	20% / $120
Alternative 3	50% / $300	40% / $240	30% / $180

[1]Baseline cost sharing limits that currently apply to ground ambulance services are codified in § 422.100(f)(6)(i).
[2]Alternative 1-3 ground ambulance cost sharing limits are projected contract year 2027 values (based on the most recent weighted average Medicare FFS data projection from the OACT) that are actuarially equivalent to the percentages shown and described in the discussions of each alternative (see sections X.D.1.d.(1) through (3) of this proposed rule). The OACT employed generally accepted actuarial principles and practices in calculating these projected amounts (per § 422.100(f)(7)).

(1) Alternative 1

In this alternative, CMS would not make changes to the coinsurance standard that currently applies to ground ambulance services. Instead, CMS would use existing authority to set an actuarially equivalent copayment limit to the 50 percent coinsurance limit. As discussed in the April 2022 final rule, CMS may calculate actuarially equivalent copayment limits for the service categories subject to § 422.100(f)(6)(i) (such as ambulance services) when feasible and appropriate to carry out program purposes. Based on contract year 2027 weighted average Medicare FFS data projections, this alternative would result in a $300 copayment limit for ground ambulance services.

For this alternative, consistent with April 2022 final rule, CMS considered the following factors: (1) the availability and suitability of Medicare FFS data projections on which the copayment limit would be based; and (2) whether setting such a copayment limit would assist

CMS in protecting against discriminatory cost sharing and avoiding unnecessary fluctuations in cost sharing that may confuse beneficiaries.

First, the OACT provided the contract year 2027 weighted average Medicare FFS projection for ground ambulance services that was developed following the actuarial principles and practices outlined at § 422.100(f)(7). Regarding a potential median projection, the OACT did not provide this for this category. Specifically, the OACT determined that the mean (weighted average) rather than the median of the distribution of the cost of ground ambulance trips was more appropriate to use for purposes of setting an actuarially equivalent copayment limit because the cost per trip is close to a bell-shaped curve (normal distribution). As a result, CMS believes the weighted average projection is sufficient for purposes of setting an actuarially equivalent ground ambulance copayment limit.

Second, CMS analyzed the potential impact a $300 copayment limit (the actuarially equivalent value to 50 percent coinsurance based on the $598 contract year 2027 weighted average Medicare FFS projection for ground ambulance services) would have on continuing MA plans. As shown in Table X.D-4 and X.D-5, based on contract year 2026 MA plan data, setting a $300 copayment limit would result in approximately 31 percent of MA plans decreasing their ground ambulance cost sharing amounts by about $38 on average to come into compliance with the $300 limit.

If an MA plan would need to decrease their ground ambulance cost sharing amount by $38 under this alternative, because of the requirement for the overall MA plan cost sharing to be actuarially equivalent to original Medicare, this MA plan would also need to make offsetting adjustments elsewhere that in essence, increase enrollee liability by $38. Continuing this scenario, an MA plan could choose to utilize the cost sharing flexibility proposed for emergency services, by raising their cost sharing amount for that category by $38. As this example is representative of the average ground ambulance cost sharing reduction posed by this alternative,

CMS expects that this alternative—for most MA plans—would result in minimal cost sharing adjustments across benefit categories.

However, CMS understands this assessment of cost sharing impact is only a rough estimate because:

- CMS expects some contract year 2026 plans will not continue in contract year 2028 (the first applicable year to which this proposal applies).
- The $38 dollar figure assumes that MA organizations would only lower their existing ground ambulance cost sharing amount (which may be based on the plan's total financial liability for the benefit) by the minimum amount necessary to come into compliance with the $300 limit.
- The 31 percent figure assumes that MA organizations with existing ground ambulance cost sharing amounts equal to or less than $300 would not change their cost sharing amount.

TABLE X.D-4: PERCENT OF CONTRACT YEAR 2026 MA PLANS AND ENROLLEES WITH GROUND AMBULANCE COST SHARING AMOUNTS GREATER THAN ALTERNATIVES 1 – 3

Contract Year 2026	Cost Sharing Greater than Alternative 1	Cost Sharing Greater than Alternative 2	Cost Sharing Greater than Alternative 3/Proposed Standard
Plans	31%	92%	65%
Enrollees	29%	94%	64%

TABLE X.D-5: CALCULATION OF EXPECTED AVERAGE CONTRACT YEAR 2028 MA PLAN GROUND AMBULANCE COST SHARING CHANGE IF ALTERNATIVE 1 COST SHARING STANDARD IS FINALIZED (BASED ON CONTRACT YEAR 2026 MA PLAN DATA*)

Service Category	Column A: Alternative 1 Cost Sharing Limit	Column B: Contract Year 2026 MA Plan Weighted Average Copayment (of MA Plans with a Copayment Greater than $300)	Column C: Expected Average Contract Year 2028 MA Plan Ground Ambulance Cost Sharing Change if Alternative 1 Applies (The Difference between Column A and Column B)**
Ground Ambulance Services	$300.00	$338.39	($38.39)

* Based on maximum cost sharing values of contract year 2026 MA plans (excluding employer, D-SNP, and MSA plans).

**This dollar difference assumes that MA organizations would only lower their existing ground ambulance cost sharing amount (which may be based on the plan's total financial liability for the benefit) by the minimum amount necessary to come into compliance with the $300 limit. This value is a rough parameter to assess the potential

impact of this alternative on the average MA plan ground ambulance cost sharing amount and is subject to the limitations noted throughout this section.

Despite these limitations, CMS believes the estimated impact of this alternative on ground ambulance MA plan cost sharing amounts can be used to assess whether setting a $300 copayment limit would protect against discriminatory cost sharing and avoid unnecessary fluctuations in cost sharing that may confuse beneficiaries. In brief, CMS believes a $38 dollar decrease for less than a third of MA plans would not sufficiently address CMS concerns on this matter. As shown in Table III.D-4, the weighted average Medicare cost sharing for ground ambulance services (based on contract year 2027 Medicare FFS data projections) is $120, compared to the $275 weighted average contract year 2026 MA plan cost sharing for the same benefit. Given that the weighted average cost sharing is $275 in comparison to the illustrative $300 limit that may result from this alternative (based on contract year 2027 Medicare FFS data projections), this means that most plans would not need to lower their ground ambulance cost sharing if this alternative was finalized. Given the limited financial impact of this alternative in comparison to the low cost sharing for ground ambulance services in Original Medicare, CMS believes this alternative may not sufficiently protect: (1) MA enrollees from ground ambulance cost sharing amounts that are significantly greater than cost sharing in Original Medicare for that benefit; and (2) ground ambulance providers from excessive uncollectable bad debt risk. As a result, it would be worth exploring another alternative that more fully addresses the disparity in cost sharing for ground ambulance services between MA and original Medicare.

This alternative does not improve the existing cost-sharing incentives for MA plans to establish lower MOOP amounts because the proposed ground ambulance cost-sharing standard (50 percent coinsurance or an actuarially equivalent copayment) would be unchanged and it applies equally to all MOOP types. Given that the proposed changes to emergency services cost sharing limits (or alternative 3 in section X.D.1.c.(3). of this proposed rule) may reduce the existing cost sharing incentives for lower MOOP adoption, another alternative that improves

upon the existing cost-sharing incentives for lower MOOP types would be appropriate to consider. For these reasons, CMS is not proposing this alternative at this time.

(2) Alternative 2

In this alternative, CMS would propose that MA plan ground ambulance cost sharing must be no greater than original Medicare to provide the most protection for beneficiaries compared to the other alternatives considered. As a result, as shown in Table X.D-9, under this alternative the cost sharing limit for ground ambulance services would be 20 percent or $120 (based on contract year 2027 weighted average Medicare FFS data projections). In addition, as shown in Tables X.D-4 and X.D-6, requiring cost sharing no greater than original Medicare would result in approximately 92 percent of MA plans (based on contract year 2026 plan data) decreasing their ground ambulance cost sharing amounts by about $161 on average.[297] However, because of the requirement for the overall MA plan cost sharing to be actuarially equivalent to original Medicare, those MA plans would also need to make offsetting adjustments elsewhere to account for the specific changes they make to come into compliance with this alternative's ground ambulance cost sharing standard. For example, if an MA plan would need to decrease their ground ambulance cost sharing amount by $161 under this alternative, they would also need to increase cost sharing elsewhere by $161 in total to maintain actuarial equivalence with original Medicare. Continuing this scenario, this MA plan – at most by having a lower MOOP type—could choose to increase their emergency services cost sharing amount by $90 (from $150 (the current maximum allowed for the lower MOOP type) to $240 (the illustrative dollar limit for the lower MOOP type that results from this proposal/alternative). Under this example, there would still be $71 of cost sharing increases the MA plan would need to make to reach actuarial equivalence (that is, $161 minus $90 equals $71). As this example is representative of the average ground ambulance cost sharing reduction posed by this alternative and reflects the maximum cost sharing flexibilities afforded to the lower MOOP type, CMS expects that this

[297] The same limitations that apply in analyzing the estimate of impact from alternative 1 also apply here.

alternative—for most MA plans—would result in significant cost sharing changes across multiple benefit categories given the actuarial equivalence requirement at § 422.100(j)(2).

TABLE X.D-6: CALCULATION OF EXPECTED AVERAGE CONTRACT YEAR 2028 MA PLAN GROUND AMBULANCE COST SHARING CHANGE IF ALTERNATIVE 2 COST SHARING STANDARD IS FINALIZED (BASED ON CONTRACT YEAR 2026 MA PLAN DATA*)

Service Category	Column A: Alternative 2 Cost Sharing Limit	Column B: Contract Year 2026 Weighted Average Copayment (of MA Plans with a Copayment Greater than $120)	Column C: Expected Average Contract Year 2028 MA Plan Ground Ambulance Cost Sharing Change if Alternative 2 Applies (The Difference between Column A and Column B)**
Ground Ambulance Services	$120.00	$281.44	($161.44)

*Based on maximum cost sharing values of contract year 2026 MA plans (excluding employer, D-SNP, and MSA plans).

**This dollar difference assumes that MA organizations would only lower their existing ground ambulance cost sharing amount (which may be based on the plan's total financial liability for the benefit) by the minimum amount necessary to come into compliance with the $120 limit. This value is a rough parameter to assess the potential impact of this alternative on the average MA plan ground ambulance cost sharing amount and is subject to the limitations noted throughout this section.

While this alternative is the most protective of beneficiaries requiring ground ambulance services and ground ambulance providers, like alternative 1, this alternative does not improve the existing cost-sharing incentives for MA plans to establish lower MOOP amounts because the proposed ground ambulance cost-sharing standards would apply equally to all MOOP types. Given that the proposed changes to emergency services cost sharing limits (or alternative 3 in the following section X.D.1.d.(3). of this proposed rule) may reduce the existing cost sharing incentives for lower MOOP adoption, CMS believes another alternative that improves upon the existing cost-sharing incentives for lower MOOP types would be appropriate to consider.

Given the reasons discussed, CMS is not proposing this alternative.

(3) Alternative 3 (Proposed)

In this alternative/proposal, CMS proposes to set ground ambulance services cost sharing limits based on the range of cost sharing limits codified at § 422.100(f)(6)(iii), beginning in

contract year 2028, and the most recent weighted average Medicare FFS data projections. As shown in Table X.9, this alternative results in ground ambulance cost sharing limits ranging from $180 to $300 based on MOOP type. Given that the current ground ambulance cost sharing standard (50 percent coinsurance) applies equally to all MA plans, CMS expects this alternative – by itself – will improve upon the existing cost sharing incentives for lower MOOP adoption.

As shown in Tables III.D-7 and X.D-2, this alternative would result in approximately 65 percent of MA plans decreasing their ground ambulance cost sharing amounts by about $75 on average (or between $38 to $126, based on MOOP type). However, this expected impact to MA plan ground ambulance cost sharing is a rough estimate for the same reasons discussed in relation to alternative 1's impact assessment—and because it does not account for how this alternative (which assigns unique cost sharing limits based on MOOP type) may result in more MA plans choosing lower MOOP types (and the increased cost sharing flexibility for ground ambulance services). As a result, CMS emphasizes that all estimates of expected decreases to average MA plan ground ambulance cost sharing amounts are only rough parameters of impact.

Under this alternative, for example, MA plans may decrease their ground ambulance cost sharing amount by roughly $75 on average based on Table III.D-7. Given the flexibility afforded by the cost sharing standards proposed for emergency services, CMS believes a plan in this situation could make the necessary cost sharing offset ($75) by primarily increasing their emergency services cost sharing amount. For example, an existing MA plan with a mandatory MOOP type (that chooses not to switch MOOP types) and a $115 emergency services dollar limit (the maximum allowed under the current regulations) may choose to increase their emergency services cost sharing amount up to CMS's proposed limit for the mandatory MOOP type ($180). That would be a $65 increase and leave only $10 unaccounted for. Alternatively, if the MA plan chose to lower their MOOP type they would gain access to additional emergency services cost sharing flexibility (and not necessarily need to adjust other benefit category cost sharing amounts in response to maintain actuarial equivalence to original Medicare). As a result,

CMS believes this alternative would: (1) better allocate cost sharing revenue between ground ambulance and emergency services, (2) reduce the risk for ground ambulance providers to gain uncollectable bad debt due, and (3) require minimal changes to other aspects of the plan's benefit design to come into compliance with the proposed and existing actuarial equivalence standard.

As discussed in section III.D. of this proposed rule, CMS is considerate that the $155 imbalance in ground ambulance cost sharing between original Medicare ($120 based on contract year 2027 Medicare FFS data projections) and MA ($275, based on contract year 2026 MA weighted average plan data) may result in significantly more uncollectable bad debt for ground ambulance providers when they provide ambulance services to MA enrollees over beneficiaries in original Medicare. Regarding this risk of uncollectable bad debt, this alternative is expected to reduce the difference in average ground ambulance cost sharing responsibility between MA plans and original Medicare from $155 (comparing the values in Table III.D-4) by about $75 (as shown in Table III.D-7 with the limitations noted throughout this section) to $80. In other words, CMS expects this proposal will reduce average MA plan ground ambulance cost sharing from $275 to about $200, based on the minimum $75 average change necessary for current plan designs to become compliant with the proposed standards (though this assumes current MOOP type allocation). While this alternative does not fully address the imbalance of cost sharing between original Medicare and MA for ground ambulance services, it may make a meaningful improvement (and thus address uncollectible bad debt concerns of ground ambulance providers).

In summary, CMS concludes that this alternative (in combination with the proposal for emergency services) best addresses the following goals because it:

- Negates the potential financial incentive most MA organizations have under the current cost sharing standards to raise cost sharing for benefit categories that are not emergency services, such as ground ambulance services, to make up for the out-of-date cost sharing limit for emergency services.
- Addresses concerns raised by interested parties, including ground ambulance

providers, from uncollectable bad debt.

- Maintains or improve upon the existing cost sharing incentives for MA organizations to adopt lower MOOP amounts.

- Uses the most recent Medicare FFS data projections to set copayment and dollar limits for ground ambulance and emergency services that align with industry trends for that benefit.

E. Regulatory Review Cost Estimation

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret the proposed rule, then we should estimate the cost associated with regulatory review. We have received approximately 20,000 comments specific to the provisions of our recent proposed 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 services managers (code 11–9111), we estimate that the cost of reviewing this proposed rule is $135.54 per hour, including fringe benefits, overhead, and other indirect costs (http://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it will take approximately 10 hours for each person to review this proposed rule. For each entity that reviews the rule, the estimated cost is therefore $1,355.40 (10 hours x $135.54). Therefore, we estimated that the maximum total cost of reviewing the proposed rule is $27.1 million ($1,355.40 x 20,000 reviewers). However, we expected that many reviewers, for example pharmaceutical companies and PBMs, will not review the entire rule but review just the sections that are relevant to them. We expect that on average (with fluctuations) 10 percent of the proposed rule will be reviewed by an individual reviewer; we, therefore, estimate the total cost of reviewing to be $2.7 million. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

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

Table X.F-1 summarizes costs, savings, and transfers by provision. As required by OMB Circular A-4 (available at https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf), we have prepared an accounting statement in Table X.F-1 showing the transfers and costs associated with the provisions of this rule over a 10-year period or for contract years 2028 through 2037.

TABLE X.F-1: ACCOUNTING STATEMENT - CONTRACT YEARS 2028-2037 (MILLIONS)

Category	3% Discount Rate	7% Discount Rate
COSTS		
Annualized monetized costs to MA Organization and PD Sponsors	-240.1	-240.2
TRANSFERS		
Annualized monetized transfers	-9,776.5	-8,704.9
From Federal Government to MA Organizations and PD Sponsors		

G. Impact on Small Businesses - Regulatory Flexibility Act (RFA)

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

We believe this proposed rule will have a direct economic impact on beneficiaries and health insurance plans. Based on the size standards set by the Small Business Administration (SBA) effective March 17, 2023, (for details, see the Small Business Administration's website at *https://www.sba.gov/document/support-table-size-standards*), Direct Health and Medical Insurance Carriers, classified using the NAICS code 524114, have a $47 million threshold for "small size." Many Medicare Advantage organizations (about 30 to 40 percent) are not-for-

profit,[298] which allows them to qualify as "small entities" so long as they are independently owned and operated and nondominant in their field. We believe all of the not-for-profit organizations qualify as small under the aforementioned criteria. Of the 1,071 businesses using this NAICS code, we believe 799 (or 74.6 percent) are small businesses.

Using CMS's own payment records, we have been able to make estimates as to the minimum size of the smallest Medicare Advantage and Part D insurance contracts. The smallest Medicare contracts are primarily those held by PACE programs, which must adhere to the majority of Part D requirements. For the last year for which we have complete financial records (2024), we believe the smallest PACE programs had gross receipts between $200,000 and $300,000. The vast majority of other Part D contracts and MA organizations must meet minimum size and financial thresholds that make them substantially larger. Excluding the smallest non-PACE contracts paid in 2024, which primarily represent those which did not operate for the full calendar year or new entities excluded from CMS enrollment thresholds, the smallest MA organizations averaged over $650,000 in total receipts.

The RFA does not define the terms "significant economic impact" or "substantial number." The SBA advises that this absence of statutory specificity allows what is "significant" or "substantial" to vary, depending on the problem that is to be addressed in the rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. Nevertheless, HHS typically considers a "significant economic impact" to be 3 to 5 percent or more of the affected entity's costs or revenues, and a "substantial number" to mean 5 percent or more of affected small entities within a given industry.[299]

1. Operational Aspects of the Medicare Program

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[298] Medicare Advantage/Part D Contract and Enrollment Data, *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data.*

[299] U.S. Department of Health and Human Services, Guidance on Proper Consideration of Small Entities in Rulemaking, https://aspe.hhs.gov/sites/default/files/documents/dd6288d1b8db19ee8a1f37b3ce775003/guidance-proper-consideration-hhs-2003-rulemaking.pdf.

To explain our position, we will first note certain operational aspects of the Medicare program. Each year, MA organizations submit a bid for each plan for furnishing Parts A and B benefits and the entire bid amount is paid to the plan by the government through the Medicare Trust Funds, if the plan's bid is below an administratively set benchmark. If the plan's bid exceeds that benchmark, the beneficiary pays the difference in the form of a basic premium (note that, historically, only 2 percent of plans bid above the benchmark, and they contain roughly 1 percent of all plan enrollees). Part D sponsors also submit a bid for each plan, and the payments made to stand-alone Part D plans (PDPs) are covered by the Supplementary Medical Insurance Medicare Trust Fund. PACE organizations are paid a capitation amount that is funded by both the Medicare Trust Funds (the Hospital Insurance and Supplementary Medical Insurance trust funds) as well as the State Medicaid programs they contract with.

MA plans can also offer enhanced benefits—that is, benefits not covered under Original Medicare. These enhanced benefits are paid for through enrollee premiums, rebates or a combination. Under the statutory payment formula, if the plan bid submitted by an MA organization for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a rebate. The rebate must be used to provide supplemental benefits (that is, benefits not covered under Original Medicare) and/or to lower beneficiary cost sharing, Part B or Part D premiums. Some examples of these supplemental benefits include vision, dental, and hearing, fitness and worldwide coverage of emergency and urgently needed services.

Part D sponsors submit bids and plans are paid through a combination of Medicare funds and beneficiary premiums. In addition, for enrolled low-income beneficiaries, Part D plans receive special government payments to cover most of premium and cost sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by these insurers is funded by the government and, in some cases, by enrollee premiums. As a result, MA plans, Part D plans, Prescription Drug Plans,

and PACE organizations are not expected to incur burden or losses since the private companies' costs are being supported by the government and enrolled beneficiaries. This lack of expected burden applies to both large and small health plans.

In addition to the direct costs discussed earlier, there are certain indirect consequences of these provisions which also create impact. We have already explained that 98 percent of MA plans (including MA-PD plans) bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal Government, given that as previously noted, under the statutory payment formula, if a bid submitted by a MA plan for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a beneficiary rebate, which must be used to provide supplemental benefits or lower beneficiary cost sharing or both, Part B or Part D premiums. If the plan's bid exceeds the administratively set benchmark, the beneficiary pays the difference in the form of a basic premium. However, as also noted previously, the number of MA plans bidding above the benchmark to whom this burden applies does not meet the RFA criteria of a significant number of firms.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This analysis must conform to the provisions of section 603 of the RFA. Therefore, the Secretary has certified that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

If the provisions of the rule were to cause bids to increase and if the benchmark remains unchanged or increases by less than the bid does, the result could be a reduced rebate. Plans have different ways to address this in the short-term, such as reducing administrative costs, modifying benefit structures, or adjusting profit margins. These decisions may be driven by market forces.

Part of the challenge in pinpointing the indirect effects is that there are many other factors combining with the effects of the rule, making it effectively impossible to determine whether a particular policy had a long-term effect on bids, administrative costs, margins, or supplemental benefits.

2. Anticipated Costs and Savings

As indicated in Table X.C-1, the proposals described in this rule are expected to result in cost savings amounting to approximately $240.5 million in 2028, with comparable cost savings expected in subsequent years. MA organizations and Part D sponsors will be the entities most economically impacted by this rule. Some provisions are expected to increase costs for insurers, but most MA organizations and Part D sponsors, including small entities, will likely have greater savings than costs.

The Updating Agent and Broker Compensation and Oversight provision is expected to save MA organizations and Part D sponsors $82.0 million annually. The Removing the Requirement for the TPMO Disclaimer provision is expected to save MA organizations and Part D sponsors $33,963 annually. The Expanding Electronic Delivery of Required Enrollee Communications provision is expected to save MA organizations and Part D sponsors $187.2 million annually. Averaged across all 761 entities, MA organizations and Part D contracts would be expected to save $353,666 each. While we anticipate that larger contracts may receive greater total cost savings due to their higher engagement with brokers and the reduced volume of paper deliveries resulting from this rule, smaller organizations could be expected to reap savings that are higher in proportion to their total revenues. D-SNPs, a type of plan offered by MA organizations, are also expected to have cost savings amounting to at least $1,161 per entity (as each D-SNP is required to have a minimum of one approved Model of Care).

The costs incurred by MA and Part D contracts fall below the HHS significance threshold. In the case of Medicare contracted insurers, we consider the 5 percent threshold to be more appropriate, as these insurers include the cost of following regulatory requirements in their

bids. Part D-only contracts are expected to face new costs of $469 per entity, primarily from the information collection components of the Updating Agent and Broker Oversight provision—likely less than what many of these businesses will save due to that same provision.

In summation, this proposed rule will not have a significant economic impact on a substantial number of small entities. The vast majority of MA organizations and Part D sponsors are expected to see cost savings as a result of this rule.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately $193 million. This proposed rule is not anticipated to have an unfunded effect on State, local, or Tribal governments, in the aggregate, or on the private sector of $193 million or more.

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on State or local governments, preempt State law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

J. E.O. 14192, "Unleashing Prosperity Through Deregulation"

E.O. 14192, titled "Unleashing Prosperity Through Deregulation" was issued on January 31, 2025, and requires that "any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations." This proposed rule, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action. We estimate that this rule generates $178.1 million in annualized cost savings at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

K. Conclusion

This proposed rule, if finalized, will result in net annualized cost savings ranging between $240.1 and $240.2 million for calendar years 2028 to 2037, at the 3 percent and 7 percent discount rates, respectively. The savings are primarily attributable to the provision to default to electronic delivery of all required materials for MA organization and Part D sponsors. This proposed rule will also result in net annualized monetized transfers ranging between $9,776.5 million and $8,704.9 million for calendar years 2028 to 2037, at the 3 percent and 7 percent discount rates respectively. These transfers primarily result from the provisions Effects of Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System and Improvements for Special Needs Plans.

XII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on November 20, 2026.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Citizenship and naturalization, Civil rights, Health, Health care, Health records, Incorporation by reference, Individuals with disabilities, Medicaid, Medicare, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

42 FR Part 516

Administrative practice and procedure, Medicare Advantage, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

1. The authority for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w-21 through 1395w-28, and 1395hh.

2. Section 422.2 is amended by—

a. Revising the definition of "aligned enrollment" and paragraph (1) of the definition of "fully integrated special needs plan"; and

b. Adding paragraph (1)(iv) for the definition of "Highly integrated dual eligible special needs plan".

c. Adding definitions for "Maximum fair price (MFP)" and "Selected drug" in alphabetical order.

The revisions and additions read as follows:

§ 422.2 Definitions

* * * * *

Aligned enrollment refers to the enrollment in a dual eligible special needs plan of full-benefit dual eligible individuals whose Medicaid benefits are covered under a Medicaid managed care organization contract under section 1903(m) of the Act between the applicable State and: the dual eligible special needs plan's (D-SNP's) MA organization, the D-SNP's parent organization or another entity that is owned and controlled by the D-SNP's parent organization, or an entity that has a contractual relationship with the MA organization that requires the MA organization to assume clinical and financial responsibility for Medicare and Medicaid benefits with regard to individuals so enrolled. When State policy limits a D-SNP's membership to individuals with aligned enrollment, this condition is referred to as exclusively aligned enrollment.

* * * * *

Fully integrated dual eligible special needs plan means a dual eligible special needs plan—

(1) Offered by an MA organization that provides coverage of Medicaid benefits under a capitated contract 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;

* * * * *

Highly integrated dual eligible special needs plan means a dual eligible special needs plan offered by an MA organization that provides coverage of Medicaid benefits under a capitated contract that meets the following requirements—

(1) * * *

(iv) An entity that has a contractual relationship with the MA organization that requires the MA organization to assume clinical and financial responsibility for Medicare and Medicaid benefits with respect to individuals enrolled in the D-SNP whose Medicaid benefits are covered under the capitated contract.

* * * * *

Maximum fair price (MFP) has the meaning set forth in section 1191(c)(3) of the Act.

* * * * *

* * * * *

* * * * *

Selected drug has the meaning given such term in section 1192(c) of the Act and any

applicable regulations and guidance.

* * * * *

3. Section 422.60 is amended by—

a. Revising paragraphs (b)(1) and (b)(2); and

b. Removing paragraph (b)(3).

The revisions read as follows:

§ 422.60 Election process.

* * * * *

(b) *Capacity to accept new enrollees*.

(1) MA organizations may submit information on enrollment capacity of plans as part of the annual bid submission described at § 422.254(c)(4) or § 422.254(e)(1), as applicable.

(2) MA organizations must deny enrollment requests at the point of initial receipt once their CMS-approved enrollment capacity limit has been reached.

* * * * *

4. Section 422.62 is amended by--

a. Revising paragraphs (b)(1) and (b)(2);

b. Adding paragraphs (b)(3)(iii) and (iv);

c. and Redesignating paragraphs (b)(18)(ii) through (iv) as paragraphs (b)(18)(iii) through (v), respectively;

d. Adding a new paragraph (b)(18)(ii);

e. Revising paragraphs (b)(23)(ii) and (iii);

f. Redesignating paragraph (b)(27) as paragraph (b)(28);

g. Adding a new paragraph (b)(27); and

h. Revising newly redesignated paragraph (b)(28).

The revisions and additions read as follows:

§ 422.62 Election of coverage under an MA plan.

* * * * *

(b) * * *

(1) * * *

(i) *Non-renewal effective January 1*. This SEP begins December 8 of the contract year and ends the last day of the following February. Enrollment requests received December 8 through December 31 will have an effective date of January 1. Enrollment requests received in January will have an effective date of February 1. Enrollment requests received in February will have an effective date of March 1.

(ii) *Termination or modification by plan or mutual consent*. This SEP begins 2 months before the termination effective date and ends 1 month after termination effective date. An individual may request an effective date for the month after notice is given, or up to 2 months after the effective date of the termination, but the effective date may not be earlier than the date the new MA organization receives the enrollment request.

(iii) *CMS termination of contract*. This SEP begins 1 month before the effective date of the termination and ends 2 months after the termination effective date. Individuals may select an effective date for the month after notice is given or up to 3 months after the effective date of the termination, but the effective date may not be earlier than the date the new MA organization receives the enrollment request.

(2) * * *

(i) This SEP begins on--

(A) The date of the change in permanent residence;

(B) The month before the change in permanent residence, for an individual who notifies the MA organization in advance of the change; or

(C) The first day of the sixth month the individual has been absent from the service area, when the MA organization has not been able to confirm the individual's residency status.

(ii) This SEP ends the later of 2 calendar months following the month it begins or 2 calendar months following the month of the move.

(3) * * *

(iii) This SEP begins the month CMS determines that a contract violation or material misrepresentation has occurred and ends 90 days after the date of CMS's determination.

(iv) An individual may elect another MA plan for an effective date of the first day of the month after the month the new sponsor receives the completed enrollment request. The individual may also choose an effective date of enrollment in the new plan beginning any of the 3 months after the month in which the sponsor receives the completed enrollment request. The effective date may not be earlier than the date the sponsor receives the completed enrollment request.

* * * * *

(14) * * *

(iii) This SEP begins upon the individual's disenrollment from a Part D plan and ends on the first day of the month following the month in which the disenrollment request is received by the plan.

* * * * *

(18) * * *

(ii) The individual must use a CMS-operated election mechanism, in a form and manner specified by CMS, to make an election using this SEP. To be eligible, the individual must demonstrate to CMS that the requirements in paragraphs (b)(18)(iii) to (b)(18)(v) are met.

* * * * *

(23) * * *

(i) * * *

(ii) An enrollee is affected by a significant network change when the enrollee is currently receiving care from, or has received care within the past 12 months, from the contracted provider or facility being terminated from the MA plan's provider network.

(iii) When CMS has determined that a provider termination is significant under § 422.112(d), the MA plan must include in the provider termination notice described at § 422.111(e) information regarding the affected enrollee's eligibility for the SEP and how to use the SEP as described in § 422.2267(e)(12)(ii)(D).

* * * * *

(27) The individual's enrollment request was denied because of a CMS-approved capacity limit, as specified in § 422.60(b)(2), and the individual was unable to make another election during the same election period because that election period had expired. The individual must use a CMS-operated mechanism, in a form and manner specified by CMS, to make an election using this SEP. The SEP begins the date the individual is notified of the enrollment denial and ends 2 calendar months after notification.

(28) The individual meets such other exceptional conditions as CMS may provide. This SEP requires CMS approval prior to use. The individual must use a CMS-operated mechanism, in a form and manner specified by CMS, to make an election using this SEP.

(i) This SEP begins upon CMS determination and notification to enrollee and ends on a case-by-case basis, as determined by CMS.

(ii) The effective date for an enrollment or disenrollment election using an approved enrollment exception is based on the individual's circumstances and will be effective the first of the month and may be either prospective or retroactive. The earliest prospective enrollment effective date is the first day of the calendar month following the month in which the election is made.

* * * * *

5. Section 422.66 is amended by--

a. Revising paragraphs (c)(2)(i)(A);

b. Redesignating paragraphs (c)(2)(i)(B) as (c)(2)(i)(B) introductory text;

c. Adding paragraphs (c)(2)(i)(B)(*1*) and (*2*);

d. Revising paragraph (c)(2)(i)(G);

e. Adding paragraph (c)(2)(i)(H); and

f. Revising paragraph (g)(2).

The revisions and additions read as follows:

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) At the time of the deemed election, the individual either--

(*1*) Remains enrolled in an affiliated Medicaid managed care plan; or

(*2*) Is transitioning from Medicaid fee-for-service to a Medicaid managed care plan affiliated with the MA organization offering the D-SNP, as part of a state-initiated transition to Medicaid managed care.

(*i*) *Concurrent enrollment requirement*. Default enrollment of an individual into a D-SNP under paragraph (c)(2)(i)(A)(*2*) must be concurrent with, and contingent upon, the individuals' enrollment into the affiliated Medicaid managed care plan, such that the D-SNP and Medicaid managed care plan enrollment is effectuated simultaneously. An MA organization must not effectuate the default enrollment under this paragraph prior to the individual's enrollment in the affiliated Medicaid managed care plan.

(*ii*) [Reserved]

* * * * *

(B) * * *

(*1*) An individual may be deemed enrolled under paragraph (c)(2)(i)(A)(*2*) of this section if the State administering the Medicaid program has initiated the transition described in paragraph (c)(2)(i)(A)(*2*) of this section and has identified the individual as eligible for enrollment in the affiliated Medicaid managed care plan. States transitioning from Medicaid fee-for-service to Medicaid managed care will identify individuals eligible for enrollment in the affiliated Medicaid managed care plan consistent with beneficiary choice in § 438.52, including the ability to make an affirmative plan selection and disenrollment protections at § 438.56, including beneficiaries' rights to disenroll for cause at any time and without cause during the 90 days following the date of the beneficiary's initial enrollment into the MCO.

(*2*) [Reserved]

* * * * *

(G) The MA organization does not have any prohibition on new enrollment imposed by CMS; and

(H) For purposes of this section, an affiliated Medicaid managed care plan is one that is offered by the MA organization that offers the dual eligible MA special needs plan or is offered by an entity that shares a parent organization with such MA organization.

* * * * *

(iv) * * *

(D) For default enrollment consistent with 422.66(c)(2)(i)(A)(*2*)(*i*), MA organizations must send the required notice described at § 422.66(c)(2)(iv) and default enrollment transaction to CMS no fewer than 60 calendar days prior to the month in which the individual is first entitled to both Part A and Part B.

* * * * *

(g) * * *

(2) *Special election periods*. All of the following SEPs require CMS approval prior to use:

(i) SEP for contract violation, § 422.62(b)(3).

(ii) SEP for individuals who disenroll in connection with CMS sanction, § 422.62(b)(5).

(iii) SEP for individuals who were not adequately informed of a loss of creditable prescription drug coverage, § 422.62(b)(20).

(iv) SEP for individuals affected by a government-entity-declared disaster or other emergency, § 422.62(b)(18).

(v) SEP for individuals who were denied enrollment due to a capacity limit, § 422.62(b)(27).

(vi) SEP for individuals who are enrolled or not enrolled in Part D due to an error by a federal employee, § 422.62(b)(21).

(vii) SEP for individuals affected by a significant change in provider network, § 422.62(b)(23).

(viii) SEP for other exceptional circumstances, § 422.62(b)(28).

6. Section 422.100 is amended by **r**evising paragraphs (f)(6), (f)(6)(i), (f)(6)(ii), and (f)(6)(ii)(A) to read as follows:

§ 422.100 General requirements.

* * * * *

(f) * * *

(6) General cost sharing limits. Cost sharing for basic benefits specified by CMS does not exceed levels annually determined by CMS to be discriminatory for such services. For each year beginning on or after January 1, 2023, a MA organization must establish cost sharing for basic benefits that complies with the cost sharing limits in this paragraph (f)(6), paragraph (j) of this section, and § 422.113(b)(2), which are separate from and in addition to any other limits (such as maximum out-of-pocket limits) and rules applicable to MA cost sharing, including the requirement in § 422.254(b)(4) that overall MA cost sharing for basic benefits be actuarially equivalent to Medicare FFS cost sharing. Cost sharing may be a coinsurance or copayment; a

cost sharing limit is calculated for a plan benefit package service category or for a reasonable group of benefits covered under the plan. For purposes of cost sharing evaluation, the analysis is completed at the plan (or segment) level. An MA plan must not charge an enrollee a copayment for a basic benefit that is greater than the cost of the covered service(s).

(i) *The 50 percent cap on original Medicare benefits.* For in-network basic benefits that are not specifically addressed in this paragraph (f)(6), paragraph (j)(1) of this section, or § 422.113(b)(2), and for out-of-network basic benefits, MA plans must not establish a cost sharing amount that exceeds 50 percent coinsurance or an actuarially equivalent copayment value (calculated by CMS following the requirements in paragraph (f)(7) of this section or, if CMS does not calculate a copayment limit, based on the average Medicare FFS allowable amount for the plan service area or the estimated total MA plan financial liability for the service category or for a reasonable group of benefits in the PBP for that contract year). For a selected drug payable under Part B, that is subject to a maximum fair price (as defined in § 422.2) and is furnished or administered by an out-of-network provider, MA plans must not establish a cost sharing amount that exceeds 50 percent of the cost calculated based on a price that is equal to or less than the maximum fair price. The rules in this paragraph (f)(6)(i) apply regardless of the type of MOOP limit established by the plan.

(ii) *Copayment rounding rules.* The following rounding rules apply in calculating copayment limits and in evaluating compliance with this paragraph (f)(6), paragraphs (f)(7), (f)(8), and (j)(1) of this section and § 422.113(b)(2)(v):

(A) For service categories subject to paragraph (f)(6)(i) of this section, professional services subject to paragraph (f)(6)(iii) of this section, benefits listed in paragraph (j)(1)(i) of this section, and emergency services subject to § 422.113(b)(2)(v), the final actuarially equivalent copayment value is rounded to the nearest whole $5.

* * * * *

7. Section 422.101 is amended by—

a. Revising paragraph (f)(1)(iv)(A);

b. Redesignating (f)(1)(vii)(C) to (f)(1)(vii)(F);

c. Adding a new paragraph (f)(1)(vii)(C) and paragraph (f)(1)(vii)(E);

d. Revising newly redesignated (f)(1)(vii)(F);

e. Adding paragraphs (f)(1)(vii)(G) and (H);

g. Revising paragraph (f)(1)(ix);

h. Removing and reserving paragraph (f)(2)(ii);

j. Revising paragraph (f)(2)(iii).

The revisions and additions read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(f) * * *

(1) * * *

(iv) * * *

(A) Make at least three attempts to reach the enrollee, 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. CMS may review SNP HRA communication policies or procedures upon request.

* * * * *

(vii) * * *

(C) Documents all active needs and diagnoses for the enrollee based on available data. In addition to the requirement at paragraph (vi) of this section, the SNP must utilize available enrollee-specific data, including but not limited to current diagnoses, health status information, and other clinical data where available.

(D) When enrollee input is obtainable, documents discussions between the enrollee and the interdisciplinary care team regarding all active needs, diagnoses, and available resources for

those needs. Documentation must include when the enrollee has chosen not to focus on an active need or diagnosis. The individualized care plan must reflect the enrollee's chosen person-centered goals and objectives (as prioritized by the enrollee), including measurable outcomes, as well as specific services and benefits to be provided.

(E) If the enrollee declines to participate or is unable to be reached for participation in either the HRA or the individualized care plan, identifies person-centered goals and objectives, including measurable outcomes, as well as specific services and benefits to be provided, for the enrollee based on available data as described in paragraph (f)(1)(vii)(C) of this section.

(F) Is updated as warranted by changes in the health status or care transitions of enrollees.

(G) Identifies available supplemental benefits as described in § 422.102 that the enrollee can access to address their identified care needs.

(H) The SNP must share and make accessible the most recent individualized care plan with all of the following:

(*1*) The enrollee.

(*2*) The enrollee's personal representative under 45 CFR 164.502(g), if applicable.

(*3*) The interdisciplinary care team required under paragraph (f)(1)(ix) of this section.

(*4*) For FI-SNPs, the enrollee's long-term care facility.

* * * * *

(ix) *Interdisciplinary care team (ICT)*. 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.

(A) *General interdisciplinary care team requirements*. An ICT at minimum includes a primary care provider or a member of their clinical staff such as nurse practitioners, physician assistants, or registered nurses, acting as the provider's representative, a care manager, any behavioral health provider actively treating or coordinating care for the enrollee, and at least one

other individual with clinical training or expertise who is delivering or coordinating care for the enrollee.

(B) *Additional C-SNP interdisciplinary care team requirements*. The C-SNP ICT must also include a specialist provider who focuses on at least one of the specific chronic disease(s) of focus. For C-SNPs that serve enrollees with multiple chronic conditions, the ICT only needs to include one specialist.

(C) *Additional I-SNP interdisciplinary care team requirements*. For I-SNP enrollees who are institutionalized, the ICT must also include a member of the clinical team providing care from the enrollee's long-term care facility. For I-SNP enrollees who are institutionalized-equivalent but reside in the community, the ICT must also include a home health provider, nurse, or other individual providing care in the home.

(D) *Additional D-SNP interdisciplinary care team requirements*. For D-SNP enrollees who are full-benefit dually eligible and residing in the community, the ICT must include a home health provider, nurse, personal care aide, or other individual providing care in the home.

* * * * *

(2) * * *

(ii) [Reserved].

(iii) * * *

(A) D-SNPs must coordinate the delivery of Medicaid benefits for individuals who are eligible for such services consistent with § 422.107(c)(1)(i).

(B) C-SNPs, IE-SNPs, and HI-SNPs where 60 percent or more of the plan's total enrollment are enrollees who are entitled to Medicaid, as determined by CMS using the January enrollment of the current year, must coordinate with Medicaid across healthcare settings, providers, and services. This requirement applies to:

(1) All full-benefit dually eligible enrollees in C-SNPs and IE-SNPs; and

(2) Full-benefit dually eligible enrollees who reside in the community for HI-SNPs.

(C) For these enrollees in paragraphs (B)(1) and (2), C-SNPs, IE-SNPs, and HI-SNPs must identify:

(1) Strategies for coordinating Medicaid-covered services in response to enrollee needs; and

(2) Methods for coordination.

* * * * *

8. Section 422.102 is amended by--

a. Removing paragraph (f)(1)(iii)(I); and

b. Adding paragraph (h).

The addition reads as follows:

§ 422.102 Supplemental benefits.

* * * * *

(h) *Limitation on food-related supplemental benefit*s. For any supplemental benefit offered under this part that includes food or beverage items, all such items must meet the definition of "healthy food" in paragraph (h)(1) of this section.

(1) *Definition*. For purposes of supplemental benefits under this section, healthy foods are defined as whole, nutrient-dense foods. Healthy foods include, but are not limited to the following:

(i) Proteins from a variety of animal- and plant-based sources, including eggs, poultry, seafood, red meat and soy.

(ii) Fresh fruits and vegetables, as well as frozen, dried, or canned fruits and vegetables with no or limited added sugars.

(iii) Legumes including beans, chickpeas, and lentils.

(iv) Nuts, seeds, and natural nut butters with limited added sugars or hydrogenated oils.

(v) Fats and oils including olive oil, avocado oil, butter, and beef tallow.

(vi) Dairy products with limited added sugars.

(vii) Whole grains including sprouted bread, whole grain rye or pumpernickel bread, whole wheat pasta, buckwheat flour, and wheat or oat bran with limited added sugars.

(2) *Provider-recommended foods*. Notwithstanding paragraph (h)(1) of this section, any food or beverage specifically recommended by an enrollee's health care provider to address the enrollee's medical condition or nutritional needs qualifies as "healthy food" for purposes of this section, provided that the item is not otherwise prohibited under paragraph (f)(1)(iii) of this section or other applicable law.

9. Section 422.111 is amended by revising paragraph (e) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(e) *Changes to provider network.* The MA organization must provide enrollees notice of a termination of a contracted provider, irrespective of whether the termination was for cause or without cause, in accordance with § 422.2267(e)(12). For all terminations, the MA organization must provide:

(1) Written notice.

(2) Notice within 5 business days of the termination effective date.

(3) Notice to all enrollees who are currently receiving care from, or have received care within the past 12 months from, the contracted provider being terminated.

* * * * *

10. Section 422.112 is amended by –

a. Revising paragraph (a)(4); and

b. Adding paragraphs (b)(9) and (d).

The revision and additions read as follows:

§ 422.112 Access to services.

(a) * * *

(4) *Service area expansion.* An MA plan with an approved service area expansion must demonstrate that the number and type of providers available to plan enrollees are sufficient to meet the needs of the population served.

* * * * *

(b) * * *

(9) Policies and procedures to ensure that, upon the termination of a contract between an MA organization and a provider or facility, the MA organization must continue to provide coverage for basic benefits, including items and services furnished by the terminated provider to affected enrollees at the applicable in-network cost-sharing rate for a minimum coverage period of 90 days beginning on the termination effective date. Affected enrollees are the enrollee populations identified at § 422.111(e)(3). This continuity of care requirement does not extend to payments to providers that have been terminated for cause, including where the provider is excluded by the OIG or included on the preclusion list as described at §§ 422.222 and 422.224.

* * * * *

(d) *Significant change in plan provider network.*

(1) An MA plan must notify CMS of a contracted provider termination that meets either of the following criteria at least 60 days prior to the effective date of the termination for without-cause terminations and when practicable for for-cause terminations:

(i) At least 10 percent of the MA plan's enrollees would be affected by the provider termination as defined under § 422.62(b)(23)(ii).

(ii) The provider termination would constitute at least 10 percent of the MA plan's network for a given provider specialty described under § 422.116(b)(1) or facility specialty described under § 422.116(b)(2).

(2) The MA plan must notify enrollees who are eligible for the SEP at § 422.62(b)(23) in the provider termination notice in accordance with §§ 422.62(b)(23)(iii) and 422.2267(e)(12)(ii).

11. Section 422.113 is amended by--

a. Revising paragraphs (a), (b)(2)(v) introductory text, (b)(2)(v)(A) through (C), and (vi); and

b. Adding paragraphs (b)(2)(vi)(A) and (B), (vii) and (viii).

The revisions and additions read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

(a) *Ambulance services*. The MA organization is financially responsible for ambulance services, including ambulance services dispatched through 911 or its local equivalent, where other means of transportation would endanger the beneficiary's health. For 2028 and subsequent years, MA plans must not establish in-network cost sharing for ground ambulance services that exceeds the limits specified for professional services in § 422.100(f)(6)(iii)(F).

(b) * * *

(2) * * *

(v) With a maximum dollar limit permitted per visit for emergency services for 2028 and subsequent years that corresponds to the MA plan MOOP type as follows:

(A) *Mandatory MOOP*: The dollar limit is calculated based on 15 percent of the most recent Medicare FFS data projections.

(B) *Intermediate MOOP*: The dollar limit is calculated based on the numeric midpoint between the dollar limits for the lower and mandatory MOOP types.

(C) *Lower MOOP*: The dollar limit is calculated based on 20 percent of the most recent Medicare FFS data projections.

(vi) If CMS does not calculate a cost sharing dollar limit for emergency services based on the most recent Medicare FFS data projections, then the MA plan must not establish--

(A) A cost sharing dollar limit that exceeds an actuarially equivalent value to the percentages in this paragraph (b)(2)(v) based on the estimated total MA plan financial liability for emergency services for that contract year; or

(B) A coinsurance limit that exceeds the percentages applicable based on MOOP type from this paragraph (b)(2)(v).

(vii) For each year beginning on or after January 1, 2023, with a cost sharing limit on urgently needed services that does not exceed the limits specified for professional services in § 422.100(f)(6)(iii).

(viii) The cost sharing standards for ground ambulance services in paragraph (a) of this section, emergency services in paragraph (b)(2)(v) of this section, and urgently needed services in paragraph (b)(2)(vii) of this section are subject to the rounding rules and actuarial requirements in § 422.100(f)(6)(ii) and (f)(7).

* * * * *

12. Section 422.116 is amended by—

a. Revising paragraph (a)(2)(i);

b. Removing and reserving paragraph (a)(2)(ii);

c. Removing paragraphs (b)(1)(xxviii) and (xxix);

d. Revising paragraph (b)(2)(xiv);

e. Revising paragraph (c)(4)(ii);

f. Revising table 1 to paragraph (d)(2);

g. Removing and reserving paragraphs (d)(5)(xiii) and (xxiv);

h. Removing paragraph (d)(7);

i. In table 2 to paragraph (e)(3)(i)(C) removing the entries for “Clinical Psychology” and “Clinical Social Work”; and

(j) Revising paragraph (f)(1)(i)(A).

The revisions read as follows:

§ 422.116 Network adequacy.

(a) * * *

(2) * * *

(i) A network-based MA plan, as described in § 422.2 but not including MSA plans, must demonstrate that it has an adequate contracted provider network that is sufficient to provide access to covered services in accordance with access standards described in section 1852(d)(1) of the Act and in §§ 422.112(a) and 422.114(a)(1) and by meeting the standard in paragraph (a)(3) of this section. An organization applying for a new service area must attest upon application that at the beginning of the applicable contract year, the MA organization will be in full compliance with network adequacy standards under this section. When required by CMS, an MA organization must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year.

(ii) [Reserved]

(b) * * *

(2) * * *

(xiv) Outpatient behavioral health, which can include marriage and family therapists (as defined in section 1861(lll) of the Act), mental health counselors (as defined in section 1861(lll) of the Act), clinical social workers (as defined in section 1861(hh) of the Act), clinical psychologists (as defined in § 410.71(d)), opioid treatment programs (as defined in section 1861(jjj) of the Act), community mental health centers (as defined in section 1861(ff)(3)(b) of the Act), and certified peer support specialists and community health workers furnishing services as auxiliary personnel under the supervision of a physician (or other eligible practitioner) as described at § 410.26(a)(1), or those of the following who regularly furnish or will regularly furnish behavioral health counseling or therapy services including psychotherapy or prescription of medication for substance use disorders; physician assistants, nurse practitioners and clinical nurse specialists (as defined in section 1861(aa)(5) of the Act); addiction medicine physicians; or outpatient mental health and substance use treatment facilities.

* * * * *

(c) * * *

(4) * * *

(ii) A population size less than 10,000 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 4999.9 persons per square mile.

* * * * *

(d) * * *

(2) * * *

TABLE 1 TO PARAGRAPH (d)(2)

Specialty Type	Large Metro		Metro		Micro		Rural		CEAC	
	Time	Distance	Time	Distance	Time	Distance	Time	Distance	Time	Distance
		* *	*	*	*	*	*			
Outpatient Behavioral Health	20	10	25	15	35	25	45	35	95	85
		* *	*	*	*	*	*			

* * * * *

(f) * * *

(1) * * *

(i) * * *

(A) Certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type based on substantial and credible evidence, in the form and manner requested by CMS, regarding the following valid rationales:

(*1*) Provider is no longer practicing (for example, deceased, retired).

(*2*) Provider does not provide services at the office or facility address listed in the Provider Supply file § 422.116(a)(5)(ii).

(*3*) Provider does not provide services for the specialty type listed in the Provider Supply file § 422.116(a)(5)(ii).

(*4*) Provider has opted out of Medicare (in compliance with § 422.204(b)(4)).

(*5*) Provider does not contract with any MA organizations or contracts exclusively with another MA organization.

(*6*) Provider is a sanctioned provider on the List of Excluded Individuals and Entities (in compliance with § 422.204); or provider is on the CMS preclusion list (in compliance with § 422.222).

(7) Provider has the potential to cause beneficiary harm.

(8) Provider is at capacity and is not accepting new patients; and

* * * * *

13. Section 422.166 is amended by--

a. Adding paragraphs (a)(2)(iv) and (v), (a)(3)(vi), (b)(1)(iii); and

b. Revising paragraphs (f)(1) and (f)(1)(i), (f)(2), (g)(1)(i) and (ii), (h)(2), and (i)(5).

The revisions and additions read as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(iv) Beginning with the 2031 Star Ratings and for the duration of the ADVaNCE MA model, measure scores for contracts participating in the model will be adjusted for the estimated average impact of the model prior to determining measure-level cut points for all measures except the improvement measures.

(A) The average impact of the ADVaNCE MA model will be estimated for each measure each year using a regression model that includes all contracts' (model and non-model) measure scores as outcomes, and an indicator of model participation, contract-specific baseline quality, and state-level baseline quality as explanatory variables.

(*1*) Contract-specific baseline quality is the contract measure score from the measurement year prior to implementation of the ADVaNCE MA model where available. For contracts that did not have measure scores in the measurement year prior to implementation of the model,

including model contracts that spanned multiple states prior to model implementation, the parent organization-level measure score is used. If no contracts in the parent organization have measure scores in the measurement year prior to model implementation, the national-level measure score calculated using patient-level data is used. CMS will use the national-level measure score when a contract's measure data are inaccurate, incomplete, or biased.

(*i*) The parent organization-level measure score is calculated following the measure specifications for case-mix adjusted measures, but case-mix adjustment is applied at the level of the parent organization. For measure that are not case-mix adjusted and not based on survey data, the parent organization-level measure score is calculated as the weighted average measure score across contracts in the same parent organization that had measure scores in the measurement year prior to implementation of the model, where the weights are contract enrollment in July of the measurement year prior to the implementation of the model. For HEDIS-HOS measures, the parent organization-level measure score is calculated as the weighted average of the measure scores across contracts in the same parent organization that had measure scores in the measurement year prior to implementation of the model, where the weights are contract enrollment at the time the sample is pulled.

(*2*) State-level baseline quality is calculated as the weighted average of state-level average measure scores, where the weights represent the proportion of total enrollees from the contract that reside in each state as of July of the current measurement year for the applicable Star Ratings year. State-level average measure scores are calculated as average scores using patient-level data from the measurement year prior to model implementation across enrollees residing within the state as of July of the measurement year prior to model implementation.

(B) For measures that are new to the Star Ratings or are returning to the Star Ratings after a substantive specification change for the applicable year, contract-level and state-level baseline quality will be calculated following the methodology explained at paragraphs (a)(2)(iv)(A)(*1*) and (*2*) of this section but, instead of using measure-specific data, the calculations will use

averages of all existing Star Ratings measures in the applicable year using data from the measurement year prior to ADVaNCE MA model implementation.

(v) Contracts participating in the ADVaNCE MA model will be excluded from the calculation of the improvement measures and of the cut points for improvement measures.

* * * * *

(3) * * *

(vi) Beginning with the 2031 Star Ratings and for the duration of the ADVaNCE MA model, measure scores for contracts participating in the model will be adjusted for the estimated average impact of the model prior to applying the relative distribution and significance testing methodology for CAHPS measures, following the methodology at paragraph (a)(2)(iv) of this section.

* * * * *

(b) * * *

(1) * * *

(iii) Domains are displayed on Medicare Plan Finder only if they contain measures included in the Star Ratings for the applicable year.

* * * * *

(f) * * *

(1) *Reward factor*. Through the 2029 Star Ratings, this rating-specific reward factor is added to both the summary and overall ratings of contracts that qualify for this reward factor based on both high and stable relative performance for the rating level. Beginning with the 2030 Star Ratings, the reward factor does not apply.

(i) The contract's performance will be assessed using its weighted mean and its ranking relative to all rated contracts in the rating level (overall for MA-PDs; Part C summary for MA-PDs and MA-only; and Part D summary for MA-PDs and PDPs) for the same Star Ratings year. The contract's stability of performance will be assessed using the weighted variance and its

ranking relative to all rated contracts in the rating type (overall for MA-PDs; Part C summary for MA-PDs and MA-only; and Part D summary for MA-PDs and PDPs). The weighted mean and weighted variance are compared separately for MA-PD and standalone Part D contracts (PDPs). The measure weights are specified in paragraph (e) of this section. Since highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean are calculated both with and without the improvement measures. For an MA-PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance and weighted mean for the rating type (Part C summary, Part D summary) with the improvement measure. Beginning with the 2031 Star Ratings and for the duration of the ADVaNCE MA model, ADVaNCE MA model contracts are excluded from the calculation of the weighted variance and weighted mean.

* * * * *

(2) *Categorical adjustment index.* CMS applies the categorical adjustment index (CAI) as provided in this paragraph (f)(2) to adjust for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low income subsidy or are dual eligible (LIS/DE) or have disability status. The factor is calculated as the mean difference in the adjusted and unadjusted ratings (overall, Part C, Part D for MA-PDs, Part D for PDPs) of the contracts that lie within each final adjustment category for each rating type. Beginning with the 2031 Star Ratings and for the duration of the ADVaNCE MA model, ADVaNCE MA model contracts are excluded from the calculation of the categorical adjustment index.

* * * * *

(g) * * *

(1) * * *

(i) If the highest rating for each contract-type is 4.5 stars or more (or 4 stars or more through the 2029 Star Ratings) without the use of the improvement measure(s) and with all

applicable adjustments (CAI and the reward factor), a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.

(ii) If the highest rating is less than 4.5 stars (or less than 4 stars through the 2029 Star Ratings) without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), the rating will be calculated with the improvement measure(s).

* * * * *

(h) * * *

(2) *Plan preview of the Star Ratings.* CMS will have two plan preview periods before each Star Ratings release during which MA organizations can preview their preliminary Star Ratings data in HPMS prior to display on the Medicare Plan Finder. During the second plan preview, CMS will display de-identified contract-level sample data for one of each type of measure needed to replicate the cut point methodology, as determined by CMS. MA organizations and first tier, downstream, and related entities may not disclose the preliminary Star Ratings data to the public through any means until the Star Ratings have been finalized and released publicly on the Medicare Plan Finder.

* * * * *

(i) * * *

(5) *New measure adjustments.* For affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, CMS holds the affected contract harmless by using the higher of the contract's summary or overall rating or both with and without including all of the applicable new measures. Contracts that do not have enough measures to have the summary or overall rating or both calculated either with or without including all applicable new measures will receive the rating from the summary or overall rating that had enough measures to be calculated.

* * * * *

14. Section 422.202 is amended by revising paragraph (c) to read as follows:

§ 422.202 Participation procedures.

* * * * *

(c) *Use of Prior Authorization API.* (1) Beginning January 1, 2028, an MA organization must include in each contract with a provider for participation in the MA organization's network, the requirement that the provider use the Prior Authorization API to transmit information pertaining to a prior authorization request for non-drug items and services, including supplemental benefits, to the MA organization. This requirement applies only to in-network providers that furnish non-drug items and services, including supplemental benefits, for which the MA organization uses prior authorization processes.

(2) MA organizations must include in each contract with a provider for participation in the MA organization's network, the requirement to annually participate in testing. The MA organization must confirm with each contracted provider that the Prior Authorization API features are bi-directionally functional, useable, and accessible for both the MA organization and the contracted provider, consistent with their intended use and the standards set forth in § 422.122(b), as applicable. This requirement applies only to providers that furnish non-drug items and services, including supplemental benefits, for which the MA organization uses prior authorization processes.

* * * * *

15. Section 422.254 is amended by adding new paragraphs to (c)(4) and (e)(1)(i) through (e)(1)(iv) to read as follows:

§ 422.254 Submission of bids.

* * * * *

(c) * * *

(4) * * *

(i) Proposed enrollment capacity limits must not be below the current enrollment as of June 1 of the year preceding the contract year for the planned service area.

(ii) Plans submitting a proposed enrollment capacity limit must include a supporting narrative that describes how the limit was derived.

(iii) For a plan in a new contract or a new plan to be offered under an existing contract without any non-renewing plans in the proposed service area for the contract year, there is no minimum limit for acceptance.

(iv) For a new plan to be offered under an existing contract, the proposed enrollment capacity limit must not be below the aggregate current enrollment as of June 1 of the year preceding the contract year for the planned service area for any non-renewing plans of the same plan type within the contract.

* * * * *

(e) * * *

(1) * * *

(i) Proposed enrollment capacity limits must not be below the current enrollment as of June 1 of the year preceding the contract year for the planned service area.

(ii) Plans submitting a proposed enrollment capacity limit must include a supporting narrative that describes how the limit was derived.

(iii) For a plan in a new contract or a new plan to be offered under an existing contract without any non-renewing plans in the proposed service area for the contract year, there is no minimum limit for acceptance.

(iv) For a new plan to be offered under an existing contract, the proposed enrollment capacity limit must not be below the aggregate current enrollment as of June 1 of the year preceding the contract year for the planned service area for any non-renewing plans of the same plan type within the contract.

16. Section 422.504 is amended by adding paragraphs (p), and (q) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(p) *Enrollment in the Medicare Transaction Facilitator Data Module for the Medicare Drug Price Negotiation Program.* For contract year 2028 and all subsequent years, any contract between the MA organization and a provider (as defined in § 422.2), or between a first tier, downstream, or related entity and a provider on the MA organization's behalf, for participation in one or more of the MA organization's networks must include a provision requiring that if the provider furnishes or administers selected drugs payable under Part B during the period when such drugs are subject to a maximum fair price (as defined in § 422.2), the provider must 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 such provider 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, in a form and manner determined by CMS.

(q) *Requirement to submit data for encounters involving selected drugs for effectuation of the maximum fair price in the Medicare Drug Price Negotiation Program.*

(1) For contract year 2028 and all subsequent years, MA organizations are required, within 30 days of the claim-from date:

(i) To submit MA encounter data (as described at § 422.310(d)(5)) records involving the furnishing or administration of a selected drug payable under Part B for which a maximum fair price (as defined in § 422.2) is in effect on the claim-from date. CMS uses such data for risk adjustment purposes unless the MA organization submits risk adjustment data required under § 422.310 by the final risk adjustment submission deadline under § 422.310(g).

(ii) To collect and submit NDC-11 codes on each MA encounter data record for a selected drug payable under Part B for which a maximum fair price is in effect on the claim-from date.

(2) The Chief Executive Officer (CEO), Chief Financial Officer (CFO), or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to

such officer, must certify (based on best knowledge, information, and belief), in a form and manner and by a deadline specified by CMS, that the data it submits under § 422.504(q)(1) are accurate, complete, and truthful.

17. Section 422.514 is amended by revising paragraph (h)(1)to read as follows:

§ 422.514 Enrollment requirements.

* * * * *

(h) * * *

(1) Where an MA organization offers a dual eligible special needs plan and the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization, or any entity that has a contractual relationship with the MA organization that requires the MA organization to assume clinical and financial responsibility for Medicare and Medicaid benefits also contracts with a State as a Medicaid managed care organization (MCO) (as defined in § 438.2) that enrolls full-benefit dual eligible individuals as defined in § 423.772, during the effective dates and in the same service area (even if there is only partial overlap of the service areas) of that Medicaid MCO contract, the MA organization--

* * * * *

§ 422.530 [Amended]

18. Section 422.530 is amended by—

a. In paragraph (b)(2)(ii)(A) removing the terms “Institutional SNP” and “Institutional/Institutional Equivalent SNP” adding in its place the terms “Facility-based Institutional special needs plan (FI-SNP)” and “Hybrid Institutional special needs plan (HI-SNP),” respectively; and

b. In paragraph (b)(2)(ii)(B) removing the terms “Institutional Equivalent SNP” and “Institutional/Institutional Equivalent SNP” adding in its place the terms “Institutional-equivalent special needs plan (IE-SNP)” and “Hybrid Institutional special needs plan (HI-SNP),” respectively; and

c. In paragraph (b)(2)(ii)(C) removing the terms “Institutional/Institutional Equivalent SNP” and “Institutional SNP” adding in its place the terms “Hybrid Institutional special needs plan (HI-SNP)” and “Facility-based Institutional special needs plan (FI-SNP),” respectively; and

d. In paragraph (b)(2)(ii)(D) removing the terms “Institutional/Institutional Equivalent SNP” and “Institutional Equivalent SNP” adding in its place the terms “Hybrid Institutional special needs plan (HI-SNP)” and “Institutional-equivalent special needs plan (IE-SNP),” respectively; and

e. In paragraph (b)(2)(ii)(E) removing the term “Institutional/Institutional Equivalent SNP” and adding in its place the term “Hybrid Institutional special needs plan (HI-SNP).”

19. Section 422.582 is amended by revising paragraph (i) to read as follows:

§ 422.582 Request for a standard reconsideration.

* * * * *

(i) *Effect of dismissal*. The MA organization's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(i) or the decision is vacated under paragraph (h) of this section.

20. Section 422.2260 is amended by adding the definitions of “Base compensation outlier”, “Compensation”, “Fair market value (FMV)” “Initial enrollment year”, “Like plan type”, and “Plan year”, “Renewal year” and “Unlike plan type” in alphabetical order to read as follows:

§ 422.2260 Definitions.

* * * * *

Base compensation outlier means any base compensation amounts, submitted to CMS by any MA organizations, in accordance with §§ 422.2271(b)(3)(ii) and 423.2271(b)(3)(ii), that are above the third quartile. as calculated in a distribution, using a box plot method and determined by CMS in accordance with §§ 422.2274(b) and 423.2274(b). Base compensation outliers will be determined based on all base compensation amounts submitted by all MA organizations.

* * * * *

Compensation means monetary or non-monetary remuneration of any kind relating to the sale and renewal of a plan or product offered by an MA organization. For purposes of this definition, compensation falls into the following two categories, both of which must be Fair Market Value as defined in this subpart:

(1) Base compensation: any monetary renumeration for the actual initial or renewal enrollment, as referenced in §§ 422.2274(a) and 423.2274(a).

(2) Supplemental compensation: any monetary or non-monetary remuneration, above and beyond base compensation, related to the sale and renewal of a plan or product offered by an MA organization, such as bonuses, gifts, prizes or awards. Supplemental compensation is an additional incentive offered by an MA organization or Part D sponsor to agents and brokers, typically tied to a performance metric.

Fair market value means the compensation amount (which includes base and supplemental compensation) that would be paid to a licensed insurance agent or broker at the time the parties enter into an arrangement, as the result of bona fide bargaining between well-informed parties acting at arm's length and under comparable market conditions. Such payments must be consistent with prevailing market rates for comparable services and must not reflect consideration of any business generated between the parties except as expressly permitted by applicable law and regulation.

* * * * *

Initial enrollment year means the first year that a beneficiary is enrolled in a plan versus subsequent years (c.f., *renewal year*) that a beneficiary remains enrolled in a plan.

* * * * *

Like plan type means one of the following:

(i) PDP replaced with another PDP.

(ii) MA or MA-PD replaced with another MA or MA-PD.

(iii) Cost plan replaced with another cost plan.

* * * * *

Plan year and *enrollment year* mean the year beginning January 1 and ending December 31.

* * * * *

Renewal year means all years following the initial enrollment year in the same plan or in different plan that is a like plan type.

* * * * *

Unlike plan type means one of the following:

(i) An MA or, MA-PD plan to a PDP or section 1876 Cost Plan.

(ii) A PDP to a section 1876 Cost Plan or an MA or MA-PD plan.

(iii) A section 1876 Cost Plan to an MA or MA-PD plan or PDP.

* * * * *

21. Section 422.2262 is amended by revising paragraph (a)(1)(xvii) as follows:

§ 422.2262 General communications materials and activity requirements.

(a) * * *

(1) * * *

(xvii) Use the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card, in a misleading way.

* * * * *

22. Section 422.2263 is amended by revising paragraph (b)(7)(i)(A) to read as follows:

§ 422.2263 General marketing requirements.

* * * * *

(b) * * *

(7) * * *

(i) * * *

(A) Conduct marketing activities that focus on other enrollment opportunities, including but not limited to marketing to age-ins (who have not yet made an enrollment decision), marketing by 5-star plans regarding their continuous enrollment special election period (SEP), and marketing to full-benefit dual eligible individuals that may be eligible for a SEP per § 423.38(c)(35);

* * * * *

§ 422.2265 [Amended]

23. Section 422.2265 is amended by—

a. Removing paragraph (a)(1)(ii); and

b. Redesignating paragraphs (a)(1)(iii) through (v) as paragraphs (a)(1)(ii) through (iv).

24. Section 422.2267 is amended by—

a. Revising paragraph (d)(2);

b. Revising paragraphs (e)(12)(ii)(A), (C), and (D);

c. Adding paragraph (e)(12)(ii)(F);

d. Removing paragraph (e)(12)(iii);

e. Redesignating paragraph (e)(16) as (e)(16) introductory text;

f. Adding paragraphs (e)(16)(i) and (ii);

g. Adding paragraph (e)(31);

h. Removing paragraphs (e)(33) and (e)(36);

i. Redesignating paragraphs (e)(34), (35), (37), (38), (39), and (40) as paragraphs (e)(33) through (38), respectively; and

j. Removing paragraph (e)(41).

The revisions and additions read as follows:

§ 422.2267 Required materials and content.

(d) * * *

(2) *Electronic delivery of required materials*. Unless otherwise specified in paragraph (e) of this section or other applicable law, an MA organization may electronically deliver required materials and content without prior authorization from the enrollee if the MA organization satisfies the requirements in paragraphs (d)(2)(i) through (iii) of this section.

(i) *Notice requirement*. Except as provided in paragraph (d)(2)(ii) of this section, an MA organization must mail a notice to all new and current enrollees that includes the following information:

(A) Instructions for electronically accessing the required materials, including the applicable website address or portal information;

(B) Instructions, including a telephone number, for requesting hard copies of one or more required materials. The request may be material specific and must be available as a one-time request or as a permanent request that remains in place until the enrollee chooses to receive electronic materials again; and

(C) The date the materials will be available, if not currently available.

(ii) *Electronic delivery of notice*. The notice required under paragraph (d)(2)(i) of this section may be furnished electronically if the new or current enrollee has opted into electronic communications before delivery of the notice.

(iii) *Hard copy and unsuccessful electronic delivery*. An MA organization must mail hard copies of requested materials within 3 business days of the request and must have a reasonable process to furnish hard copy or another enrollee-selected available format if electronic delivery is unsuccessful.

(iv) *State requirements for D-SNPs*. Nothing in this paragraph authorizes a dual eligible special needs plan (D-SNP) to electronically deliver required materials or content when an applicable State Medicaid agency contract requirement or other applicable State requirement specifies a different form or manner of delivery.

* * * * *

(e) * * *

(12) * * *

(ii) * * *

(A) Inform the enrollee that the provider is no longer in the network and the date the provider left the network.

* * * * *

(C) Explain how the enrollee may request a continuation of ongoing medical treatment or therapies with their current provider. If the provider is deceased, the notice must instead explain how the enrollee may find a new in-network provider and transfer their medical records.

(D) Provide information about the annual coordinated election period and the MA open enrollment period, as well as explain that an enrollee who is impacted by the provider termination may contact 1-800-MEDICARE to request assistance in identifying and switching to other coverage, or to request consideration for a special election period, as specified in § 422.62(b)(28), based on the individual's unique circumstances and consistent with existing parameters for this SEP, or when applicable, explain that an enrollee who is affected by the significant provider termination is eligible for a special election period, as specified in § 422.62(b)(23) (including the start and end dates of that SEP), and Medigap guaranteed issue (GI) rights. The notice must advise individuals who have coverage through an employer or union to contact their benefits administrator before leaving their current MA plan to find out how making such a change may affect their employer or union health benefits.

* * * * *

(F) Inform the enrollee that the enrollee qualifies for a minimum of 90 days of continued coverage in accordance with the continuity of care requirement at § 422.112(b)(9), if applicable. The notice must advise the enrollee of the dates of the continued coverage period beginning on the termination effective date, that coverage is provided at the applicable in-network cost-sharing rate, and that coverage applies to basic benefits furnished by the terminated provider.

* * * * *

(16) * * *

(i) *Coverage Decision Letter (CDL)*. This is a standardized communication material used to notify enrollees of an integrated organization determination as described in § 422.631, when applicable integrated plans, as defined in § 422.561, reduce, stop, suspend, deny, or change, in whole or in part, a request for a medical service/item, and/or Medicare Part B drug or Medicaid drug or a request for payment of a medical service/item, and/or Medicare Part B drug or Medicaid drug the enrollee has already received. This letter must be used in place of the Notice of Denial of Medical Coverage or Payment.

(ii) [Reserved]

* * * * *

(31) *Low performing icon (LPI) Notice.* This is a standardized written notice that an MA organization that has received an overall Star Rating of less than 3 stars for 3 or more consecutive contract years must provide to each beneficiary enrolled in the plan during the current plan year, using CMS-approved standardized language, as specified by CMS in guidance. The notice must inform the beneficiary of their ability to use a special enrollment period (SEP) to enroll in a plan that is not identified as a low-performing plan. The MA organization must mail the notice to each enrolled beneficiary no later than November 15 of each contract year.

* * * * *

25. Section 422.2271 is added to read as follows:

§ 422.2271 MA requirements, MA reporting requirements, and MA oversight of agent/broker/TPMO requirements.

MA organizations are responsible for the actions of their first tier, downstream, related entities, and TPMOs, that represent the MA organization and must ensure the following requirements in paragraphs (a) through (c) of the section are met. Representation includes selling products (including Medicare Advantage plans, Medicare Advantage-Prescription Drug plans,

Medicare Prescription Drug plans, and section 1876 Cost plans) as well as outreach to existing or potential enrollees and answering or potentially answering questions from existing or potential enrollees.

(a) *General MA oversight requirements*. MA organizations must do all of the following:

(1) Establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS.

(2) Oversee first tier, downstream, and related entities, including agents and brokers, to ensure agents and brokers abide by all applicable State and Federal laws, regulations, and requirements.

(3)

(i) Must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct.

(ii) CMS will share compliance and oversight information with States about licensed agents' and brokers' performance via a memorandum of understanding or other appropriate means.

(4) Must demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(b) *MA reporting requirements*. MA organizations must provide CMS, and the State, if specified, in the form and manner prescribed by CMS, the following:

(1) Terminated agents and brokers, reported as required:

(i) Report to the State all terminations of agents and brokers who are licensed and appointed, as required, in that State and the reasons for termination, as required by State law.

(ii) Report to CMS, in the form and manner prescribed by CMS, within 15 calendar days of the termination, all terminations of an agent or broker due to violations of Federal law, CMS regulations, or relevant State laws, as well as any other for cause termination of an agent or broker, and the reasons for termination.

(2) Report all enrollments made by unlicensed agents and brokers.

(3) On an annual basis, by the last Friday in July, report to CMS:

(i) Whether the MA organization intends to use employed, captive, and/or independent agents or brokers in the upcoming plan year;

(ii) The specific base compensation amounts, as defined at § 422.2260, the plan will pay independent agents and brokers for each plan.

(iii) Supplemental compensation, as defined at § 422.2260, the plan will pay independent agents and brokers for each plan, including--

(A) The specific type, such as bonuses, gifts, prizes or awards,

(B) Monetary amounts or retail value of non-monetary compensation; and

(C) Detailed explanation of supplemental compensation programs including payment schedules.

(iv) Documentation, including contracts regarding compensation associated with their relationships with first tier, downstream, related entities, and TPMOs as requested by CMS.

(c) *MA oversight of agent/broker/TPMO requirements*. MA organizations must ensure agents, brokers and TPMOs who represent MA organizations meet the requirements in paragraphs (c)(1) through (7) of this section.

(1) Agents and brokers are licensed and appointed under State law, if required.

(2) Agents and brokers are trained and tested annually meeting the following requirements:

(i) Training and testing must cover relevant Medicare rules and regulations and relevant State and Federal requirements, as well as any additional topics, as specified annually by CMS.

(ii) Must achieve at least 85 percent or higher on all testing.

(iii) If trained and tested by a third-party or another MA organization, agents and brokers must meet the requirements in (c)(2)(i) and (ii) of this section.

(3) Beneficiaries are not charged fees by agents, brokers, or TPMOs when operating under a health insurance license under State law.

(4) Meet the following requirements:

(i) Verify, prior to entering into a contract with an agent, broker, or TPMO, that the individual or entity is not currently terminated from participation in the Federally Facilitated Exchange (FFE), as outlined at 45 CFR 155.220(g) by CMS.

(ii) Monitor the termination status with the FFE monthly for agents and brokers with whom they have existing contracts.

(iii) Terminate within 15 calendar days, any existing contract with an agent or broker upon determining that the agent or broker has been terminated from the FFE by CMS.

(5) All marketing and sales calls, including the audio portion of calls conducted via web-based technology, must be recorded and retained in their entirety for a minimum period of 6 years. For the first 3 years of the retention period, records must be maintained in audio format. For years 4, 5, and 6, records may be maintained in either audio format or as complete and accurate transcript recordings.

(6) The TPMO, when conducting lead generating activities, either directly or indirectly for an MA organization, must, when applicable:

(i) Disclose to the beneficiary that their information will be provided to a licensed agent for future contact. This disclosure must be provided as follows:

(A) Verbally, when communicating with a beneficiary through telephone.

(B) In writing, when communicating with a beneficiary through mail or other paper.

(C) Electronically, when communicating with a beneficiary through email, online chat, or other electronic messaging platform.

(ii) Disclose to the beneficiary that they are being transferred to a licensed agent who can enroll them into a new plan.

(7) Personal beneficiary data collected by a TPMO for marketing or enrolling them into an MA plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained through a clear and conspicuous disclosure that lists each entity receiving the data and allows the beneficiary to consent or reject to the sharing of their data with each individual TPMO.

§ 422.2272 [Amended]

26. Section 422.2272 is removed and reserved.

27. Section 422.2274 is revised to read as follows:

§ 422.2274 Agent, broker, and other third-party requirements.

If an MA organization uses independent agents and brokers to sell its Medicare plans, the requirements in § 422.2271 and paragraphs (a) and (b) of this section are applicable.

(a) *Compensation requirements*. MA organizations must comply with the requirements in paragraphs (a)(1) through (8) of this section in paying and recovering compensation. These compensation requirements only apply to independent agents and brokers.

(1) *Compensation amount.* MA organizations, in paying compensation, must pay the same base compensation amount to all agents and brokers for the same product line under a contract. CMS defines product lines as one of the following:

(i) HMO.

(ii) PPO.

(iii) PFFS.

(iv) RPPO

(v) MSA.

(vi) Cost.

(2) *Compensation payment schedule.* MA organizations who are paying compensation may determine their compensation payment schedule.

(3) *Initial enrollment year compensation*. For each enrollment in an initial enrollment year MA organizations may determine the amount of compensation to be paid, provided it complies with requirements outlined in this section.

(i) MA organizations may pay either a full or pro-rated initial enrollment year compensation for--

(A) A beneficiary's first year of enrollment in any plan; or

(B) A beneficiary's move from an employer group plan to a non-employer group plan (either within the same parent organization or between parent organizations).

(ii) MA organizations may pay pro-rated initial enrollment year compensation for--

(A) A beneficiary's plan change(s) during their initial enrollment year.

(B) A beneficiary's selection of an “unlike plan type” change. In that case, the new plan would only pay the months that the beneficiary is enrolled, and the previous plan would recoup the months that the beneficiary was not in the plan.

(4) *Renewal compensation*. For each enrollment in a renewal year, MA organizations may determine, the amount of compensation to be paid, provided it complies with requirements outlined in this section.

(i) MA plans may pay compensation for a renewal year--

(A) In any year following the initial enrollment year the beneficiary remains in the same plan; or

(B) When a beneficiary enrolls in a new “like plan type”.

(ii) [Reserved]

(5) *Changes to compensation.* MA organizations may make changes to compensation amounts reported in accordance with § 422.2271(b)(3), following a 30-day advance notice to CMS, made in the form and manner prescribed by CMS.

(i) Changes to base compensation amounts will be reviewed against CMS’ original base compensation outlier review in accordance with paragraph (b) in this section.

(6) *Payment of compensation.* MA organizations may only pay compensation for the number of months a member is enrolled.

(7) *Other compensation scenarios*. When a beneficiary--

(i) Enrolls in an MA-PD, MA organizations may pay only the MA compensation (and not compensation for Part D enrollment under 42 CFR 423.2274);

(ii) Enrolls in both a section 1876 Cost Plan and a stand-alone PDP, the 1876 Cost Plan sponsor may pay compensation for the cost plan enrollment and the Part D sponsor may pay compensation for the Part D enrollment;

(iii) Enrolls in an MA-only plan and a PDP plan, the MA plan sponsor may pay for the MA plan enrollment and the Part D plan may pay for the PDP plan enrollment; or

(iv) Changes from two plans (for example, an MA plan and a stand-alone PDP) (dual enrollments) to one plan (MA-PD), the MA organization may only pay compensation at the renewal rate for the MA-PD product.

(8) *Additional compensation, payment, and compensation recovery requirements (Charge-backs).*

(i) MA organizations electing to pay compensation must retroactively pay or recoup funds for retroactive beneficiary changes for the current and immediately preceding calendar years. MA organizations may choose to recoup or pay compensation for years prior to the immediately preceding calendar year, but they must do both (recoup amounts owed and pay amounts due) during the same year.

(ii) Compensation recovery is required when--

(A) A beneficiary makes any plan change (regardless of the parent organization) within the first 3 months of enrollment (known as rapid disenrollment), except as provided in paragraph (a)(8)(iii) of this section; and

(B) Any other time period a beneficiary is not enrolled in a plan, but the plan paid compensation based on that time period.

(iii) Rapid disenrollment compensation recovery does not apply when:

(A) A beneficiary enrolls effective October 1, November 1, or December 1 and subsequently uses the Annual Election Period to change plans for an effective date of January 1.

(B) A beneficiary's enrollment change is based on one of the following reasons:

(*1*) Other creditable coverage (for example, an employer plan).

(*2*) Moving into or out of an institution.

(*3*) Gain or loss of employer/union sponsored coverage.

(*4*) Plan termination, non-renewal, or CMS imposed sanction.

(*5*) To coordinate with Part D enrollment periods or the State Pharmaceutical Assistance Program.

(*6*) Becoming LIS or dually eligible for Medicare and Medicaid.

(*7*) Qualifying for another plan based on special needs.

(*8*) Due to an auto, facilitated, or passive enrollment.

(*9*) Death.

(*10*) Moving out of the service area.

(*11*) Non-payment of premium.

(*12*) Loss of entitlement or retroactive notice of entitlement.

(*13*) Moving into a 5-star plan.

(*14*) Moving from an LPI plan into a plan with three or more stars.

(iv)(A) When rapid disenrollment compensation recovery applies, the entire compensation must be recovered.

(B) For other compensation recovery, plans must recover a pro-rated amount of compensation paid (whether paid for an initial enrollment year or renewal year) from an agent or broker equal to the number of months not enrolled.

(b) *Compensation Outlier Review*. CMS reviews MA base compensation submissions annually, prior to the start of marketing, October 1 of each year, as required in

§ 422.2271(b)(3)(ii) and (iii), to ensure the base compensation submitted is within Fair Market Value. CMS has the authority to deny base compensation outliers as defined in § 422.2260.

(1) CMS will calculate two separate reviews based on geography. One review will be calculated for Puerto Rico and the Virgin Islands combined. The second review for all other geographic areas.

(2) CMS will provide MA organizations, whose compensation submission is determined to be an outlier, as follows:

(i) Prior to October 1 of each year, CMS will notify MA organizations that have outlier compensation rates, that their rates are considered outliers, and provide MA organizations with the CMS calculated FMV amount. After receipt, MA organizations--

(ii) Must submit revised compensation rates; and

(iii) Are prohibited from paying base compensation until submitted rates fall at or below FMV.

(c) *Payments other than compensation (administrative payments)*. Payments made for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace. Administrative payments can be based on enrollment provided the payments are at or below the value of those services in the marketplace..

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

26. The authority for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w-101 through 1395w-152, and 1395hh.

X. Section 423.32 is amended by—

a. Redesignating paragraph (k)(2)(iv) as (k)(2)(vii) and adding new paragraphs (k)(2)(iv), (k)(2)(v) and (k)(2)(vi); and

b. Updating the cross-reference in newly redesignated paragraph (k)(2)(vii) from § 423.38(c)(36) to § 423.38(c)(37).

§ 423.32 Enrollment process.

* * * * *

(k) * * *

(2) * * *

(iv) SEP for individuals affected by a government-entity-declared disaster or other emergency, § 423.38(c)(23).

(v) SEP for individuals who were denied enrollment due to a capacity limit, § 423.38(c)(36).

(vi) SEP for individuals who are enrolled or not enrolled in Part D due to an error by a federal employee, § 423.38(c)(3).

* * * * *

27. Section 423.36 is amended by redesignating paragraph (g)(2)(iv) as (g)(2)(vi) and adding new paragraphs (g)(2)(iv) and (g)(2)(v) to read as follows:

§ 423.36 Disenrollment process.

* * * * *

(g) * * *

(2) * * *

(iv) SEP for individuals affected by a government-entity-declared disaster or other emergency, § 423.38(c)(23).

(v) SEP for individuals who are enrolled or not enrolled in Part D due to an error by a federal employee, § 423.38(c)(3).

* * * * *

28. Section 423.38 is amended by—

a. Revising paragraphs (c)(1) through (3), and (6);

b. Adding paragraphs (c)(7)(iii), (8)(iv) and (v);

c. Revising paragraphs (c)(18) and (36);

d. Redesignating paragraphs (c)(23)(ii) through (iv) as paragraphs (c)(23)(iii) through (v), respectively;

e. Adding new paragraph (c)(23)(ii);

f. Redesignating paragraph (c)(36) as (c)(37); and

g. Adding new paragraph (c)(36).

The revisions and additions read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) * * *

(1) The individual involuntarily loses creditable prescription drug coverage or such coverage is involuntarily reduced so that it is no longer creditable coverage as defined under § 423.56(a). Loss of credible prescription drug coverage due to failure to pay any required premium is not considered involuntary loss of the coverage. This SEP begins on the date the individual is notified of the loss or reduction of creditable coverage and ends 2 calendar months after either the loss or reduction occurs or the individual receives notice of the loss or reduction, whichever is later.

(2) The individual was not adequately informed, as required by standards established by CMS under § 423.56, that he or she has lost his or her creditable prescription drug coverage, that he or she never had credible prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage. This SEP begins the month CMS determines the individual is eligible and ends 2 calendar months following CMS's determination of eligibility.

(3) The individual's enrollment or non-enrollment in a Part D plan is unintentional, inadvertent, or erroneous because of the error, misrepresentation, or inaction of a Federal employee, or any person authorized by the Federal government to act on its behalf. This SEP begins the month CMS approves the individual's eligibility for this special enrollment period and ends 2 calendar months following CMS's approval.

* * * * *

(6) * * *

(i) *Non-renewal effective January 1*. This SEP begins December 8 of the contract year and ends the last day of the following February. Enrollment requests received December 8 through December 31 will have an effective date of January 1. Enrollment requests received in January will have an effective date of February 1. Enrollment requests received in February will have an effective date of March 1.

(ii) *Termination or modification by plan or mutual consent*. This SEP begins 2 months before the termination effective date and ends 1 month after the effective date of the termination. An individual may request an effective date for the month after notice is given or up to 2 months after the effective date of the termination, but the effective date may not be earlier than the date the new plan receives the enrollment request.

(iii) *CMS termination of contract*. This SEP begins one month before the effective date of the termination and ends 2 months after the effective date of the termination. Individuals may select an effective date for the month after notice is given or up to 3 months after the effective

date of the termination, but the effective date may not be earlier than the date the new plan receives the enrollment request.

(7) * * *

(iii) This special enrollment period begins on--

(A) The date of the change in permanent residence;

(B) The month before the change in permanent residence, for an individual who notifies the Part D plan sponsor in advance of the change; or

(C) The first day of the 12th month the individual has been absent from the service area, when the Part D plan sponsor has not been able to confirm the individual's residency status.

(iv) This special enrollment period ends the later of 2 calendar months following the month it begins or 2 calendar months following the month of the move.

(8) * * *

(iv) This SEP begins the month CMS determines that a contract violation or material misrepresentation has occurred and ends 90 calendar days after the date of CMS's determination.

(v) An individual may elect another Part D plan for an effective date of the first day of the month after the month the new sponsor receives the completed enrollment request.

(A) The individual may also choose an effective date of enrollment in the new plan beginning any of the 3 months after the month in which the sponsor receives the completed enrollment request.

(B) The effective date may not be earlier than the date the sponsor receives the completed enrollment request.

* * * * *

(18) The individual is enrolled in a Part D plan and elects to disenroll from that Part D plan to enroll in or maintain other creditable prescription drug coverage. This SEP begins upon the individual's disenrollment from the Part D plan and ends on the first day of the month following the month in which the disenrollment request is received by the plan.

* * * * *

(23) * * *

(ii)The individual must use a CMS-operated election mechanism, in a form and manner specified by CMS, to make an election using this SEP. To be eligible, the individual must demonstrate to CMS that the requirements in paragraphs (b)(23)(iii) to (b)(23)(v) are met.

* * * * *

(36) The individual's enrollment request into an MA plan was denied because of a CMS-approved capacity limit, as specified in § 422.60(b)(2), and the individual was unable to elect a PDP during the same election period because that election period had expired. The individual must use a CMS-operated mechanism, in a form and manner specified by CMS, to make an election using this SEP. The SEP begins the date the individual is notified of the enrollment denial and ends 2 calendar months after notification.

(37) * * *

(i) This SEP begins upon CMS determination and notification to enrollee and ends on a case-by-case basis, as determined by CMS.

(ii) The effective date for an enrollment or disenrollment election using an approved enrollment exception is based on the individual's circumstances and will be effective the first of the month and may be either prospective or retroactive. The earliest prospective enrollment effective date is the first day of the calendar month following the month in which the election is made.

* * * * *

29. Section 423.100 is amended by adding the definition of "formulary crosswalk" in alphabetical order to read as follows:

§ 423.100 Definitions.

* * * * *

Formulary crosswalk means the process during bid submission through which a Part D sponsor assigns a formulary (as defined at § 423.4) to one or more Part D plans with single- or multi-tier benefit structures.

* * * * *

30. Section 423.104 is amended by—

a. Adding paragraph (d)(2)(iv)(E) introductory text;

b. Redesignating (d)(2)(iv)(A)(5) as (d)(2)(iv)(E)(1);

c. Revising newly redesignated paragraph (d)(2)(iv)(E)(1);

d. Redesignating (d)(2)(iv)(A)(6) as (d)(2)(iv)(E)(2);

e. Revising (f)(1)(ii)(B)(*1*); and

f. Adding paragraphs (d)(2)(iv)(E)(3) and (f)(1)(ii)(D).

The additions and revision read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(d) * * *

(2) * * *

(iv) * * *

(E) *Specialty-tier placement.*

(*1*) *Claims history*. Except as provided in paragraphs (d)(2)(iv)(E)(*2*) and (*3*) of this section, CMS approves placement of a Part D drug on a specialty tier when that Part D sponsor's claims data from the time period specified in paragraph (d)(2)(iv)(C) of this section demonstrates that greater than 50 percent of the Part D sponsor's PDEs for a given Part D drug, when adjusted for 30-day equivalent supplies, have ingredient costs for 30-day equivalent supplies, as described in paragraph (d)(2)(iv)(A)(2) of this section, that exceed the specialty-tier cost threshold.

(*2*) * * *

(3) *Selected drugs.* For a selected drug, as defined in § 423.100, with a maximum fair price, as defined in section 1191(c)(3) of the Act, in effect for the contract year, CMS approves placement of a selected drug on a specialty tier only if the maximum fair price in effect for that contract year exceeds the specialty-tier cost threshold.

(f) * * *

(1) * * *

(ii) * * *

(B) * * *

(*1*) A reduction in the annual deductible described in paragraph (d)(1) of this section, including waiving a deductible for a subset of its formulary tiers;

* * * * *

(D)*(1) Enhanced alternative value threshold*.

(i) An enhanced alternative plan that provides supplemental benefits, as described in paragraph (f)(1)(ii)(B) of this section, must meet a minimum 15 percent value threshold when compared to the actuarial value of Defined Standard coverage, as determined using the Part D out-of-pocket cost (OOPC) model described in paragraph (f)(1)(ii)(D)(*2*) of this section.

(ii) PACE organizations, Employer Group Waiver Plans and dual-eligible special needs plans are exempted from the requirement in paragraph (f)(1)(ii)(D)(*1*)*(i)* of this section.

(iii) For any special needs plan that CMS requires to change from a basic plan to an enhanced alternative plan following the initial bid submission deadline, the estimated enhanced alternative OOPC value must be no worse than the estimated defined standard OOPC value.

(2) Part D OOPC model. In advance of each contract year, CMS will release the Part D OOPC model that takes the drug utilization of a sample cohort of Part D beneficiaries and conducts a simulated processing of claims using each plan's bid submission, including formulary data, to estimate a monthly Part D OOPC value. The Part D OOPC model release additionally includes a simulated Defined Standard benefit scenario.

(3) Enhanced alternative value calculation. CMS will evaluate the 15 percent value threshold using the following steps:

(*i*) The Part D OOPC model estimates the OOPC value (that is, the estimated beneficiary out-of-pocket costs per month) for beneficiaries in an enhanced alternative plan.

(ii) The Part D OOPC model estimates the OOPC value for the same formulary used by the enhanced alternative plan using the simulated Defined Standard benefit scenario.

(iii) CMS calculates the percent difference by subtracting the value estimated according to paragraph (f)(1)(ii)(D)(3)*(i)* of this section from the value estimated according to (f)(1)(ii)(D*)(3)(ii)* of this section, dividing by the value estimated according to (f)(1)(ii)(D*)(3)(ii),* then multiplying by 100.

* * * * *

31. Section 423.120 is amended by adding paragraph (b)(8) and revising paragraph (d)(2) to read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(b) * * *

(8) *Single-tier benefit requirement for defined standard coverage*.

(i) *Single-tier requirement*. A Part D sponsor must apply a single-tier benefit structure to a Part D plan offering defined standard coverage and such benefit must be administered consistent with defined standard coverage as defined at § 423.100.

(ii) *Formulary assignment*. Except as provided in paragraph (iii) of this section, a Part D sponsor may not assign a formulary (as defined in § 423.4) with a multi-tier benefit structure to a plan offering defined standard coverage via the formulary crosswalk (as defined in § 423.100).

(iii) *Exception*. When a Part D sponsor offers both defined standard coverage plan(s) and one or more other Part D plans with multi-tier benefit structures, the Part D sponsor may assign a formulary with a multi-tiered benefit structure to a plan offering defined standard coverage,

provided that the benefit administered with respect to the defined standard plan is consistent with paragraph (i) of this section, and the formulary communications reflect a single-tier benefit structure (consistent with § 423.2267(e)(52)).

* * * * *

(d) * * *

(2) Establish consistent rules for beneficiary payment liabilities for ingredients of the Part D compound that independently meet the definition of a Part D drug and for non-Part D ingredients.

(i) For subsidy-eligible individuals (as defined at § 423.4) the copayment amount is based on whether the most expensive ingredient that independently meets the definition of a Part D drug in the Part D compound is a generic or brand name drug (as described under § 423.782).

(ii) For plan years beginning before January 1, 2028, for any non-Part D ingredient of the Part D compound (including drugs described under § 423.104(f)(1)(ii)(A)), the Part D sponsor's contract with the pharmacy must prohibit balance billing the beneficiary for the cost of any such ingredients.

* * * * *

32. Section 423.186 is amended by--

a. Adding paragraphs (a)(2)(iv) and (v), (a)(3)(vi), (b)(1)(iii); and

b. Revising paragraphs (f)(1) and (f)(1)(i), (f)(2), (g)(1)(i) and (ii), (h)(2), and (i)(3).

The revisions and additions read as follows:

§ 423.186 Calculation of Star Ratings.

(a) * * *

(2) * * *

(iv) Beginning with the 2031 Star Ratings and for the duration of the ADVaNCE MA model, measure scores for contracts participating in the model will be adjusted for the estimated

average impact of the model prior to determining percentiles for all measures except the improvement measures.

(A) The average impact of the ADVaNCE MA model will be estimated for each measure each year using a regression model that includes all contracts' (model and non-model) measure scores as outcomes, and an indicator of model participation, contract-specific baseline quality, and state-level baseline quality as explanatory variables.

(*1*) Contract-specific baseline quality is the contract measure score from the measurement year prior to implementation of the ADVaNCE MA model where available. For contracts that did not have measure scores in the measurement year prior to implementation of the model, including model contracts that spanned multiple states prior to model implementation, the parent organization-level measure score is used. If no contracts in the parent organization have measure scores in the measurement year prior to model implementation, the national-level measure score calculated using patient-level data is used. CMS will use the national-level measure score when a contract's measure data are inaccurate, incomplete, or biased.

(*i*) The parent organization-level measure score is calculated following the measure specifications for case-mix adjusted measures, but case-mix adjustment is applied at the level of the parent organization. For measure that are not case-mix adjusted and not based on survey data, the parent organization-level measure score is calculated as the weighted average measure score across contracts in the same parent organization that had measure scores in the measurement year prior to implementation of the model, where the weights are contract enrollment in July of the measurement year prior to the implementation of the model. For HEDIS-HOS measures, the parent organization-level measure score is calculated as the weighted average of the measures scores across contracts in the same parent organization that had measures scores in the measurement year prior to implementation of the model, where the weights are contract enrollment at the time the sample is pulled.

(*2*) State-level baseline quality is calculated as the weighted average of state-level average measure scores, where the weights represent the proportion of total enrollees from the contract that reside in each state as of July of the current measurement year for the applicable Star Ratings year. State-level average measure scores are calculated as average scores using patient-level data from the measurement year prior to model implementation across enrollees residing within the state as of July of the measurement year prior to model implementation.

(B) For measures that are new to the Star Ratings or are returning to the Star Ratings after a substantive specification change for the applicable year, contract-level and state-level baseline quality will be calculated following the methodology explained at paragraphs (a)(2)(iv)(A)(*1*) and (*2*) of this section but, instead of using measure-specific data, the calculations will use averages of all existing Star Ratings measures in the applicable year using data from the measurement year prior to ADVaNCE MA model implementation.

(v) Contracts participating in the ADVaNCE MA model will be excluded from the calculation of the improvement measures and of the cut points for improvement measures.

* * * * *

(3) * * *

(vi) Beginning with the 2031 Star Ratings and for the duration of the ADVaNCE MA model, measure scores for contracts participating in the model will be adjusted for the estimated average impact of the model prior to applying the relative distribution and significance testing methodology for CAHPS measures, following the methodology at paragraph (a)(2)(iv) of this section.

* * * * *

(b) * * *

(1) * * *

(iii) Domains are displayed on Medicare Plan Finder only if they contain measures included in the Star Ratings for the applicable year.

* * * * *

(f) * * *

(1) *Reward factor*. Through the 2029 Star Ratings, this rating-specific reward factor is added to both the summary and overall ratings of contracts that qualify for this reward factor based on both high and stable relative performance for the rating level. Beginning with the 2030 Star Ratings, the reward factor does not apply.

(i) The contract's performance will be assessed using its weighted mean and its ranking relative to all rated contracts in the rating level (overall for MA-PDs; Part C summary for MA-PDs and MA-only; and Part D summary for MA-PDs and PDPs) for the same Star Ratings year. The contract's stability of performance will be assessed using the weighted variance and its ranking relative to all rated contracts in the rating type (overall for MA-PDs; Part C summary for MA-PDs and MA-only; and Part D summary for MA-PDs and PDPs). The weighted mean and weighted variance are compared separately for MA-PD and standalone Part D contracts (PDPs). The measure weights are specified in paragraph (e) of this section. Since highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean are calculated both with and without the improvement measures. For an MA-PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance and weighted mean for the rating type (Part C summary, Part D summary) with the improvement measure. Beginning with the 2031 Star Ratings and for the duration of the ADVaNCE MA model, ADVaNCE MA model contracts are excluded from the calculation of the weighted variance and weighted mean.

* * * * *

(2) *Categorical adjustment index.* CMS applies the categorial adjustment index (CAI) as provided in this paragraph (f)(2) to adjust for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low income subsidy or are dual eligible (LIS/DE) or have disability status. The factor is calculated as the mean

difference in the adjusted and unadjusted ratings (overall, Part D for MA-PDs, Part D for PDPs) of the contracts that lie within each final adjustment category for each rating type. Beginning with the 2031 Star Ratings and for the duration of the ADVaNCE MA model, ADVaNCE MA model contracts are excluded from the calculation of the categorical adjustment index.

* * * * *

(g) * * *

(1) * * *

(i) If the highest rating for each contract-type is 4.5 stars or more (or 4 stars or more through the 2029 Star Ratings) without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.

(ii) If the highest rating is less than 4.5 stars (or less than 4 stars through the 2029 Star Ratings) without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), the rating will be calculated with the improvement measure(s).

* * * * *

(h) * * *

(2) *Plan preview of the Star Ratings.* CMS will have two plan preview periods before each Star Ratings release during which the Part D sponsor can preview their preliminary Star Ratings data in HPMS prior to display on the Medicare Plan Finder. During the second plan preview, CMS will display de-identified contract-level sample data for one of each type of measure needed to replicate the cut point methodology, as determined by CMS. Part D sponsors and first tier, downstream, and related entities may not disclose the preliminary Star Ratings data to the public through any means until the Star Ratings have been finalized and released publicly on the Medicare Plan Finder.

* * * * *

(i) * * *

(3) *New measure adjustments.* For affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, CMS holds the affected contract harmless by using the higher of the contract's summary or overall rating or both with and without including all of the applicable new measures. Contracts that do not have enough measures to have the summary or overall rating or both calculated either with or without including all applicable new measures will receive the rating from the summary or overall rating that had enough measures to be calculated.

* * * * *

32. Section 423.265 is amended by --

a. Revising paragraph (b)(2)(i);

b. Adding paragraph (b)(2)(i)(A) and (B); and

c. Adding paragraph (b)(6).

The revisions and additions read as follows:

§423.265 Submission of bids and related information.

* * * * *

(b) * * *

(2) *Substantial differences between bids —*

(i) *General rule.* Except as provided in paragraph (b)(2)(ii) of this section, a potential Part D sponsors' bid submissions must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a potential sponsor's other bid submissions. In order to be considered “substantially different,” each bid must be meaningfully different from the sponsor's other bids with respect to beneficiary out-of-pocket costs or formulary structures. A bid satisfies this requirement if, as measured through the OOPC model described in § 423.104(f)(1)(ii)(D)(*2*), it meets the thresholds established by CMS in paragraphs (b)(2)(i)(A) and (B) of this section.

(A) *Meaningful Difference Value Threshold*. Each enhanced alternative plan's estimated Part D OOPC value generated from the OOPC model must be at least 15 percent lower than the estimated OOPC value for the basic plan offered by the PDP sponsor in the same region as the enhanced alternative plan. This requirement does not apply to MA-PD plans. To calculate the percent difference, CMS will first calculate the meaningful difference by subtracting the estimated enhanced alternative OOPC value from the estimated basic OOPC value. CMS will then divide this value by the estimated basic OOPC value and multiply by 100 to generate a percent.

(B) *Formulary Robustness and Benefit Design Value Threshold*. CMS will calculate metrics to assess formulary robustness and benefit design for Part D enhanced plan offerings using the following steps:

(1) CMS will estimate the OOPC value for each basic plan's and enhanced alternative plan's formulary using the OOPC model and applying the Defined Standard benefit scenario described in § 423.104(f)(1)(ii)(D)*(2)*.

(2) CMS will determine the proportion of the meaningful difference that is attributed to formulary robustness by subtracting the enhanced alternative OOPC value from the basic OOPC value, both estimated according to paragraph (b)(2)(i)(B)*(1)* of this section, then dividing by the meaningful difference as calculated in paragraph (b)(2)(i)(A) of this section, and multiplying the result by 100 to generate a percent. For each enhanced alternative plan, this value must be greater than or equal to zero percent.

(3) CMS will determine the proportion of the meaningful difference that is attributed to the benefit design by subtracting the proportion associated with formulary robustness, as calculated according to paragraph (b)(2)(i)(B)*(2)* of this section, from 100. For each enhanced alternative plan, the proportion attributed to the benefit design must be greater than 50 percent.

* * * * *

(6) *Post-acquisition transition period.* The requirements in paragraphs (b)(2) and (3) of this section do not apply during the transition period for PDP sponsors with new acquisitions described in § 423.272(b)(3)(ii).

X. Section 423.315 is amended by revising paragraph (d) to read as follows:

* * * * *

(d) *Low-income subsidies*. (1) CMS makes payments for premium and cost sharing subsidies on behalf of certain subsidy-eligible individuals as provided in §§ 423.329(d) and 423.780.

(2) CMS provides low-income cost-sharing subsidy payments described in § 423.329(d) through interim payments of amounts as provided under § 423.329(d)(2)(i) and reconciliation to total low-income cost-sharing subsidy costs as provided in § 423.343(d).

* * * * *

33. Section 423.343 is amended by revising paragraphs (c)(2), (d)(2), and (e)(2) to read as follows:

* * * * *

(c) * * *

(2) *Payments*. (i) CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between monthly reinsurance payments made during the coverage year and the amount payable in § 423.329(c) for the coverage year.

(ii) CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the payment year following the coverage year if the monthly reinsurance payments made during the coverage year exceed the amount payable under § 423.329(c) or if the Part D sponsor does not provide the data in paragraph (c)(1) of this section.

* * * * *

(d) * * *

(2) *Payments*. (i) CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between interim low-income cost-sharing subsidy payments and total low-income cost-sharing subsidy costs eligible for subsidy under § 423.329(d) submitted by the plan for the coverage year.

(ii) CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the payment year following the coverage year if interim low-income cost-sharing subsidy payments exceed the amount payable under § 423.329(d) or if the Part D sponsor does not provide the data in paragraph (d)(1) of this section.

* * * * *

(e) * * *

(2) *Payments*. (i) CMS at its discretion either makes lump-sum payments or adjusts monthly payments throughout the remainder of the payment year following the coverage year based on the difference between interim selected drug subsidy payments and total selected drug subsidy costs eligible for subsidy under § 423.329(e) submitted by the plan for the coverage year.

(ii) CMS may recover payments made through a lump sum recovery or by adjusting monthly payments throughout the remainder of the payment year following the coverage year if the interim selected drug subsidy payments exceed the amount payable under § 423.329(e) of if the Part D sponsor does not provide the data in paragraph (e)(1) of this section.

34. Section 423.2260 is amended by adding the definitions for “Base compensation outlier”, “Compensation”, “Fair market value”, Initial enrollment year”, “Like plan type”, “Plan”, “Renewal year” and “Unlike plan type” in alphabetical order to read as follows:

§ 423.2260 Definitions.

Base compensation outlier means any base compensation amounts submitted to CMS by any Part D sponsor, in accordance with §§ 422.2271(b)(3)(ii) and 423.2271(b)(3)(ii), that are above the third quartile, as calculated in a distribution, using a box plot method and determined by CMS in accordance with §§ 422.2274(b) and 423.2274(b). Base compensation outliers will be determined based on all base compensation amounts submitted by all Part D sponsors.

* * * * *

Compensation means monetary or non-monetary remuneration of any kind relating to the sale and renewal of a plan or product offered by a Part D sponsor. For purposes of this definition, compensation falls into the following two categories, both of which must be Fair Market Value as defined in this subpart:

(1) Base compensation: any monetary renumeration for the actual initial or renewal enrollment, as referenced in §§ 422.2274(a) and 423.2274(a).

(2) Supplemental compensation: any monetary or non-monetary remuneration, above and beyond base compensation related to the sale and renewal a plan or product offered by a Part D sponsor, such as bonuses, gifts, prizes or awards. Supplemental compensation is an additional incentive offered by an MA organization or Part D sponsor to agents and brokers, typically tied to a performance metric.

* * * * *

Fair Market Value means the compensation amount (which includes base and supplemental compensation) that would be paid to a licensed insurance agent or broker at the time the parties enter into an arrangement, as the result of bona fide bargaining between well-informed parties acting at arm's length and under comparable market conditions. Such payments must be consistent with prevailing market rates for comparable services and must not reflect consideration of any business generated between the parties except as expressly permitted by applicable law and regulation.

* * * * *

Initial enrollment year means the first year that a beneficiary is enrolled in a plan versus subsequent years (c.f., *renewal year*) that a beneficiary remains enrolled in a plan.

* * * * *

Like plan type means one of the following:

(i) PDP replaced with another PDP.

(ii) MA or MA-PD replaced with another MA or MA-PD.

(iii) Cost plan replaced with another cost plan.

* * * * *

Plan year and *enrollment year* mean the year beginning January 1 and ending December 31.

* * * * *

Renewal year means all years following the initial enrollment year in the same plan or in different plan that is a like plan type.

* * * * *

Unlike plan type means one of the following:

(i) An MA or, MA-PD plan to a PDP or section 1876 Cost Plan.

(ii) A PDP to a section 1876 Cost Plan or an MA or MA-PD plan.

(iii) A section 1876 Cost Plan to an MA or MA-PD plan or PDP.

* * * * *

35. Section 423.2262 is amended by revising paragraph (a)(1)(xvi) to read as follows:

§ 423.2262 General communications materials and activity requirements.

(a) * * *

(1) * * *

(xvi) Use of the Medicare name, CMS logo, and products or information issued by the Federal Government, including the Medicare card in a misleading way.

* * * * *

36. Section 423.2263 is amended by revising paragraph (b)(7)(i)(A) to read as follows:

§ 423.2263 General marketing requirements.

* * * * *

(b) * * *

(7) * * *

(i) * * *

(A) Conduct marketing activities that focus on other enrollment opportunities, including but not limited to marketing to age-ins (who have not yet made an enrollment decision), marketing by 5-star plans regarding their continuous enrollment special election period (SEP), and marketing to full-benefit dually eligible individuals that may be eligible for a SEP per § 423.38(c)(35);

* * * * *

§ 423.2265 [Amended]

37. Section 423.2265 is amended by removing paragraph (a)(1)(ii) and redesignating paragraphs (a)(1)(iii) through (v) as paragraphs (a)(1)(ii) through (iv).

X. Section 423.2267 is amended by—

a. Revising paragraph (d)(2);

b. Adding paragraph (e)(17)(vi);

c. Adding paragraph (e)(33);

d. Removing paragraphs (e)(35), (e)(37), and (e)(41);

e. Adding paragraph (e)(52); and

f. Redesignating paragraph (e)(36), (38) through (40), and (42) through (52), as paragraphs (e)(35) through (49), respectively.

The revision and additions read as follows:

§ 423.2267 Required materials and content.

(d) * * *

(2) *Electronic delivery of required materials*. Unless otherwise specified in paragraph (e) of this section or other applicable law, a Part D sponsor may electronically deliver required materials and content without prior authorization from the enrollee if the Part D sponsor satisfies the requirements in paragraphs (d)(2)(i) through (iii) of this section.

(i) *Notice requirement*. Except as provided in paragraph (d)(2)(ii) of this section, a Part D sponsor must mail a notice to all new and current enrollees that includes the following information:

(A) Instructions for electronically accessing the required materials, including the applicable website address or portal information.

(B) Instructions, including a telephone number, for requesting hard copies of one or more required materials. The request may be material specific and must be available as a one-time request or as a permanent request that remains in place until the enrollee chooses to receive electronic materials again.

(C) The date the materials will be available, if not currently available.

(ii) *Electronic delivery of notice*. The notice required under paragraph (d)(2)(i) of this section may be furnished electronically if the new or current enrollee has opted into electronic communications before delivery of the notice.

(iii) *Hard copy and unsuccessful electronic delivery*. A Part D sponsor must mail hard copies of requested materials within 3 business days of the request and must have a reasonable process to furnish hard copy or another enrollee-selected available format if electronic delivery is unsuccessful.

(iv) State requirements for D-SNPs. Nothing in this paragraph authorizes a dual eligible special needs plan (D-SNP) to electronically deliver required materials or content when an applicable State Medicaid agency contract requirement or other applicable State requirement specifies a different form or manner of delivery.

(e) * * *

(33) *Low performing icon (LPI) Notice.* A Part D sponsor that has received an overall Star Rating of less than three stars for three or more consecutive contract years must provide written notice to each beneficiary enrolled in the plan during the current plan year, using CMS-approved standardized language, as specified by CMS in guidance. The notice must inform the beneficiary of their ability to use a Special Enrollment Period (SEP) to enroll in a plan that is not identified as a low-performing plan. The Part D sponsor must mail the notice to each enrolled beneficiary no later than November 15 of each contract year.

* * * * *

(52) *Required content when offering defined standard coverage.* This is model content which—

(i) Applies to all plans offering defined standard coverage (as defined at § 423.100);

(ii) Must be used in all relevant communications (as defined at § 423.2260) that pertain to the formulary (as defined at § 423.4); and

(iii) When addressing the Part D sponsor's plan formulary, conveys that all covered Part D drugs on such plan offering defined standard coverage have a single-tier benefit structure.

* * * * *

38. Section 423.2271 is added to read as follows:

§ 423.2271 Part D requirements, Part D reporting requirements, and Part D oversight of agent/broker/TPMO requirements.

Part D sponsors are responsible for the actions of their first tier, downstream, related entities, and TPMOs, that represent the Part D sponsor and must ensure the following requirements in paragraphs (a) through (c) of the section are met. Representation includes selling products (including Medicare Advantage plans, Medicare Advantage-Prescription Drug plans, Medicare Prescription Drug plans, and section 1876 Cost plans) as well as outreach to existing or potential beneficiaries and answering or potentially answering questions from existing or potential beneficiaries.

(a) *General Part D oversight requirements*. Part D sponsors must do all of the following:

(1) Establish and implement an oversight plan that monitors agent and broker activities, identifies non-compliance with CMS requirements, and reports non-compliance to CMS.

(2) Oversee first tier, downstream, and related entities, including agents and brokers, to ensure agents and brokers abide by all applicable State and Federal laws, regulations, and requirements.

(3)(i) Must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct.

(ii) CMS will share compliance and oversight information with States about licensed agents' and brokers' performance via a memorandum of understanding or other appropriate means.

(4) Must demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(b) *Part D reporting requirements*. Part D sponsors must provide CMS, and the State, if specified, in the form and manner prescribed by CMS, the following:

(1) Terminated agents and brokers, reported as required:

(i) Report to the State all terminations of agents and brokers who are licensed and appointed, as required, in that State and the reasons for termination, as required by State law.

(ii) Report to CMS, in the form and manner prescribed by CMS, within 15 calendar days of termination, all terminations of an agent or broker due to violations of Federal law, CMS regulations, or relevant State laws, as well as any other for cause termination of an agent or broker, and the reasons for termination.

(2) Report all enrollments made by unlicensed agents and brokers.

(3) On an annual basis, by the last Friday in July, report to CMS:

(i) Whether the MA organization intends to use employed, captive, and/or independent agents or brokers in the upcoming plan year;

(ii) The specific base compensation amounts, as defined at § 423.2260, the plan will pay independent agents and brokers for each plan.

(iii) Supplemental compensation, as defined at § 423.2260, the plan will pay independent agents and brokers for each plan, including all of the following:

(A) The specific type, such as bonuses, gifts, prizes or awards.

(B) Monetary amounts or retail value of non-monetary compensation.

(C) Detailed explanation of supplemental compensation programs including payment schedules.

(iv) Documentation, including contracts regarding compensation associated with their relationships with first tier, downstream, related entities, and TPMOs as requested by CMS.

(c) *Part D oversight of agent/broker/TPMO requirements*. Part D sponsors must ensure agents, brokers and TPMOs who represent Part D sponsors meet the requirements in paragraphs (c)(1) through (7) of this section.

(1) Agents and brokers are licensed and appointed under State law, as required.

(2) Agents and brokers are trained and tested annually meeting the following requirements:

(i) Training and testing must cover relevant Medicare rules and regulations and relevant State and Federal requirements, as well as any additional topics, as specified annually by CMS.

(ii) Must achieve at least 85 percent or higher on all testing.

(iii) If trained and tested by a third-party or another Part D sponsor, agents and brokers must meet the requirements in paragraphs (c)(2)(i) and (ii) of this section.

(3) Beneficiaries are not charged fees by agents, brokers, or TPMOs when operating under a health insurance license under State law.

(4) Meet the following requirements:

(i) Verify, prior to entering into a contract with an agent, broker, or TPMO that the individual or entity is not currently terminated from participation in the Federally Facilitated Exchange (FFE), as outlined at 45 CFR 155.220(g) by CMS.

(ii) Monitor the termination status with the FFE monthly for agents and brokers with whom they have existing contracts.

(iii) Terminate with 15 calendar days, any existing contract with an agent or broker upon determining that the agent or broker has been terminated from the FFE by CMS.

(5) All marketing and sales calls, including the audio portion of calls conducted via web-based technology, must be recorded and retained in their entirety for a minimum period of 6 years. For the first 3 years of the retention period, records must be maintained in audio format. For years 4, 5, and 6, records may be maintained in either audio format or as complete and accurate transcript recordings.

(6) The TPMO, when conducting lead generating activities, either directly or indirectly for a Part D sponsor, must, when applicable:

(i) Disclose to the beneficiary that their information will be provided to a licensed agent for future contact. This disclosure must be provided as follows:

(A) Verbally, when communicating with a beneficiary through telephone.

(B) In writing, when communicating with a beneficiary through mail or other paper.

(C) Electronically, when communicating with a beneficiary through email, online chat, or other electronic messaging platform.

(ii) Disclose to the beneficiary that they are being transferred to a licensed agent who can enroll them into a new plan.

(7) Personal beneficiary data collected by a TPMO for marketing or enrolling them into an Part D plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained through a clear and

conspicuous disclosure that lists each entity receiving the data and allows the beneficiary to consent or reject to the sharing of their data with each individual TPMO.

§ 423.2272 [Amended]

39. Section 423.2272 is amended by removing and reserving the section.

40. Section 423.2274 is revised to read as follows:

§ 423.2274 Agent, broker, and other third-party requirements.

If a Part D sponsor uses independent agents and brokers to sell its Medicare plans, the requirements in § 423.2271 and paragraphs (a) and (b) of this section are applicable.

(a) Compensation requirements. Part D sponsors must comply with the requirements in paragraphs (a)(1) through (8) of section in paying and recovering compensation. These compensation requirements only apply to independent agents and brokers.

(1) *Compensation amount.* Part D sponsors, in paying compensation, must pay the same base compensation amount to all agents and brokers for the same product line under a contract.

(2) *Compensation payment schedule.* Part D sponsors who are paying compensation may determine their compensation payment schedule.

(3) *Initial enrollment year compensation.* For each enrollment in an initial enrollment year Part D sponsors may determine the amount of compensation to be paid, provided it complies with requirements outlined in this section.

(i) Part D sponsors may pay either a full or pro-rated initial enrollment year compensation for--

(A) A beneficiary's first year of enrollment in any plan; or

(B) A beneficiary's move from an employer group plan to a non-employer group plan (either within the same parent organization or between parent organizations).

(ii) Part D sponsors may pay pro-rated initial enrollment year compensation for--

(A) A beneficiary's plan change(s) during their initial enrollment year; or

(B) A beneficiary's selection of an “unlike plan type” change. In that case, the new plan would only pay the months that the beneficiary is enrolled, and the previous plan would recoup the months that the beneficiary was not in the plan.

(4) *Renewal compensation*. For each enrollment in a renewal year, Part D sponsors may determine, the amount of compensation to be paid, provided it complies with requirements outlined in this section.

(i) Part D plans may pay compensation for a renewal year--

(A) In any year following the initial enrollment year the beneficiary remains in the same plan; or

(B) When a beneficiary enrolls in a new “like plan type”.

(ii) [Reserved]

(5) *Changes to compensation.* Part D sponsors may make changes to compensation amounts reported in accordance with § 423.2271(b)(3), following a 30-day advance notice to CMS, made in in the form and manner prescribed by CMS.

(i) Changes to base compensation amounts will be reviewed against CMS’ original base compensation outlier review in accordance with paragraph (b) in this section.

(6) *Payment of compensation.* Part D sponsors may only pay compensation for the number of months a member is enrolled.

(7) *Other compensation scenarios*. When a beneficiary--

(i) Enrolls in a PDP, Part D sponsors may pay only the PDP compensation (and not compensation for MA enrollment under 42 CFR 422.2274).

(ii) Enrolls in both a section 1876 Cost Plan and a stand-alone PDP, the 1876 Cost Plan sponsor may pay compensation for the cost plan enrollment and the Part D sponsor may pay compensation for the Part D enrollment.

(iii) Enrolls in an MA-only plan and a PDP plan, the MA plan may pay for the MA plan enrollment and the Part D sponsor may pay for the PDP plan enrollment.

(8) *Additional compensation, payment, and compensation recovery requirements (Charge-backs).*

(i) Part D sponsors electing to pay compensation must retroactively pay or recoup funds for retroactive beneficiary changes for the current and immediately preceding calendar years. Part D sponsors may choose to recoup or pay compensation for years prior to the immediately preceding calendar year, but they must do both (recoup amounts owed and pay amounts due) during the same year.

(ii) Compensation recovery is required when--

(A) A beneficiary makes any plan change (regardless of the parent organization) within the first 3 months of enrollment (known as rapid disenrollment), except as provided in paragraph (a)(8)(iii) of this section; and

(B) Any other time period a beneficiary is not enrolled in a plan, but the plan paid compensation based on that time period.

(iii) Rapid disenrollment compensation recovery does not apply when:

(A) A beneficiary enrolls effective October 1, November 1, or December 1 and subsequently uses the Annual Election Period to change plans for an effective date of January 1; or

(B) A beneficiary's enrollment change is based on one of the following reasons:

(*1*) Other creditable coverage (for example, an employer plan).

(*2*) Moving into or out of an institution.

(*3*) Gain or loss of employer/union sponsored coverage.

(*4*) Plan termination, non-renewal, or CMS imposed sanction.

(*5*) To coordinate with Part D enrollment periods or the State Pharmaceutical Assistance Program.

(*6*) Becoming LIS or dually eligible for Medicare and Medicaid.

(*7*) Qualifying for another plan based on special needs.

(*8*) Due to an auto, facilitated, or passive enrollment.

(*9*) Death.

(*10*) Moving out of the service area.

(*11*) Non-payment of premium.

(*12*) Loss of entitlement or retroactive notice of entitlement.

(*13*) Moving into a 5-star plan.

(*14*) Moving from an LPI plan into a plan with three or more stars.

(iv)(A) When rapid disenrollment compensation recovery applies, the entire compensation must be recovered.

(B) For other compensation recovery, plans must recover a pro-rated amount of compensation paid (whether paid for an initial enrollment year or renewal year) from an agent or broker equal to the number of months not enrolled.

(b) *Compensation Outlier Review*. CMS reviews Part D base compensation submissions, prior to the start of marketing, October 1 of each year, as required in § 423.2271(b)(3)(i) through (iii), to ensure the base compensation submitted is within Fair Market Value. CMS has the authority to deny base compensation outliers as defined in § 423.2260.

(1) CMS will calculate two separate reviews based on geography. One review will be calculated for Puerto Rico and the Virgin Islands combined. The second review for all other geographic areas.

(2) CMS will provide Part D sponsors, whose compensation submission is determined to be an outlier, as follows:

(i) Prior to October 1 of each year, CMS will notify Part D sponsors that have outlier compensation rates, that their rates are considered outliers, and provide Part D sponsors with the CMS calculated FMV amount. After receipt, Part D sponsors--

(ii) Must submit revised compensation rates.

(iii) Are prohibited from paying base compensation until submitted rates fall at or below FMV.

(c) *Payments other than compensation (administrative payments).* Payments made for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace. Administrative payments can be based on enrollment provided the payments are at or below the value of those services in the marketplace.

§ 423.2504 [Amended]

41. Section 423.2504 is amended by—

a. In paragraph (a)(2), removing the phrase "LI NET coverage." and adding in its place the phrase "LI NET coverage once every 12 months."; and

b. In paragraph (c)(1), adding ", unless the individual's enrollment ends under 423.2504(d) prior to the end of 2 months" to the end of the last sentence.

42. Section 423.2508 is amended by revising paragraph (b) to read as follows.

§ 423.2508 LI NET benefits and beneficiary protections.

* * * * *

(b) *Network.* The LI NET sponsor must allow its network and out-of-network pharmacies that are in good standing to process claims under the program. Licensed pharmacies are considered to be in good standing for the LI NET program so long as they—

(1) Are not revoked from Medicare under § 424.535;

(2) Do not appear on the Office of Inspector General's list of entities excluded from Federally funded health care programs in accordance with section 1128 of the Act or from Medicare and State health care programs under section 1156 of the Act (unless waived by the OIG);

(3) Do not appear on the preclusion list as defined at § 423.100;

(4) Do not have a determination by the LI NET sponsor of a credible allegation of fraud as defined at § 423.4; and

(5) Agree to and comply with the LI NET sponsor's standard audit and record retention standards for their network pharmacies when submitting a claim.

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

43. The authority for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u-4(f).

44. Section 460.158 is amended by revising the section to read as follows.

§ 460.158 Effective date of enrollment.

* * * * *

(a) *Effective date.* A participant's enrollment in the program is effective on the first day of the calendar month following the date the PACE organization receives the signed enrollment agreement.

(b) *Retroactive effective dates for Medicare status for PACE participants who gain entitlement to Medicare.*

(1) CMS may grant a retroactive effective date of up to 3 months prior to the month the retroactive request is received by CMS when a PACE participant becomes entitled to Medicare retroactively. A retroactive effective date beyond the 3-month timeframe may be approved by CMS in exceptional circumstances, provided that CMS determines neither the PACE organization nor the participant was at fault for the circumstances giving rise to the retroactive effective date request.

(2) A retroactive enrollment request may be approved when a PACE participant receives retroactive Medicare entitlement from SSA or becomes entitled to Medicare for a reason other than aging into Medicare (for example, disability, ESRD) that was not immediately identified.

45. Part 516 is added to Subchapter H to read as follows:

PART 516—ALIGNING DATA AND VALUE TO NURTURE COMPETITION AND EFICIENCY IN MEDICARE ADVANTAGE (ADVaNCE MA) MODEL

Sec.

Subpart A – General Provisions

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516.2 ADVaNCE MA: Model duration.

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Subpart D – Socioeconomic Status Targeting of Supplemental Benefits

516.300 Supplemental Benefit Targeting under the ADVaNCE MA Model.

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Subpart G – Waivers

516.600 ADVaNCE MA Model Medicare Program Waivers

516.605 Application of Star Ratings-based provisions to ADVaNCE MA model contracts.

Subpart H – Standard Provisions of the Mandatory ADVaNCE MA Model

516.610 Beneficiary protections.

516.622 Reconsideration review process.

516.623 Termination of ADVaNCE MA contract.

516.625 Extreme and uncontrollable circumstances.

Authority: 42 U.S.C.1302, 1315a, and 1395hh.

Subpart A – General Provisions

§ 516.1 Basis and scope.

(a) *Basis*. This part implements the test of the Aligning Data and Value to Nurture Competition and Efficiency in Medicare Advantage (ADVaNCE MA) model under section 1115A of the Act. Except as specifically noted in this part, the regulations under this part must not be construed to affect requirements (including those in part 422 of this chapter and Title XVIII of the Act) that apply to MA organizations and providers under this chapter.

(b) *Scope*. This part sets forth the following:

(1) Inclusion criteria and participation in the ADVaNCE MA model.

(2) The alternative Medicare Advantage quality program being tested in the model.

(3) Targeted supplemental benefit flexibilities being tested in the model.

(c) *Applicability*. Except as otherwise specified in this part, ADVaNCE MA model participants are subject to the standard provisions for Innovation Center models set forth in 42 CFR 512 subpart A.

§ 516.2 ADVaNCE MA: Model duration.

(a) The ADVaNCE MA model pre-implementation period encompasses the period beginning on June 8, 2027, the CY 2028 bid deadline, and ending December 31, 2028, during which pre-performance contracting and operational activities required for appropriate implementation of the model would occur.

(b) The ADVaNCE MA model performance period consists of 10 consecutive performance years, each aligned with the calendar year, beginning January 1, 2029, and ending

December 31, 2038, unless the ADVaNCE MA model is terminated earlier either in accordance with 42 CFR 512.165 or to effectuate an expansion of the model in accordance with section 1115A(c) of the Act.

(c) The ADVaNCE MA model post-implementation period consists of the 3 consecutive payment years that immediately follow the model performance period under paragraph (b) of this section (for example, if the model performance period ends December 31, 2038, the post-implementation period begins January 1, 2039, and end December 31, 2041). The purpose of the post-implementation period is for CMS to provide final payments associated with the model's Diamond Ratings system in accordance with subpart C of this part.

§ 516.5 Definitions.

For purposes of this part the following definitions are applicable unless otherwise stated:

ADVaNCE MA contract means an eligible contract type (Health Maintenance Organizations (HMOs), Local Preferred Provider Organizations (PPOs), Private Fee-for-Service Plans (PFFS), Chronic Condition Special Needs Plans (C-SNPs), and Dual Eligible Special Needs Plans (D-SNPs)) operating with service areas in a Mandatory State.

ADVaNCE MA Diamond Ratings system ("Diamond Ratings system") means the quality assessment and payment framework described in Subpart C of this part.

ADVaNCE MA model participant means a Medicare Advantage organization, as defined in 42 CFR 422.2, that operates one or more eligible plans within a Mandatory State.

ADVaNCE MA Individual Measure Diamond means an individual quality measure's numeric rating as calculated in the Diamond Ratings system and as described in § 516.215(c)(1). Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures are displayed to the nearest whole Diamond. Non-CAHPS measures are displayed to the nearest one-tenth Diamond.

ADVaNCE MA model performance period means the 10-year period of time beginning on January 1, 2029, through December 31, 2038, as specified in § 516.2(b).

ADVaNCE MA Overall Diamond Rating means a rating on a scale of one to five Diamonds displayed in increments of one-tenth of a Diamond increment on Medicare Plan Finder. This rating communicates the quality of the ADVaNCE MA model participant's parent organization (for the cohort within the Mandatory State) to beneficiaries choosing a plan in the relevant Mandatory State and cohort.

ADVaNCE MA Payment means changes to an ADVaNCE MA model participant's benchmarks and rebates as described in § 516.230.

Aligning Data and Value to Nurture Competition and Efficiency (ADVaNCE) in Medicare Advantage (MA) model means the CMS Innovation Center mandatory healthcare payment and delivery model test focused on the MA population in Mandatory States.

Bid refers to the bid submitted under section 1854(a)(1) of the Act.

Cohort means the classification of contracts into one of two groups based on whether they offer:

(1) A Dual Eligible Special Needs Plan (D-SNP); or

(2) A General Enrollment plan (HMO, PPO, PFFS, C-SNP).

CY means calendar year.

Guardrail has the same meaning as set forth in 42 CFR 422.162(a), but with the reference to Star Ratings replaced with a reference to Diamond Ratings.

Insufficient data means a situation in which an ADVaNCE MA model participant does not meet the minimum reporting requirements under § 516.215(d)(1).

Low enrollment means a designation that is assigned to an ADVaNCE MA model participant whose parent organization has fewer than 500 enrollees across all of its ADVaNCE MA contracts in a given cohort within a Mandatory State. An ADVaNCE MA model participant with a low enrollment designation has insufficient data to receive an ADVaNCE MA Overall Score under § 516.215(d).

Low-income subsidy (LIS)-eligible individual has the same meaning as set forth in 42 CFR 423.34(b)(2).

MA and Part D Star Ratings assesses plan quality in MA and Part D Star Ratings and the associated quality bonus payments, as described in 42 CFR 422.160 through 422.166 and 42 CFR 423.180 through 423.186, for contracts not subject to the requirements of the ADVaNCE MA model.

Mandatory State means a State within which CMS has required parent organizations offering MA plans in such a State to participate in the ADVaNCE MA model.

Mandatory supplemental benefits has the same meaning as set forth in 42 CFR 422.2.

Measurement period has the same meaning as set forth in 42 CFR 422.162.

Measure score has the same meaning as set forth in 42 CFR 422.162.

Model Test means the full period over which the ADVaNCE MA model is implemented, operated, and evaluated, consisting of three phases: the pre-implementation period, a 10-year performance period, and the post-implementation period

New entrant means a parent organization that is new to the Mandatory State, meaning no prior MA or QBP participation in the Mandatory State for at least one performance year. A parent organization can be a new entrant in either or both cohorts in a Mandatory State in a given year.

Non-missing zero measure score means a rescaled measure score of zero due to failure to adhere to reporting or data integrity requirements for a measure as required under § 516.200(a)(3).

Parent organization has the same meaning as set forth in 42 CFR 422.2.

*Payment year means the calendar year*for which the CMS will provide ADVaNCE MA payments to ADVaNCE MA model participants as described in § 516.200(c).

Performance year (PY) means the 12-month period beginning on January 1 and ending on December 31 during the ADVaNCE MA model test period as specified in § 516.2(b).

Quality Bonus Payment (QBP) system are the ratings for MA plans that determine CMS payments under section 1853(o) of the Act, and increase beneficiary rebate retention allowances under section 1854(b) of the Act. QBP ratings are determined based on the Star Ratings calculated under the MA and Part D Star Ratings system.

Rebate refers to the beneficiary rebate described in section 1854(b)(1)(C) of the Act.

Rescaled measure score means the converted measure score with a rescaled point value between 0 and 100.

Traditional rounding rules has the same meaning as set forth in 42 CFR 422.162(a) and 423.182(a).

Tukey outer fence outliers has the same meaning as set forth in 42 CFR 422.162(a).

Subpart B – Inclusion in the Model

§ 516.100 ADVaNCE MA Model – Mandatory participation.

(a) *General*. Participation in the ADVaNCE MA model is mandatory for all Medicare Advantage organizations, as defined in 42 CFR 422.2, that operate one or more eligible plans, as defined in paragraph (b) of this section, within a Mandatory State designated under paragraph (e) of this section during the performance period at § 516.2(b). All eligible plans offered under a contract to Medicare beneficiaries residing in a service area, as defined in 42 CFR 422.2, within a Mandatory State are subject to the requirements of this part. The participation unit is at the contract level in accordance with § 516.150.

(b) *Plan eligibility*.

(1) *Plans which are eligible for the ADVaNCE MA model.* For purposes of this part, an eligible plan is one that operates within a Mandatory State, is not ineligible under paragraph (b)(2) of this section, and is one or more of the following plan types:

(i) Health Maintenance Organizations (HMOs).

(ii) Local Preferred Provider Organizations (PPOs).

(iii) Chronic Condition Special Needs Plans (C-SNPs).

(iv) Private Fee-For-Service Plans (PFFS).

(v) Dual Eligible Special Needs Plans (D-SNPs) of all integration levels, subject to paragraph (c) of this section.

(2) *Plans which are ineligible for the ADVaNCE MA model.* For the purposes of this part, an ineligible plan is one of the following plan types:

(i) Institutional Special Needs Plans (I-SNPs).

(ii) Medical Savings Accounts (MSAs).

(iii) Regional Preferred Provider Organization (RPPOs).

(iv) EGWPs.

(c) *D-SNP State opt-out*.

(1) *General*. Notwithstanding paragraph (b)(1)(v) of this section, all D-SNPs operating in a Mandatory State are excluded from the mandatory participation requirements for the entirety of the model's performance period at § 516.2(b) if the State Medicaid Director has submitted a written opt-out notification to CMS via email at ADVaNCEMA@cms.hhs.gov, provided in accordance with paragraph (c)(3) of this section, and CMS has accepted the opt-out notification.

(2) *Eligible D-SNP categories for opt-out*. Subject to paragraph (c)(3) of this section, if a State Medicaid Director elects to submit an opt-out notification, the opt-out must apply to all D-SNPs in the Mandatory State without consideration to the plan's integration level.

(3) *Opt-out process*.

(i) *Submission*. To request exclusion of all D-SNP types under paragraph (c)(2) of this section, the State Medicaid Director must email CMS a written opt-out notification that meets the requirements of paragraph (ii) of this subsection.

(ii) *Criteria for the opt-out notification*. To be considered a complete opt-out notification, the notification must--

(A) Describe the Mandatory State's specific concerns regarding D-SNP inclusion and the potential impact of ADVaNCE MA model participation on the State's Medicaid program

obligations and coordination arrangements under the State Medicaid Agency Contract(s) applicable to D-SNPs operating in that State; and

(B) Be submitted by the State Medicaid Director or a designee with authority to bind the State Medicaid Agency; and

(C) Be submitted in writing via email to ADVaNCEMA@cms.hhs.gov between June 8, 2027 and October 1, 2027 with the subject line "[State Name] D-SNP Opt-Out Notification."

(4) *CMS determination*. CMS will review each opt-out notification submitted in accordance with paragraph (c)(3) of this section. CMS will accept notifications submitted according to the submission process in paragraph (c)(3)(i) of this section and meeting the criteria in paragraph (c)(3)(ii) of this section. CMS will announce which States have had their D-SNPs opted out of the model in October 2027 on the ADVaNCE MA model website.

(5) *Effect on contract restructuring*. D-SNPs that CMS accepts to be excluded from mandatory participation in accordance with the opt-out process under paragraph (c)(3) of this section must be treated as ineligible plans for purposes of the contract restructuring requirements in accordance with § 516.150(b)(3).

(6) *Scope of approved opt-out*. Where CMS receives and accepts an opt-out notification meeting the requirements established under § 516.100(c)(3), the exclusion applies to all D-SNP types in a Mandatory State for which the State Medicaid Director submitted the opt-out notification. D-SNPs operating in a Mandatory State for which opt-out was not requested, or for which CMS did not accept the opt-out notification, remain subject to mandatory participation requirements under paragraph (b)(1)(v) of this section.

(7) *Requests for delayed participation.*

(*i*) *Submission.* A State Medicaid Director who wishes to delay D-SNPs' participation in the ADVaNCE MA model by up to 2 years beginning with the model's first performance year must email CMS a written request for delayed participation that meets the requirements of paragraph (ii) of this subsection.

(ii) *Criteria for requests for delayed participation*. To be considered a complete request for delayed participation , the request must—

(A) Specify the performance year, no later than two years after the ADVaNCE MA model's first performance year, in which the State Medicaid Agency would initiate participation of its D-SNPs in the ADVaNCE MA model.

(B) Justify the request for delayed participation as necessary due to either an ongoing Medicaid managed care procurement cycle or Medicaid managed care plan readiness reviews.

(C) Be submitted in writing via email to ADVaNCEMA@cms.hhs.gov between the June 8, 2027 and October 1, 2027 with the subject line "[State Name] D-SNP Opt-Out Notification."

(*iii*) *CMS determinations.*

(A) CMS will review each request for delayed participation submitted in accordance with paragraph (c)(7) of this section. CMS will accept requests for delayed participation submitted according to the submission process in paragraph (c)(7)(i) of this section that meet the criteria in paragraph (c)(7)(ii) of this section. State Medicaid Agencies whose requests for delayed participation are accepted may not submit an opt-out notification in accordance with paragraph (c)(3) of this section. CMS will announce which States have had their requests for delayed participation accepted in October 2027 on the ADVaNCE MA model website.

(B) CMS will reject requests for delayed participation that do not meet the criteria in paragraph (c)(7)(ii) of this section. If CMS rejects the request, the State Medicaid Director may submit an opt-out notification in accordance with paragraphs (c)(1) through (c)(6) of this section prior to the deadline established at § 516.100(c)(3)(ii)(C).

(d) *[RESERVED]*

(e) *Geographic Areas*

(1) CMS identifies the Mandatory States, including the District of Columbia, for the ADVaNCE MA model through a stratified random sampling methodology.

(i) *Selection Methodology.* States, including the District of Columbia, in the United States are stratified into seven mutually exclusive groups according to the characteristics that CMS determines are necessary to ensure that the model is tested on a nationally representative sample of State MA Markets and to meet model evaluation requirements under section 1115A(b)(4) of the Act.

(ii) *Exclusions*. The following categories of geographic areas are excluded from eligibility for selection as Mandatory States:

(A) All U.S. Territories.

(B) Any State that, based on the Monthly Enrollment by Contract/Plan/State/County data, MA State/County Penetration data, and Special Needs Plan (SNP) data made publicly available for the timeframe described, had fewer than 1,000 beneficiaries enrolled in eligible plans described under paragraph (b) of this section. For Alaska and Connecticut, the applicable timeframe is July 2024. For all other States, the applicable timeframe is March 2026.

(2) The list of Mandatory States will remain fixed for all performance years of the ADVaNCE MA model and will not be revised or updated, except as may be required under applicable State or federal law, including the authority of the Secretary to expand models under section 1115A(c) of the Act.

§ 516.150 ADVaNCE MA Contract requirements.

(a) *Applicability*. This section applies to any MA organization that plans to establish a contract under 42 CFR 422.504 in a given contract year during the model's performance period described in § 516.2(b) that includes one or more eligible plans defined at § 516.100(b)(1), that operate in a Mandatory State defined at § 516.5.

(b) *General contract structure requirements*.

(1) *General Enrollment cohort contracts*. Beginning in CY 2029, ADVaNCE MA model participants must operate State-specific contracts containing only eligible plans, as described in

§ 516.100(b)(1)(i) through (iv), whose service areas fall entirely within a single Mandatory State. The contracts must be designated as General Enrollment cohort contracts, as defined in § 516.5.

(2) *D-SNP cohort contracts*. Beginning in CY 2029, ADVaNCE MA model participants must operate State-specific contracts containing only D-SNP plans, as defined in § 516.100(b)(1)(v), whose service areas fall entirely within a single Mandatory State, subject to the requirements in § 516.100(c). The contracts must be designated as D-SNP cohort Contracts, as defined in § 516.5.

(3) *Ineligible Plans.* Beginning in CY 2029, no ineligible plan, as described at § 516.100(b)(2), is permitted in an ADVaNCE MA General Enrollment or D-SNP cohort contract.

(4) *Non-ADVaNCE MA contracts.* Refers to MA contracts that include ineligible plans, as defined at § 516.100(b)(2), within Mandatory States and/or eligible plans, as defined at § 516.100(b)(1), operating outside of Mandatory States.

(c) *Operationalization of ADVaNCE MA contracts.*

(1) *Criteria for Determining Contract Split Eligibility.* An existing MA contract is subject to a contract split if it –

(i) Operates across multiple states and offers one or more eligible plan types, as described in § 516.100(b)(1), whose service area includes counties within a Mandatory State;

(ii) Operates exclusively within a Mandatory State that offers both eligible and ineligible plans as described at § 516.100(b); or

(iii) Subject to § 516.100(c), operates exclusively in a Mandatory State that only offers eligible plans, as described at § 516.100(b)(1), and includes both eligible D-SNPs, described at § 516.100(b)(1)(v), and any eligible plans that are not D-SNPs.

(2) *Creating ADVaNCE MA Contracts.*

(i) For CY 2029, CMS will split existing MA contracts that meet the criteria set forth in § 516.150(c)(1) into non-ADVaNCE MA contracts, General Enrollment cohort contracts, and,

subject to § 516.100(c), D-SNP cohort contracts as described in this section. The service areas for contracts resulting from CMS' split process will be restructured to reflect the previously established service areas of plans from the existing contracts that qualify for either--

(A) ADVaNCE MA Contracts meeting the requirements at § 516.150(b)(1) and (2); or

(B) non-ADVaNCE MA model contracts.

CMS will split and restructure existing contracts on behalf of MA organizations and without requiring the submission of application materials.

(ii) For contracts meeting the criteria set forth in § 516.150(c)(1)(i) or 516.150(c)(1)(ii) CMS must effectuate a contract split by –

(A) Retaining the existing contract number for the non-ADVaNCE MA contract and restructuring its service areas as described in § 516.150(c)(2)(i); and

(B) Establishing new contract numbers for General Enrollment cohort contracts and, subject to § 516.100(c), D-SNP cohort contracts and restructuring their service areas as described in § 516.150(c)(2)(i).

(iii) For contracts meeting the criteria set forth in § 516.150(c)(1)(iii), CMS will effectuate a contract split by retaining the existing contract number and establishing applicable service areas as described in § 516.150(c)(2)(i) for General Enrollment cohort contracts in the Mandatory State and establishing new contract numbers and applicable service areas for eligible plans in the D-SNP cohort in the Mandatory State.

(iv) Existing MA contracts that are confined to a Mandatory State and meet the requirements established at § 516.150(b)(1) or (b)(2) are not subject to contract splits.

(v) MA organizations seeking to establish new service areas with eligible plans that include counties in Mandatory States must submit initial MA or service area expansion applications, and SNP applications when applicable, under 42 CFR 422.501 in accordance with the ADVaNCE MA model's contract structure requirements, described at § 516.150(b).

(vi) Ineligible Contracts include existing MA contracts that operate outside of ADVaNCE MA Mandatory States and do not meet the eligibility criteria, described at § 516.150(c)(1), to undergo contract splits are not subject to restructuring under this section and continue to operate under the standard MA regulatory framework at 42 CFR part 422.

(d) *MA organization responsibilities and considerations*.

(1) MA organizations with existing contracts that are subject to restructuring under § 516.150(c) will receive a preview of their restructured contracts and their associated service areas prior to the deadline for filing a Notice of Intent to Apply as required by 42 CFR 422.501(b)(1).

(2) MA organizations that receive a preview of their restructured contracts in accordance with § 516.150(d)(1) will be responsible for allocating plans amongst their restructured contracts through the Medicare Advantage bid process.

(3) *ADVaNCE MA plan crosswalks*. An MA organization whose existing contract is restructured in accordance with the procedures at § 516.150(c) will be allowed to crosswalk enrolled beneficiaries, in accordance with the process at 42 CFR 422.530(d)(1), across their restructured contracts provided that these crosswalks do not occur between different plan types (for example, HMO to PPO).

(e) *Total beneficiary cost and network adequacy treatment.*

(1) Total beneficiary cost. For purposes of the TBC threshold requirements during bid submission in 2028 for contract year 2029, ADVaNCE MA plans under the model are treated as if they are new plans.

(2) Network adequacy reviews. For purposes of network adequacy reviews, ADVaNCE MA contracts under the model are treated as if they are existing contracts.

Subpart C – Diamond Ratings System

§ 516.200 Schedule of measurement, display, and payment.

(a) *Measurement periods*.

(1) CMS will assess ADVaNCE MA model participants' performance on each of the quality measures described at § 516.205(a) during each of the measurement periods.

(i) ADVaNCE MA model measurement periods will align with the corresponding measurement periods under the MA and Part D Star Ratings system.

(2) The first measurement period for ADVaNCE MA model participants will be the measurement period applicable to the 2031 Diamond ratings. The last measurement period for the ADVaNCE MA model will be the measurement period applicable to the 2040 Diamond Ratings. ADVaNCE MA model participants will resume participation in the MA and Part D Star Ratings system for the CY 2041 Star Ratings.

(3) ADVaNCE MA model participants are required, as applicable, to collect, analyze, report, or otherwise make available data that permit measurement of quality and outcome measures. ADVaNCE MA model participants must provide unbiased, accurate, and complete quality data to CMS. Failure to adhere to reporting or data integrity requirements for a measure required under § 516.205(a) will result in a rescaled measure score of zero as described at § 516.215(d)(1) and an ADVaNCE MA Individual Measure Diamond of one Diamond as described at § 516.215(c)(1).

(b) *Ratings Display for ADVaNCE MA model participants.*

(1) *CY 2029 and CY 2030.*

(i) ADVaNCE MA model participants, as defined at § 516.5, remain subject to the MA and Part D Star Ratings system for CY 2029 and CY 2030. The resulting Star Ratings are displayed on Medicare Plan Finder for CY 2029 and CY 2030.

(ii) New entrants, as defined at § 516.5, will have a display of "Plan too new to be measured" in Medicare Plan Finder until sufficient data has been gathered to provide a score two years after entrance.

(2) *CY 2031 through CY 2040*. ADVaNCE MA Overall Diamond Ratings calculated under § 516.220 will be displayed on Medicare Plan Finder in October of the calendar year immediately prior to the Diamond Ratings year.

(c) *Payment years for ADVaNCE MA model participants*.

(1) *CY 2029 through CY 2031*. ADVaNCE MA model participants, as defined at § 516.5, will receive ADVaNCE MA Payment calculated under § 516.230. These payments will be based on CY 2029, CY 2030, and CY 2031 QBP ratings. New entrants will receive an increase to their benchmark of 3.5 percentage points and a rebate of 65 percent.

(2) *CY 2032 through CY 2041*. ADVaNCE MA model participants, as defined at § 516.5, will receive ADVaNCE MA Payment calculated under § 516.230. These payments will be received in the calendar year immediately following the Diamond Ratings year.

§ 516.205 Quality measurement.

(a) *ADVaNCE MA Diamond Ratings quality measures.* For a given measurement period, CMS will use the quality measure set used in the MA and Part D Star Ratings system of the same measurement period to assess performance for ADVaNCE MA model participants. Unless otherwise specified, CMS, will automatically add, remove, or make substantive or non-substantive updates to the measure set in alignment with changes made in the MA and Part D Star Ratings system. Such additions, removals, and updates in the MA and Part D Star Ratings system are not subject to paragraph (b) of this section.

(b) *Adding, updating, and removing ADVaNCE MA Diamond Ratings system quality measures.*

(1) *General.* CMS may, independently from the MA and Part D Star Ratings system, add, update, and remove measures used to calculate the ADVaNCE MA Individual Measure Diamonds and ADVaNCE MA Overall Diamond Ratings as set forth in paragraph (b)(2) through (b)(4) of this section.

(2) *Adding measures.*

(i) CMS may add a measure to the ADVaNCE MA Diamond Ratings system if the Secretary determines that a quality measure achieves at least one of the following:

(A) Is meaningful to participating plans.

(B) Addresses a priority area.

(C) Supports or advances the overall goal of the ADVaNCE MA model.

(D) Improves the comprehensiveness of the ADVaNCE MA Diamond Ratings list of quality measures.

(ii) CMS may continue to review measures that are nationally endorsed and in alignment with the private sector, such as measures developed by National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA), or endorsed by the National Quality Forum (NQF) for adoption and use in the ADVaNCE MA Diamond Rating system.

(iii) CMS may develop its own measures when appropriate to measure and reflect performance specific to the Medicare program.

(iv) In advance of the measurement period, CMS may propose and finalize new measures through rulemaking. New measures added to ADVaNCE MA Diamond Ratings measure set will be displayed on the CMS website for a minimum of one year prior to being used in the calculation of ADVaNCE MA Overall Diamond Ratings and payment. New measures added to the MA and Part D Star Ratings system are still subject to 42 CFR 422.164(c)(3) and 42 CFR 423.184(c)(3)).

(3) *Updating measures*.

(i) Non-substantive updates. For measures that are already used for the ADVaNCE MA Diamond Ratings measure set, CMS may announce non-substantive updates to measures that occur (or are announced by the measure steward) during or in advance of the measurement period through the process described for changes in and adoption of payment and risk adjustment

policies in section 1853(b) of the Act. Non-substantive measure specification updates include those that do any of the following:

(A) Narrow the denominator or population covered by the measure.

(B) Do not meaningfully impact the numerator or denominator of the measure.

(C) Update the clinical codes with no change in the target population or the intent of the measure.

(D) Provide additional clarifications including any of the following:

(*1*) Add additional tests that would meet the numerator requirements.

(*2*) Clarify documentation requirements.

(*3*) Add additional instructions to identify services or procedures.

(E) Add alternative data sources or expand modes of data collection.

(ii) *Substantive updates.* For measures that are already used for the ADVaNCE MA Diamond Ratings measure set, in the case of measure specification updates that are substantive updates not subject to paragraph (b)(3)(i) of this section, CMS will propose and finalize these measures through rulemaking similar to the process for adding new measures. Substantively updated Diamond Ratings measures will be on the CMS website for a minimum of one year prior to being used in the calculation of ADVaNCE MA Overall Diamond Rating. CMS may continue collection of performance data for the legacy measure and include it in Diamond Ratings until the updated measure has been on display for one year.

(4) *Removing measures*.

(i) CMS will remove a measure from the ADVaNCE MA Diamond Ratings measure set for any of the following reasons:

(A) If the Secretary determines that the quality measure is no longer meaningful for the ADVaNCE MA Diamond Ratings.

(B) If a measure shows low statistical reliability.

(C) If the measure steward other than CMS retires a measure.

(D) When the clinical guidelines associated with the specifications of the measure change such that the specifications are no longer believed to align with positive health outcomes.

(ii) CMS will propose and finalize the removal of a measure based upon its application of paragraph (4)(i)(A) of this section through rulemaking in advance of the measurement period.

§ 516.215 ADVaNCE MA scoring methodology.

(a) *ADVaNCE MA cohort.* ADVaNCE MA model participants are assigned to one of two cohorts, General Enrollment cohort or D-SNP cohort.

(1) An ADVaNCE MA model participant will be assigned to the General Enrollment cohort if the ADVaNCE MA model participant consists exclusively of plan types listed in §516.100(b)(1)(i) through (iv) that are not D-SNPs.

(2) An ADVaNCE MA model participant will be assigned to the D-SNP cohort if the ADVaNCE MA model participant consists of only D-SNPs per § 516.100(b)(1)(v).

(b) *Measure scores.* The data reported on measures by each ADVaNCE MA model participant under § 516.205 will be pooled with such measure data reported by all other ADVaNCE MA model participants with the same parent organization in the same cohort in the same Mandatory State and would receive an overall score if the requirements under § 516.215(d)(1) are met.

(1) To pool data, contract-level data will be combined and measure scores will be calculated using enrollment-weighted averages based on enrollment data from July of the measurement period, except for survey-based measures.

(2) The survey-based measures will use the enrollment at the time the sample is pulled for the rating year for all ADVaNCE MA model participants within the same parent organization and same cohort in the same Mandatory State.

(3) All ADVaNCE MA model participants under a single parent organization, within a Mandatory State, and within the same cohort will receive one set of measure scores for each Diamond Ratings system quality measure.

(4) ADVaNCE MA model participants under the same parent organization in a Mandatory State may have up to two sets of measure scores, one for the ADVaNCE MA model participants in the D-SNP cohort and one for the ADVaNCE MA model participants in the General Enrollment cohort.

(c) *ADVaNCE MA Individual Measure Diamonds.*

(1) CMS will assign an ADVaNCE MA Individual Measure Diamond for each measure score received by an ADVaNCE MA model participant in each Mandatory State and for each cohort.

(i) The ADVaNCE MA Individual Measure Diamond is displayed on Medicare Plan Finder on a five Diamond scale ranging from one (lowest rating) to five (highest rating). CAHPS measures are displayed to the nearest whole diamond by applying 42 CFR 422.166(a)(3) to ADVaNCE MA Individual Measure Diamonds. Non-CAHPS measures are displayed to the nearest one-tenth Diamond increment.

(2) Failure to adhere to reporting or data integrity requirements for a measure required under § 516.205(a) will result in an ADVaNCE MA Individual Measure Diamond of one Diamond.

(i) *Posting and display.* The ADVaNCE MA Individual Measure Diamonds are publicly displayed on Medicare Plan Finder and will replace Measure Stars calculated and displayed for MA and Part D Star Ratings under 42 CFR 422.166 and 42 CFR 423.186 in all Mandatory States for ADVaNCE MA model participants from CY 2031 through CY 2040.

(ii) *Cut points*. CMS will determine cut points for the assignment of ADVaNCE MA Individual Measure Diamonds for each numeric measure score by applying a modified clustering methodology for non-CAHPS measures and a relative distribution and significance testing methodology for CAHPS measures, such that ADVaNCE MA Individual Measure Diamonds for CAHPS measures will be displayed at the whole diamond increment and non-CAHPS measures will be displayed at the one-tenth diamond increment. Beginning with Individual Measure

Diamonds for the second Diamond Ratings year (CY 2032), CMS will implement guardrails so that the measure-threshold-specific cut points do not increase or decrease more than the value of the cap from one year to the next as described for the MA and Part D Star Ratings system at 42 CFR 422.166(a)(2) and 42 CFR 423.186(a)(2).

(iii) *Modified clustering algorithm for all non-CAHPS measures*. ADVaNCE MA Individual Measure Diamonds will be calculated using the pooled measure scores described in paragraph (b) of this section.

(A) The ADVaNCE MA Individual Measure Diamonds are calculated in accordance with 42 CFR 422.166(a) and 42 CFR 423.186(a), adjusted to report the resulting Diamond value at the one-tenth Diamond increment. CMS will use data from ADVaNCE MA model participants in the ADVaNCE MA model across Mandatory States and cohorts.

(B) For situations where there are not enough reporting units to create 41 intervals, CMS will calculate the largest number of discrete intervals whose minimum number of reporting units is met. CMS will determine the maximum number of intervals, k, used in the clustering algorithm for which the number of reporting units with non-null, non-outlier measure scores, N, satisfies the floor $(0.9 \times N) \geq k$. The resulting Individual Measure Diamond will be reported in increments of $4/(k - 1)$ Diamonds, rounded to the nearest hundredth and between 1.0 and 5.0.

(iv) *Relative distribution and significance testing for CAHPS measures.* This method combines evaluating the relative percentile distribution with significance testing and accounts for the reliability of scores produced from survey data; no ADVaNCE MA Individual Measure Diamond is produced if the reliability of a CAHPS measure is less than 0.60.

(A) Low reliability scores are defined as those with at least 11 respondents, reliability greater than or equal to 0.60 but less than 0.75, as well as in the lowest 12 percent of ADVaNCE MA model participants' cohorts ordered by reliability.

(B) The requirements outlined in 42 CFR 422.166(a)(3) and 42 CFR 423.186(a)(3) for the MA and Part D Star Ratings system apply to the calculation of ADVaNCE MA Individual Measure Diamonds for CAHPS measures.

(C) To establish the distribution, CMS will use data from ADVaNCE MA model participants in the ADVaNCE MA model.

(d) *Overall score*.

(1) *Minimum reporting requirements.* An ADVaNCE MA model participant will receive an overall score if, at the parent organization level within each cohort and Mandatory State, it receives measure scores for at least 50 percent of all Diamond Ratings system quality measures required to be reported under § 516.205(a) for the contract type. Receiving a rescaled measure score of zero for a measure under paragraph (d)(2)(i) of this section will count as receiving a measure score for purposes of meeting the minimum reporting requirements of this paragraph.

(i) *Improvement measure exclusion.* Any Part C or D improvement measures will be excluded from the calculation of minimum measure scores needed to meet the requirements under § 516.215(d)(1).

(ii) [Reserved]

(2) *Calculation of overall score.*

(i) *Rescaled measure score*. CMS will convert the value of each measure score to a rescaled point value between 0 and 100 to maintain the relative distribution of ADVaNCE MA model participant's performance on each measure and enable comparisons across measures. Failure to adhere to reporting or data integrity requirements for a measure required under § 516.205(a) will result in a rescaled measure score of zero for such measure.

(A) *Capping*. Before rescaling, CMS will cap upper- and lower-bound outlying values across all measures as described for the MA and Part D Star Ratings system at 42 CFR 422.166(a)(2) and 42 CFR 423.186(a)(2). Values exceeding the upper bound (third quartile plus three times the inter-quartile range (IQR)) are set to equal to the upper bound value. Values

below the lower bound (the first quartile minus three times the IQR) are set to equal the lower bound value.

(B) *Rescaling methodology*. Each raw measure score will be rescaled into a rescaled measure score using the following formula where *x* is the value of the ADVaNCE MA model participant's measure score for a given measure as calculated for the Diamond Ratings system, *min(x)* and *max(x)* are the minimum and maximum values for the measure reported by all ADVaNCE MA model participants in their cohort eligible across all Mandatory States to receive an overall score and x' is the value of the rescaled measure score on a 0 to 100 scale.

$$x' = \frac{x - min(x)}{max(x) - min(x)} * 100$$

(C) *Reorienting measure scores.* For measures such as Plan All Cause Readmissions where a lower measure score indicates a better performance, their rescaled measure scores, calculated according to § 516.215(d)(2)(i)(B), will be subtracted from 100 to orient the score correctly for future steps in calculating Overall Diamond Ratings.

(ii) *Measure weights.* Measure weights will be applied to all non-missing measures according to their weighting category.

(A) *General rules.* Except as provided in paragraph (d)(2)(ii)(B) of this section, CMS will assign weights to measures based on their categorization in the MA and Part D Star Ratings system as described in 42 CFR 422.166(e) and 42 CFR 423.186(e).

(B) *Changes to measure weighting.* CMS may add additional measure weighting categories or change measure weighting in future years through rulemaking.

(C) *Rules for new and substantively updated measures*. As provided in § 516.205(a), CMS will use the quality measure set used in the MA and Part D Star Ratings system of the same measurement period to assess performance for ADVaNCE MA model participants, and will automatically add, remove, or make substantive or non-substantive updates to the measure set in alignment with changes made in the MA and Part D Star Ratings system, except as provided in § 516.205(b).

New measures added to the Diamond Ratings system under § 516.205(b)(2) will receive a weight of one for the first year they are used in the calculation of Overall Diamond Ratings. Substantively updated Diamond Ratings measures under § 516.205(b)(3)(ii) will receive a weight of one in their first year returning to the Diamond Ratings system after being on the CMS website. In subsequent years, a new or substantively updated measure will be assigned the weight associated with its category.

(iii) *Overall score methodology*. As provided in § 516.215(d)(2)(i), CMS will convert the value of each measure score to a rescaled point value between 0 and 100.

(A) For each ADVaNCE MA model participant, CMS will obtain a weighted average of the rescaled measure scores (as defined at § 516.5) and respective measure weights in the Diamond Ratings system to calculate each overall score in each cohort.

(B) The weight of each non-missing measure will be applied to the value of the rescaled measure score. The total weighted points will be divided by the weighted count of all available measures.

(C) *Overall score equation.* The overall score will equal the sum of all non-missing measures reported by the ADVaNCE MA model participant, where x' is the rescaled measure score of each non-missing measure, w is the corresponding weight of each non-missing measure, and n indicates the number of all non-missing measures. Scoring and measure calculations will be expressed up to two decimal places.

$$\text{Overall Score} = \frac{\sum_{i=1}^{n} x'_i * w_i}{\sum_{i=1}^{n} w_i}$$

(D) *Continuous scoring*. For each ADVaNCE MA model participant, the overall score will be a value between 0 and 100. CMS will use overall scores to assess the relative performance of each ADVaNCE MA model participant in each cohort, to calculate ADVaNCE MA Overall Diamond Ratings for public display under § 516.220, and then to calculate ADVaNCE MA Payment amounts under § 516.230.

§ 516.220 ADVaNCE MA Overall Diamond Ratings.

(a) *General.* Each ADVaNCE MA model participant's overall score is translated into an ADVaNCE MA Overall Diamond Rating for both display in Medicare Plan Finder and for ADVaNCE MA Payment on a 5-point scale ranging from one (lowest rating) to five (highest rating) Diamonds, with one-tenth-point increments as the cut points.

(b) *Bounded Rescaling*. Overall scores will be converted to an ADVaNCE MA Overall Diamond Rating by applying the bounded rescaling formula. Overall scores (m) are bounded at the overall score values at the 1st percentile (p_1) and the overall score values at 99th percentile (p_{99}) within each cohort. An ADVaNCE MA model participant must receive a one Diamond if they are at or below the overall score at the 1st percentile within each cohort, and an ADVaNCE MA model participant must receive five Diamonds if they are at or above the overall score value 99th percentile within each cohort. For all ADVaNCE MA model participants with overall scores between the 1st percentile and 99th percentile, their ADVaNCE MA Overall Diamond Rating is rescaled linearly between the overall score values at the 1st percentile and 99th percentile within each cohort between one and five Diamonds.

$$ADVaNCE\ MA\ Overall\ Diamonds\ =$$
$$\begin{cases} 1\ Diamond, if\ m\ \leq\ p_1 \\ 1\ +\ (5\ -\ 1)\left(\dfrac{m\ -\ p_1}{p_{99}\ -\ p_1}\right)\ Diamond, if\ p_1\ <\ m\ <\ p_{99} \\ 5\ Diamonds, if\ m\ \geq\ p_{99} \end{cases}$$

(1) CMS rounds ADVaNCE MA Overall Diamond Ratings to the one-tenth decimal. For ADVaNCE MA Overall Diamond Ratings calculated from the bounded rescaling formula ending in five to nine in the hundredths place, CMS rounds the ADVaNCE MA Overall Diamond Rating to the next tenth place for display on the Medicare Plan Finder.

(2) *Reserved*.

(c) *Posting and display.* The ADVaNCE MA Overall Diamond Ratings are publicly displayed on Medicare Plan Finder and will replace MA and Part D Star Ratings calculated and

displayed under 42 CFR 422.166 and 42 CFR 423.186 in all Mandatory States for ADVaNCE MA model participants from CY 2031 through CY 2040.

(d) *New entrants, ADVaNCE MA model participants with low enrollment, and ADVaNCE MA model participants with insufficient data*.

(1) If the ADVaNCE MA model participant's parent organization does not meet the minimum reporting requirements of § 516.215(d)(1), the posting and display for any plan(s) under that ADVaNCE MA model participant will be "not enough data available."

(2) If the ADVaNCE MA model participant's parent organization is a new entrant as defined in § 516.5, the posting and display for any plan(s) under that ADVaNCE MA model participant will be "plan too new to be measured."

(3) If a parent organization of an ADVaNCE MA model has low enrollment, as defined in § 516.5, the posting and display for any plan(s) under that ADVaNCE MA model participant will be "not enough data available."

(e) New ADVaNCE MA model participant in a Mandatory State with a parent organization without participation in other Mandatory States, and new ADVaNCE MA model participant in a Mandatory State with a parent organization with participation in another Mandatory State.

(1) If the ADVaNCE MA model participant's parent organization has existing Medicare Advantage contracts outside of all Mandatory States and enters a Mandatory State in year 2 or subsequent years of the model, the posting and display for any plan(s) under that ADVaNCE MA model participant will be "plan too new to be measured" for the participant's first two years in the model, until it has an ADVaNCE MA Overall Diamond Rating or other applicable designation.

(2) If the ADVaNCE MA model participant's parent organization has existing Medicare Advantage contracts in another Mandatory State(s) and enters a Mandatory State in CY 2030 or subsequent years of the model, the posting and display for any plan(s) under that ADVaNCE MA

model participant will be "plan too new to be measured" for the participant's first two years in the model, until it has an ADVaNCE MA Overall Diamond Rating or other applicable designation.

(f) *ADVaNCE MA Overall Diamond Ratings preview periods.*

(1) CMS will have preview periods before each ADVaNCE MA Overall Diamond Ratings release during which ADVaNCE MA model participants can preview their ADVaNCE MA Overall Diamond Ratings data in the Health Plan Management System (HPMS) prior to display on the Medicare Plan Finder.

(2) The preview periods described in paragraph (f)(1) of this section provides ADVaNCE MA model participants an opportunity to review ADVaNCE MA Individual Measure Diamonds and ADVaNCE MA Overall Diamond Ratings prior to public display.

§ 516.230 ADVaNCE MA payment.

(a) *Changes to the applicable benchmark percentage increase for the ADVaNCE MA Payments.* For ADVaNCE MA model participants for CY 2032 through CY 2041, the benchmarking regulations under 42 CFR 422.258 are applicable to ADVaNCE MA model participants except at 42 CFR 422.258(d)(7) where paragraphs (b)(1) through (b)(5) of this section apply.

(b) *Blending benchmarks.* The blended benchmark under paragraphs § 422.258(a) and (b) of this chapter will reflect the ADVaNCE MA Overall Diamond Ratings for ADVaNCE MA model participants. Specifically, the applicable percentage under 42 CFR 422.258(d)(5) of this chapter must be changed according to criteria in paragraphs (b)(1) through (b)(5) of this section for ADVaNCE MA model participants.

(1) *Benchmark Adjustment Calculation for Mandatory States with Three or More Parent Organizations.* For ADVaNCE MA Mandatory States and cohorts with three or more parent organizations that have ADVaNCE MA model participant(s) that receive an ADVaNCE MA Overall Diamond Rating, CMS will assign applicable percentage changes using an incremental

scale based on each ADVaNCE MA model participant's ADVaNCE MA Overall Diamond Rating for each cohort and Mandatory State as follows using traditional rounding rules to the nearest 0.1 percentage point:

$$Benchmark\ Adjustment\ =\ 5\%\ *\frac{x-min(x)}{max(x)\ -\ min(x)}$$

The Benchmark Adjustment is defined such that *x* is the ADVaNCE MA model participant's ADVaNCE MA Overall Diamond Rating, min(*x*) is the ADVaNCE MA Overall Diamond Rating for the lowest performing ADVaNCE MA model participant in the Mandatory State and cohort, and max(*x*) is the ADVaNCE MA Overall Diamond Rating for the highest performing ADVaNCE MA model participant in the Mandatory State and cohort.(2) *Benchmark Adjustment Calculation for Mandatory States with Two Parent Organizations.* For ADVaNCE MA Mandatory States and cohorts with two parent organizations that have ADVaNCE MA model participant(s) that receive an ADVaNCE MA Overall Diamond Rating:

(i) The ADVaNCE MA model participant(s) with the higher ADVaNCE MA Overall Diamond Rating for the Mandatory State and cohort must have their applicable benchmarking percentage increased by 5 percentage points.

(ii) If the ADVaNCE MA model participant(s) with the lower ADVaNCE MA Overall Diamond Rating for the Mandatory State and cohort has an ADVaNCE MA Overall Diamond Rating that is greater than or equal to the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, the applicable benchmarking percentage for such ADVaNCE MA model participant(s) must be increased by 2.5 percentage points. If the ADVaNCE MA model participant(s) with the lower ADVaNCE MA Overall Diamond Rating for the Mandatory State and cohort has an ADVaNCE MA Overall Diamond Rating that is less than the enrollment-weighted average of ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, the applicable benchmarking percentage for such ADVaNCE MA model participant(s) must be increased by zero percentage points.

(iii) For ADVaNCE MA Mandatory States and cohorts with two parent organizations that have ADVaNCE MA model participants that receive an ADVaNCE MA Overall Diamond Rating, if such ADVaNCE MA Overall Diamond Ratings are within 0.2 Diamonds of each other, then the benchmark adjustment will depend on if the ADVaNCE MA Overall Diamond Ratings are greater than or equal to the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort. If the ADVaNCE MA model participant's ADVaNCE MA Overall Diamond Rating is above the average, the benchmark must be increased by 5 percentage points. If such ADVaNCE MA Overall Diamond Rating is less than the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, the applicable benchmarking percentage for the ADVaNCE MA model participants must be increased by 2.5 percentage points. If the scores straddle the average, both will receive a 5-percentage point increase.

(3) *Benchmark Adjustment Calculation for Mandatory States with One Parent Organization.* For ADVaNCE MA Mandatory States and cohorts with one parent organization that has ADVaNCE MA model participant(s) that receives an ADVaNCE MA Overall Diamond Rating, if such ADVaNCE MA Overall Diamond Rating is greater than or equal to the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, the ADVaNCE MA model participant(s) applicable benchmarking percentage must be increased by five percentage points. If such ADVaNCE MA Overall Diamond Rating is less than the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, the applicable benchmarking percentage for the ADVaNCE MA model participant(s) must be increased by zero percentage points.

(4) *New entrants, ADVaNCE MA model participants with low enrollment, ADVaNCE MA model participants with insufficient data.* For ADVaNCE MA model participants that are new entrants, as defined under § 516.5, ADVaNCE MA model participants with low enrollment, as defined under § 516.5, ADVaNCE MA model participants with insufficient data under

§ 516.215(d)(1), would receive an increase to their applicable benchmark of 3.5 percentage points.

(5) *New Entrants in a Mandatory State in CY 2030 or Subsequent Years*. If a new ADVaNCE MA model participant enters a Mandatory State in CY 2030 or subsequent years of the ADVaNCE MA model, such new ADVaNCE MA model participant would receive an increase to their applicable benchmark of 3.5 percentage points for their first three years in the ADVaNCE MA model.

(c) *Calculation of rebate for ADVaNCE MA payments.* For ADVaNCE MA model participants for CY 2032 through CY 2041, the rebate regulations at 42 CFR 422.266 are applicable to ADVaNCE MA model participants, except at 42 CFR 422.266(a)(2)(ii) where paragraphs (c)(1) to (c)(5) of this section apply.

(1) *Final applicable rebate percentage for Mandatory States and cohorts with three or more parent organizations with ADVaNCE MA model participants that receive an ADVaNCE MA Overall Diamond Rating.* The final applicable rebate percentage will be calculated using an incremental scale based on each ADVaNCE MA model participant's ADVaNCE MA Overall Diamond Rating for each cohort and Mandatory State as follows using traditional rounding rules to the nearest whole percentage point:

$$Rebate\ \%\ (x)\ =\ 50\%\ +20\% * \frac{x - min(x)}{max(x)\ -\ min(x)}$$

The rebate percentage is defined such that x is the ADVaNCE MA model participant's ADVaNCE MA Overall Diamond Rating, min(x) is the ADVaNCE MA Overall Diamond Rating for the lowest performing ADVaNCE MA model participant in a Mandatory State and cohort, and max(x) is the ADVaNCE MA Overall Diamond Rating for the highest performing ADVaNCE MA model participant in a Mandatory State and cohort.

(2) *For ADVaNCE MA Mandatory States and cohorts with two parent organizations with ADVaNCE MA model participants that receive an ADVaNCE MA Overall Diamond Rating.*

(i) The ADVaNCE MA model participant(s) with the higher ADVaNCE MA Overall Diamond Rating for the Mandatory State and cohort must have a final applicable rebate percentage of 70 percent of the average per capita savings.

(ii) If the ADVaNCE MA model participant(s) with the lower ADVaNCE MA Overall Diamond Rating for the Mandatory State and cohort has an ADVaNCE MA Overall Diamond Rating greater than or equal to the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, such ADVaNCE MA model participant's final applicable rebate must be 65 percent of the average per capita savings. If the ADVaNCE MA model participant(s) with the lower ADVaNCE MA Overall Diamond Rating for the Mandatory State and cohort has an ADVaNCE MA Overall Diamond Rating less than the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, the final applicable rebate for such ADVaNCE MA model participant(s) must be 50 percent of the average per capita savings.

(iii) For ADVaNCE MA Mandatory States and cohorts with two parent organizations that have ADVaNCE MA model participants that receive an ADVaNCE MA Overall Diamond Rating, if such ADVaNCE MA Overall Diamond Ratings are within 0.2 Diamonds of each other, then the final applicable rebate will depend on if the ADVaNCE MA Overall Diamond Ratings are greater than or equal to the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort. If the ADVaNCE MA model participant's ADVaNCE MA Overall Diamond Rating is above the average, they will receive a rebate percentage of 60 percent of the average per capita savings. If such ADVaNCE MA Overall Diamond Rating is less than the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, they would receive a rebate percentage of 65 percent of the average per capita savings. If the scores straddle the average, both will receive a rebate percentage of 60 percent of the average per capita savings.

(3) For Mandatory States and cohorts with one parent organization with ADVaNCE MA model participant(s) that receive an ADVaNCE MA Overall Diamond Rating, if the ADVaNCE MA model participant(s) has an ADVaNCE MA Overall Diamond Rating greater than or equal to the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, the final applicable rebate adjustment must be 70 percent of the average per capita savings. If the ADVaNCE MA Overall Diamond Rating is less than the enrollment-weighted average ADVaNCE MA Overall Diamond Rating across all Mandatory States for the same cohort, the final applicable rebate adjustment for the ADVaNCE MA model participant(s) must be 50 percent of the average per capita savings.

(4) *New entrants, ADVaNCE MA model participants with low enrollment, and ADVaNCE MA model participants with insufficient data*. ADVaNCE MA model participants that are new entrants, as defined under § 516.5, ADVaNCE MA model participants with low enrollment, as defined under § 516.5, and ADVaNCE MA model participants with insufficient data under § 516.215(d)(1) would receive a final applicable rebate adjustment of 65 percent of the average per capita savings.

(5) *New Entrants in a Mandatory State in CY 2030 or subsequent years*. If a new ADVaNCE MA model participant enters a Mandatory State in CY 2030 or a subsequent year of the ADVaNCE MA model, such new ADVaNCE MA model participant would receive a final applicable rebate adjustment of 65 percent of the average per capita savings for their first 3 years in the ADVaNCE MA model.

(d) *QBP-related benchmark adjustment, rebate, and Star Ratings display for consolidated contracts during the post-implementation period.*

(1) *Calculation of QBP-related benchmark adjustment and rebate.* Notwithstanding 42 CFR 422.162(b)(3)(i) through (iii), waived under § 516.605(c)(1), for a contract that consolidates, at any point during the post-implementation period, at least one model contract with one or more non-model contracts, CMS calculates the QBP related benchmark adjustment

and rebate percentage applicable to the consolidated contract, throughout the post-implementation period, as the enrollment-weighted average of—

(i) The QBP related benchmark adjustment and rebate percentage that would have been assigned to each model contract under the Diamond Ratings system described in § 516.230; and

(ii) The QBP related benchmark adjustment and rebate percentage that would have been assigned to each non-model contract under 42 CFR 422.162.

For purposes of the calculation in paragraph (d)(1) of this section, CMS determines enrollment based on the consolidated contract's enrollment in November of the year in which CMS releases preliminary QBP ratings, consistent with the methodology at 42 CFR 422.162(b)(3)(ii).

(2) *Display of measure ratings and Overall Star Rating.* Notwithstanding 42 CFR 422.162(b)(3)(iv), waived under § 516.605(c)(2), for a consolidated contract described in paragraph (d)(1) of this section, CMS displays on the Medicare Plan Finder and other CMS websites, throughout the post-implementation period, an enrollment-weighted average of the measure ratings and the Overall Star Rating calculated using only the non-model contract(s) that are part of the consolidated contract.

Subpart D – Socioeconomic Status Targeting of Supplemental Benefits

§ 516.300 Supplemental Benefit Targeting under the ADVaNCE MA Model.

(a) *General targeting flexibility*.

(1) An ADVaNCE MA model participant may offer the following supplemental benefits in a manner that is not uniform to all enrollees if offering the specified supplemental benefits based on an individual’s eligibility for the Part D low-income subsidy (LIS) defined at 42 CFR 423.34(b)(2).

(i) Healthy food and produce.

(ii) Transportation for non-medical needs.

(iii) Supports for caregivers of enrollees.

(2) Upon approval by CMS, an ADVaNCE MA model participant may offer to LIS-eligible individuals any one, or a combination, of the supplemental benefits set forth in paragraph (a)(1) of this section.

(3) Nothing in this section precludes an ADVaNCE MA model participant from offering supplemental benefits as otherwise permitted under § 422.102, including special supplemental benefits for the chronically ill (SSBCI) as outlined in § 422.102(f).

(b) *Requirements and responsibilities*. An ADVaNCE MA model participant that chooses to target one or more supplemental benefits as set forth in paragraph (a)(1) of this section must do all of the following:

(1) Offer the applicable supplemental benefit(s) as a mandatory supplemental benefit.

(2) Offer the applicable supplemental benefit(s) to all LIS-eligible individuals enrolled in the applicable contract.

(i) An ADVaNCE MA model participant may vary the maximum benefit amounts and delivery methods of the supplemental benefit across plan benefit packages within the applicable contract.

(ii) [Reserved]

(3) Make information and documentation related to verifying enrollee eligibility for LIS available to CMS upon request.

(4) Comply with all requirements at 42 CFR 422.102(g) for administering supplemental benefits, unless specifically waived for purposes of the ADVaNCE MA model.

(5) Submit data annually to CMS on the utilization and costs of supplemental benefits targeted towards LIS-eligible individuals under the ADVaNCE MA model.

(c) *CMS review of supplemental benefit offerings in ADVaNCE MA model participants' bids.*

(1) CMS may annually review, for compliance with all applicable requirements, the LIS-targeted supplemental benefits that an MA plan offers under the ADVaNCE MA model in its bid.

(2) This provision does not limit CMS' authority to review and negotiate bids or to reject bids under section 1854(a) of the Act and 42 CFR part 422, subpart F nor does it limit CMS' authority to review plan benefits and bids for compliance with all applicable requirements.

(d) *Limitation on food-related supplemental benefit*s. For any supplemental benefit offered under this part that includes food or beverage items, all such items must meet the "healthy food" standard set forth in 42 CFR 422.102(h).

Subparts E and F [Reserved]

Subpart G – Waivers

§ 516.600 ADVaNCE MA Model Medicare Program Waivers.

In accordance with the authority granted to the CMS Innovation Center under section 1115A(d)(1) of the Act, CMS waives the Medicare program requirements in the following provisions that are necessary solely for purposes of testing the ADVaNCE MA Model:

(a) *Waiver of Notice of Intent to Apply requirements.* The requirements of 42 CFR 422.501(b), (c), 42 CFR 422.503(b)(1), 42 CFR 423.502(b), and, to the extent applicable, accompanying Part D regulations under 42 CFR 423 are waived to the extent necessary to permit CMS to create new ADVaNCE MA model contracts and carry out restructuring operations described in § 516.150 on behalf of applicable MA organizations and Part D sponsors without requiring completion of a Notice of Intent to Apply. This is effective for the duration of the ADVaNCE MA model performance period and is limited to contract restructurings initiated by CMS. All other requirements of 42 CFR 422.501 and 42 CFR 423.502 remain in full force and effect.

(b) *[Reserved]*

(c) *Waiver supporting enrollment transitions – crosswalk.* 42 CFR 422.530(a)(1), (a)(2), and (b) are waived to the extent necessary to authorize MA organizations to crosswalk beneficiaries residing in Mandatory States to eligible plans in new ADVaNCE MA model contracts as part of the restructuring described in § 516.150. This waiver does not authorize MA organizations to initiate crosswalks outside the scope of existing 42 CFR 422.530 requirements or the underlying statutory authority in sections 1851(c)(3)(B), 1856(b)(1), and 1857(e)(1) of the Act. All applicable beneficiary notification and opt-out protections remain in effect. All other requirements of sections 1851, 1856, and 1857 of the Act and 42 CFR 422.530 remain in full force and effect.

(d) [Reserved](e) *Waiver of the pre-rulemaking review process.*

(1) Section 1890A(a) of the Act is waived to the extent necessary to allow CMS to add new or substantively updated measures that are specific to the Diamond Ratings system as set forth at § 516.205(b)(2)(iv) and § 516.205(b)(3)(ii) without applying the pre-rulemaking measure review process.

(2) All other provisions under section 1890A of the Act remain in full force and effect.

(f) *Waiver of minimum reporting threshold*. The minimum enrollment threshold requirement for conducting the CAHPS survey under 42 CFR 422.152(b)(5)423.156 are waived for all contracts participating in the ADVaNCE MA model for the duration of their participation, beginning with contract year 2029. The ADVaNCE MA model participants would still be required to contract with approved CAHPS survey vendors and conduct the CAHPS survey and submit the survey data to CMS as codified in 42 CFR 422.152(b). This waiver reflects that quality measure scores under the ADVaNCE MA model are aggregated and reported at the parent organization, State, and cohort levels rather than at the individual contract level. All other requirements of 42 CFR 422.152 remain in full force and effect unless otherwise specified in this proposed rule.

(g) Waiver of network adequacy requirements.

(1) *S*ection 422.116 is waived to the extent necessary to account for possible changes to network adequacy within the ADVaNCE MA model contracts as a result of changes to contract service areas to reflect the state bound service area requirements of the model.

(2) The new model-specific contracts may rely on the predecessor contract's provider network for purposes of the CY 2029 bid submission, provided that the service area of the new contract consists of the Mandatory State counties drawn from the predecessor contract's service area, and the provider network of the new contract consists of the providers in the predecessor contract's network that serve those counties.

(3) CMS will continue to conduct triennial network adequacy reviews and network adequacy reviews after triggering events for new ADVaNCE MA model contracts consistent with existing requirements following the assignment of new contract numbers.

(h) *Waiver of Star Ratings-based contract termination requirements.*

(1) Sections 422.510(a)(4)(xi) and 423.509(a)(4)(x) are waived for all contracts participating in the ADVaNCE MA model.

(2) CMS will apply Diamond Ratings system standards to evaluate participating contracts in lieu of the Star Ratings system.

(3) All other grounds for contract termination under 42 CFR 422.510 and 42 CFR 423.509 remain in full force and effect.

(i) *Waiver of quality rating system and measurement methodology requirements.* Sections 1853(o)(4) and 1853(o)(1) of the Act and 42 CFR 422.162(b)(1) through (b)(4), 422.164(f)(3), (4)(v), and (vi), 422.166(a)(1), (2)(ii), (4), (b), (c), (d)(1), (2)(i),(2)(iii), and(vi), (e) through (h), 423.182, 423.184, 423.186(a)(1) and (2)(ii), (b) and (c), (d)(1), (2)(i), (iii) and (iv), and (e) through (h) are waived to the extent necessary to implement the ADVaNCE MA Diamond Ratings system's continuous scoring methodology, parent organization-level quality assessment, cohort-based comparisons, and independent measure management process as described in § 516.200. Except as otherwise provided in this part, all other requirements of

section 1853 of the Act and 42 CFR 422.162, 422.164, 422.166, and 423.186remain in full force and effect.

(j) *Waiver of quality bonus payment structure requirements.* Sections 1853(o)(1), 1853(o)(2), 1853(o)(3)(A), and 1854(b)(1)(C)(iii), (v) and (vi) of the Act and 42 CFR 422.258(d)(7) and 422.266(a), are waived to the extent necessary to implement the Diamond Ratings system's payment structure as described in § 516.200, including by –

(1) Replacing the binary four-star qualifying plan threshold under sections 1853(o)(1) and 1853(o)(3)(A)(i) of the Act and 42 CFR 422.258(d)(7), the low enrollment exception at 1853(o)(3)(A)(ii) of the Act and 42 CFR 422.258(d)(7)(iv), and the reduced bonus structure for new plans under section 1853(o)(3)(A)(iii) of the Act and 42 CFR 422.258(d)(7)(v), with a continuous scoring scale at § 516.215(d)(2)(iii)(B). The first Diamond Ratings would be calculated based on CY 2029 measurement period data and used for payment in 2032;

(2) Eliminating the additional quality bonus for qualifying counties (commonly known as the "double bonus") that would otherwise apply under section 1853(o)(2) of the Act and 42 CFR 422.258(d)(7)(ii)(B) for ADVaNCE MA model participants operating in qualifying counties within the Mandatory States framework. The elimination of the double bonus counties begins in CY 2029;

(3) Permitting rebate percentage adjustments for ADVaNCE MA model participants to be based on ADVaNCE MA Diamond Ratings performance rather than Star Rating values as otherwise required under sections 1854(b)(1)(C)(iii), (v), and (vi) of the Act and 42 CFR 422.266(a)(2);

(4) Removing the Categorical Adjustment Index (CAI) that would otherwise apply under 42 CFR 422.166(f) and 42 CFR 423.186(f) for the Diamond Ratings system; and

(5) All other requirements of those provisions remain in full force and effect.

(k) *Waivers relating to LIS-targeting of supplemental benefits.* The uniformity requirements and restrictions on provision of non-primarily health related supplemental benefits

outside of SSBCI at sections 1852(a)(3)(A), 1852(a)(3)(D)(i), 1852(a)(3)(D)(ii)(I) and (II), 1852(d)(1)(A), and 1854(c) of the Act and 42 CFR 422.2 (uniformity requirement in the definition of "MA plan"), 422.100(c)(2)(ii)(A), 422.100(d)(2), 422.102(a)(2), 422.102(a)(6)(ii), 422.254(b)(2), and 422.262(c)(1) are waived to the extent necessary to permit ADVaNCE MA model participants to offer healthy food and produce, transportation for non-medical needs, and support for caregivers as supplemental benefits to Low-Income Subsidy (LIS)-eligible individuals, as defined at 42 CFR 423.34(b)(2). This does not modify the Special Supplemental Benefits for the Chronically Ill (SSBCI) pathway, which continues to apply on its existing terms. All other requirements of those provisions remain in full force and effect.(l) *Waiver of Part C Reporting Requirements.*

(1) The Part C Reporting Requirements at 42 CFR 422.516 are waived to the extent necessary to permit ADVaNCE MA participants to submit data annually to CMS on the utilization and costs of supplemental benefits targeted towards LIS-eligible individuals, outlined at § 516.300(b)(5).

(2) All other requirements of 42 CFR 422.516 remain in full force and effect.

§ 516.605 Application of Star Ratings-based provisions to ADVaNCE MA model contracts.

The Diamond Ratings system will adopt all provisions of the Star Ratings program unless otherwise stated within this rule and at § 516.600(h) through (j) and § 516.605. Besides what is outlined in § 516.600(h) through (j), all other requirements for quality ratings and payments for the MA and Part D Star Ratings program and quality bonus payment system program continue to apply, except where the following are referenced: Star Ratings, quality ratings, rating systems, QBP ratings, benchmarking increases to the applicable percentage for quality, and final applicable rebate percentages. Unless otherwise specified in this part, references to Star Ratings, measures Star Ratings, or quality ratings in parts 422 or 423 of this chapter must be read as references to ADVaNCE MA Overall Diamond Ratings; references to rating systems in parts 422 or 423 of this chapter must read as references to Diamond Ratings System; and references to

QBP ratings in parts 422 or 423 of this chapter must be read as references to ADVaNCE MA Overall Diamond Ratings. Furthermore, except as otherwise waived in this part, CMS will convert ADVaNCE MA Overall Diamond Ratings values to Star Ratings values using traditional rounding rules.

(a) *General substitution rule.* Except as otherwise waived, all requirements applicable to quality ratings and payments under the MA and Part D Star Ratings program, including QBP ratings, continue to apply to ADVaNCE MA model participants. In these instances, for references to overall Star Ratings and QBP ratings, ADVaNCE MA Overall Diamond Ratings would apply.

(b) *Specific applications.*

(1) *Low-performing icon.* Before an ADVaNCE MA contract receives three consecutive years of Overall Diamond Ratings, a contract's quality performance reflects both its Star Ratings and Diamond Ratings. A contract's performance is assessed using the combination of its Star Ratings from the past two years and its ADVaNCE MA Overall Diamond Ratings from the current year. The contract receives a low performing icon as a result of this combined Stars/Diamonds performance. Parent organizations found to have an ADVaNCE MA Overall Diamond Rating below 3.0 for 3 years in a row will be marked with a low performing indicator in Medicare Plan Finder. A contract must have either a Star Rating or ADVaNCE MA Overall Diamond Rating for all 3 years prior to their participation in the ADVaNCE MA model to be considered for this icon.

(2) *Conditions for default enrollment into an MA D-SNP*. To receive a default enrollment of an individual into a D-SNP, a D-SNP in ADVaNCE MA must have an ADVaNCE MA Overall Diamond Rating of at least 3.0 Diamonds, under the rating system described at §§ 516.200 through 516.220, including as calculated under § 516.200(b)(1) and (c)(1) if the ADVaNCE MA model participant has not yet completed a full performance year, or is a new MA plan as defined in 42 CFR 422.252.

(c) *Waivers related to Star Ratings, Diamond Ratings, and QBP status for consolidated contracts during the post-implementation period—*

(1) *Waiver of QBP status assignment for consolidated contracts.* CMS waives the requirements of 42 CFR 422.162(b)(3)(i) through (iii), which govern the assignment of QBP status for a consolidated contract for the first and second years following a contract consolidation, to the extent necessary to permit CMS to calculate the QBP-related benchmark adjustment and rebate for a consolidated contract in accordance with § 516.230(d)(1), rather than in accordance with 42 CFR 422.162(b)(3)(i) through (iii).

(2) *Waiver of Star Ratings calculation for consolidated contracts.* CMS waives the requirements of 42 CFR 422.162(b)(3)(iv), which govern the calculation of the Overall Star Rating, Part C summary rating, and Part D summary rating for a consolidated contract, to the extent necessary to permit CMS to calculate and display the measure ratings and Overall Star Rating for a consolidated contract in accordance with § 516.230(d)(2), rather than in accordance with 42 CFR 422.162(b)(3)(iv).

Subpart H – Standard Provisions of the Mandatory ADVaNCE MA Model

§ 516.610 Beneficiary protections.

(a) Except as modified in this section, the provisions and requirements of 42 CFR 512.120 apply to the ADVaNCE MA model.

(b) The provisions at § 512.120(a)(1) apply to ADVaNCE MA model participants only to the extent consistent with otherwise applicable MA program requirements at 42 CFR part 422 subpart E. ADVaNCE MA model participants may not impose restrictions on enrollee access to covered services beyond those otherwise permitted under part 422.

(c) All rights under part 422 subpart M, including grievance and appeals rights, continue to apply with respect to ADVaNCE MA model participating contracts.

(d) Descriptive ADVaNCE MA model materials and activities remain subject to applicable requirements of part 422, including subpart V, in addition to § 512.120(c).

§ 516.615 Monitoring and compliance.

(a) Except as modified in this section, the provisions and requirements of 42 CFR 512.150 apply to the ADVaNCE MA model.

(b) An ADVaNCE MA model participant may not request reopening of a model-specific payment determination under 42 CFR 512.150(d)(1) except as expressly provided in § 516.622(a).

(c) Nothing in this section limits CMS' authority to reopen a model-specific payment determination on its own motion or under 42 CFR 512.150(d)(2).

§ 516.621 Remedial action.

(a) The standard provisions and requirements at 42 CFR 512.160 apply to the ADVaNCE MA model and its participants.(b) The existing requirements and enforcement authorities contained in 42 CFR part 422, Subpart K are available to CMS and remain applicable to all ADVaNCE MA model participants unless otherwise specified at § 516.623(a).

§ 516.622 Reconsideration review process.

(a) The standard provisions and requirements of 42 CFR 512.190 apply to the ADVaNCE MA model and its participants, except as set forth in § 516.622(b).

(b) 42 CFR 512.190 does not apply to the provisions in paragraphs (1) and (2) of this section. Instead, the process specified in each paragraph applies:

(1) Solely with respect to the reconsideration and appeals process governing the Diamond Ratings system, the reconsideration and appeals process for the Diamond Ratings system is conducted according to 42 CFR 422.260, governing appeals of quality bonus payment determinations.

(2) Solely with respect to the appeals process governing termination of ADVaNCE MA contracts under § 516.623, the appeals process for ADVaNCE MA contract terminations is conducted according to 42 CFR 422.660.

§ 516.623 Termination of ADVaNCE MA contract.

(a) If CMS determines that the ADVaNCE MA model participant meets either of the following, it may terminate an ADVaNCE MA contract:

(1) Any of the criteria in 42 CFR 422.510(a)(1) through (3), (a)(4)(i) through (x), or (a)(4)(xii) through (xvii).

(2) For 3 consecutive performance years--

(i) Achieves less than a 2.5 Diamond Ratings score; or

(ii) Achieves a Part C summary plan rating of less than three stars, if three performance years of Diamond Ratings are unavailable.

(b) Effect of termination

(1) Termination of an ADVaNCE MA contract under paragraph (a) of this section does not automatically terminate the ADVaNCE MA model participant's participation in the ADVaNCE MA model, except if the ADVaNCE MA model participant holds only one ADVaNCE MA contract.

(2) Where an ADVaNCE MA model participant holds more than one ADVaNCE MA contract, termination of an ADVaNCE MA contract under paragraph (a) of this section affects only that contract, and any of the ADVaNCE MA model participant's remaining ADVaNCE MA contracts will continue to operate under this part, unless terminated under this section. .

(3) Termination of multiple ADVaNCE MA contracts.

(i) CMS can invoke paragraph (a)(1) of this section to terminate multiple ADVaNCE MA contracts held by a single ADVaNCE MA model participant.

(ii) Contracts subject to paragraph (a)(2)(iii) of this section are assessed individually. Termination of a contract based on paragraph (a)(2)(iii) of this section would not affect any other contract.

(iii) Contracts in the same cohort in a Mandatory State have identical Overall Diamond Ratings, and therefore, all these contracts are assessed on the termination provisions at paragraph (a)(2)(i) and (a)(2)(ii) of this section.

(4) Based on termination of multiple ADVaNCE MA contracts outlined in paragraph (b)(3) of this section, CMS gives notice under paragraph (c) of this section separately to each affected contract, and each affected contract has an independent opportunity to submit a corrective action plan under paragraph (d) of this section, where applicable, and independent appeal rights under paragraph (f) of this section.

(c) Termination of an ADVaNCE MA contract by CMS results in a notice of termination in accordance with 42 CFR 422.510(b)(1) except when 42 CFR 422.510(b)(2) is applicable.

(d) Before providing a notice of intent to terminate an ADVaNCE MA contract, CMS will offer an opportunity to develop and implement a corrective action plan in accordance with 42 CFR 422.510(c), subject to the exceptions in 42 CFR 422.510(c)(2), and provide a written notice of available appeal rights in accordance with 42 CFR 422.510(d).

(e) A determination by CMS to terminate an ADVaNCE MA contract leads to, CMS-imposed intermediate sanctions at 42 CFR 422.750(a)(1) and (3) in accordance with the procedure requirements in 42 CFR 422.510(e).

(f) Termination of an ADVaNCE MA contract in accordance with this section allows the ADVaNCE MA model participant to have access to the appeals process outlined in 42 CFR 422.660, in accordance with § 516.622(b)(2).

§ 516.625 Extreme and uncontrollable circumstances.

(a) *General.* When an extreme and uncontrollable circumstance negatively impacts a participating parent organization's ability to conduct surveys needed for accurate performance measurement, CMS calculates ADVaNCE MA Diamond Ratings as specified in paragraph (c)(2) of this section for that affected parent organization in that Mandatory State during the

performance period. The start date of the incident period determines which performance year is affected, regardless of whether the incident period extends into a subsequent calendar year.

(b) *Modified application of § 422.166(i)*. The quality measurement extreme and uncontrollable circumstances regulations at § 422.166(i)(1) through (8) apply to the ADVaNCE MA model, with the following modifications applied throughout those paragraphs:

(1) "Contract" is replaced by "participating parent organization";

(2) "Star Ratings" is replaced by "ADVaNCE MA Diamond Ratings"; "Star Rating" is replaced by "ADVaNCE MA Diamond Rating"; and "Stars" is replaced by "ADVaNCE MA Measure Diamonds"; and when the term "measure stars" appears in the compound phrases "CAHPS measure stars," "HOS and HEDIS-HOS measure stars," and "HEDIS measure stars" in paragraph (i)(2)(iii), (i)(3)(iii), and (i)(4)(iii), it is replaced by "ADVaNCE MA Individual Measure Diamonds";

(3) For purposes of paragraph (i)(5) of this section, "the contract's summary or overall rating" is replaced by "the participating parent organization's ADVaNCE MA Overall Score";

(4) "Enrollees" is replaced by "enrollees of the ADVaNCE MA model," meaning enrollees of participating contracts only;

(c) *Disaster policy*. If a participating parent organization operates contracts in more than one State, CMS evaluates a disaster or emergency declared in one State only for the enrollees and contracts within that State.

Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services.

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