

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 417, 422, and 423**

[CMS–4192–F, CMS–1744–F, and CMS–3401–F]

RIN 0938–AU30, 0938–AU31, and 0938–AU33

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

SUMMARY: This final rule will revise the Medicare Advantage (MA) (Part C) program and Medicare Prescription Drug Benefit (Part D) program regulations to implement changes related to marketing and communications, past performance, Star Ratings, network adequacy, medical loss ratio reporting, special requirements during disasters or public emergencies, and pharmacy price concessions. This final rule will also revise regulations related to dual eligible special needs plans (D–SNPs), other special needs plans, and cost contract plans. This final rule finalizes certain 2021 and 2022 Star Ratings provisions that were included in two interim final rules with comment period (IFC) that CMS issued on April 6, 2020, and September 2, 2020; other policies from those interim final rules will be addressed in other rulemakings.

DATES:

Effective dates: These regulations are effective on June 28, 2022, except for amendatory instructions 27 and 36 (regarding the definition of “negotiated price” at §§ 423.100 and 423.2305), which are effective January 1, 2024.

Applicability dates: The applicability date of the provisions in this rule is January 1, 2023, except as explained in **SUPPLEMENTARY INFORMATION**.

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SUPPLEMENTARY INFORMATION:**Acronyms**

ACC Automated Criteria Check
 AHC Accountable Health Communities
 AKS Anti-kickback Statute
 ANOC Annual Notice of Change
 ARB At-Risk Beneficiaries
 BBA Bipartisan Budget Act
 CAHPS Consumer Assessment of Healthcare Providers and Systems
 CAI Categorical Adjustment Index
 CMS Centers for Medicare & Medicaid Services
 COI Collection of Information
 COVID–19 Coronavirus 2019 Disease
 C–SNP Chronic Condition Special Needs Plan
 DME Durable Medical Equipment
 D–SNP Dual Eligible Special Needs Plan
 EGWP Employer Group Waiver Plan
 EOC Evidence of Coverage
 FAI Financial Alignment Initiative
 FDR First-Tier Downstream and Related Entity
 FFS Fee-for-Service
 FIDE SNP Fully Integrated Dual Eligible Special Needs Plan
 FQHC Federally Qualified Health Center
 HEDIS Healthcare Effectiveness Data and Information Set
 HHS Department of Health and Human Services
 HIDE SNP Highly Integrated Dual Eligible Special Needs Plan
 HIPAA Health Insurance Portability and Accountability Act of 1996
 HOS Health Outcomes Survey
 HPMS Health Plan Management System
 HRA Health Risk Assessment
 HSD Health Service Delivery
 ICR Information Collection Requirement
 IRE Independent Review Entity
 I–SNP Institutional Special Needs Plan
 LOI Letter of Intent
 LTSS Long Term Services and Supports
 MA Medicare Advantage
 MAC Medicare Administrative Contractor
 MACPAC Medicaid and CHIP Payment and Access Commission
 MA–PD Medicare Advantage Prescription Drug
 MCO Managed Care Organization
 MCMG Medicare Communications and Marketing Guidelines
 MACPAC Medicaid and CHIP Payment and Access Commission
 MedPAC Medicare Payment Advisory Commission
 MIPPA Medicare Improvements for Patients and Providers Act
 MLR Medical Loss Ratio
 MMA Medicare Prescription Drug, Improvement, and Modernization Act

MMCO Medicare-Medicaid Coordination Office
 MMP Medicare-Medicaid Plan
 MOC Model of Care
 MOOP Maximum Out-of-Pocket
 NAMBA National Average Monthly Bid Amount
 NEMT Non-emergency Medical Transportation
 NMM Network Management Module
 OACT Office of the Actuary
 OMB Office of Management and Budget
 PACE Programs of All-Inclusive Care for the Elderly
 PAHP Prepaid Ambulatory Health Plan
 PBP Plan Benefit Package
 PDE Prescription Drug Event
 PDP Prescription Drug Plan
 PHE Public Health Emergency
 PIHP Prepaid Inpatient Health Plan
 PRA Paperwork Reduction Act
 RFI Request for Information
 RFA Regulatory Flexibilities Act
 RHC Rural Health Clinic
 SAE Service Area Expansion
 SB Summary of Benefits
 SDOH Social Determinants of Health
 SHIP State Health Insurance Assistance Program
 SNP Special Needs Plan
 SSA Social Security Administration
 SSBCI Special Supplemental Benefits for the Chronically Ill
 TPMO Third-Party Marketing Organization

Additional information regarding the applicability dates: The Star Ratings provision at § 422.166(i)(12) is applicable to the calculation of the 2023 Star Ratings released in October, 2022, as discussed in section II.D.2. of this final rule. The definition of “fully integrated dual eligible special needs plans (FIDE SNP)” in § 422.2 at paragraphs (2)(i) and (iii) through (v), (5), and (6) as discussed in section II.A.5 of this final rule are applicable beginning January 1, 2025. The definition of “highly integrated dual eligible special needs plans” in § 422.2 at paragraph (3), as discussed in section II.A.5.f. of this final rule, is applicable beginning January 1, 2025. The applicability date of the requirements at § 422.101, as discussed in section II.A.4. of this final rule, is January 1, 2024. The requirements at § 423.100, as discussed in section II.H. of this final rule, are applicable beginning on January 1, 2024.

I. Executive Summary**A. Purpose**

Over 29 million individuals receive their Medicare benefits through Medicare Advantage (MA or Part C), including plans that offer Medicare Prescription Drug Benefit (Part D) coverage. Over 23 million individuals receive Part D coverage through standalone Part D plans. The primary purpose of this final rule is to

implement changes to the MA and Part D programs. This final rule implements changes related to marketing and communications, past performance, Star Ratings, network adequacy, medical loss ratio reporting, special requirements during disasters or public emergencies, and pharmacy price concessions. This final rule also revises regulations related to dual eligible special needs plans (D-SNPs), other special needs plans, and Medicare cost contract plans.

B. Summary of Major Provisions

1. Enrollee Participation in Plan Governance (§ 422.107)

Managed care plans derive significant value from engaging enrollees in defining, designing, participating in, and assessing their care systems.¹ Through this final rule, we require that any MA organization offering a D-SNP establish one or more enrollee advisory committees in each State to solicit direct input on enrollee experiences. We also establish that the committee must include a reasonably representative sample of individuals enrolled in the D-SNP(s) and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations. Public comments on our proposal reinforced our belief that the establishment and maintenance of an enrollee advisory committee is a valuable beneficiary protection to ensure that enrollee feedback is heard by managed care plans and to help identify and address barriers to high-quality, coordinated care for dually eligible individuals.

2. Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessments (§ 422.101)

Section 1859(f)(5)(A)(ii)(I) of the Social Security Act (hereafter known as the Act) requires each special needs plan (SNP) to conduct an initial assessment and an annual reassessment of the individual's physical, psychosocial, and functional needs. We codified this requirement at § 422.101(f)(1)(i) as part of the model of care requirements for all MA SNPs. Certain social risk factors can lead to unmet social needs that directly influence an individual's physical, psychosocial, and functional status. Many dually eligible individuals

contend with multiple social risk factors such as homelessness, food insecurity, lack of access to transportation, and low levels of health literacy. Building on CMS's experience with other programs and model tests, and with broad support from public commenters, we are finalizing a requirement that all SNPs include one or more questions from a list of screening instruments specified in sub-regulatory guidance on housing stability, food security, and access to transportation as part of their health risk assessments (HRAs). However, based on public comments, we are not finalizing our proposal that all SNPs use the same specific standardized questions.

Our final rule will result in SNPs having a more complete picture of the risk factors that may inhibit enrollees from accessing care and achieving optimal health outcomes and independence. We believe this knowledge will better equip the MA organizations offering these SNPs to meet the needs of their members. Our final rule will also equip these MA organizations with person-level information that will help them better connect people to covered services, social service organizations, and public programs that can help resolve housing instability, food insecurity, or transportation challenges.

3. Refining Definitions for Fully Integrated and Highly Integrated D-SNPs (§§ 422.2 and 422.107)

Dually eligible individuals have an array of choices for how to receive their Medicare coverage. We proposed several changes to how we define fully integrated dual eligible special needs plan (FIDE SNP) and highly integrated dual eligible special needs plan (HIDE SNP) to help differentiate various types of D-SNPs, clarify options for beneficiaries, and increase integration for these types of D-SNPs.

In this final rule, we are requiring, for 2025 and subsequent years, that all FIDE SNPs have exclusively aligned enrollment, as defined in § 422.2, and cover Medicare cost-sharing and three specific categories of Medicaid benefits: Home health services (as defined in § 440.70), medical supplies, equipment, and appliances (as described in § 440.70(b)(3)), and behavioral health services through a capitated contract between the State Medicaid agency and the Medicaid managed care organization that is the same legal entity as the MA organization that offers the FIDE SNP. In addition, we are requiring that, for plan year 2025 and subsequent years, each HIDE SNP have a service area that completely overlaps the service area of the affiliated Medicaid managed care

plan with the capitated contract with the State. Consistent with existing policy outlined in sub-regulatory guidance, this final rule also codifies specific, limited carve-outs of the Medicaid long-term services and supports and Medicaid behavioral health services covered under the Medicaid capitated contract affiliated with FIDE SNPs and HIDE SNPs.

We believe these policies will create better experiences for beneficiaries and move FIDE SNPs and HIDE SNPs toward greater integration, which we believe is a purpose of the amendments to section 1859(f) of the Act regarding integration made by section 50311(b) of the BBA of 2018.

4. Additional Opportunities for Integration Through State Medicaid Agency Contracts (§ 422.107)

Section 164 of Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275) amended section 1859(f) of the Act to require that a D-SNP contract with the State Medicaid agency in each State in which the D-SNP operates to provide benefits, or arrange for the provision of Medicaid benefits, to which an individual is entitled. States have used these contracts to better integrate care for dually eligible individuals. In this final rule we codify new pathways through which States can use these contracts to require that certain D-SNPs with exclusively aligned enrollment (a) establish contracts that only include one or more D-SNPs within a State, and (b) use certain integrated materials and notices for enrollees. Where States choose this opportunity, it will help individuals better understand their coverage. Because Star Ratings are assigned at the contract level, this final rule will also provide a mechanism to provide States and the public with greater transparency on the quality ratings for the D-SNP(s), helping CMS and States better identify disparities between dually eligible beneficiaries and other beneficiaries and target interventions accordingly.

We also codify mechanisms to better coordinate State and CMS monitoring and oversight of certain D-SNPs when a State has elected to require these additional levels of integration, including granting State access to certain CMS information systems. Collectively, our proposals will improve Federal and State oversight of certain D-SNPs (and their affiliated Medicaid managed care plans) through greater information-sharing among government regulators.

¹ Centers for Medicare & Medicaid Services. (n.d.). *Person & Family Engagement Strategy: Sharing with Our Partners*. Retrieved from <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Person-and-Family-Engagement-Strategy-Summary.pdf>.

5. Attainment of the Maximum Out-of-Pocket Limit (§§ 422.100 and 422.101)

In order to ensure that MA plan benefits do not discriminate against higher cost, less healthy enrollees, MA plans are required to establish a limit on beneficiary cost-sharing for Medicare Part A and B services after which the plan pays 100 percent of the service costs. Current guidance allows MA plans, including D-SNPs, to not count Medicaid-paid amounts or unpaid amounts toward this maximum out-of-pocket (MOOP) limit, which results in increased State payments of Medicare cost-sharing and disadvantages providers serving dually eligible individuals in MA plans. In this final rule we specify that the MOOP limit in an MA plan (after which the plan pays 100 percent of MA costs for Part A and Part B services) must be calculated based on the accrual of all cost-sharing in the plan benefit, regardless of whether that cost-sharing is paid by the beneficiary, Medicaid, other secondary insurance, or remains unpaid (including cost-sharing that remains unpaid because of State limits on the amounts paid for Medicare cost-sharing and dually eligible individuals' exemption from Medicare cost-sharing). The change will result in more equitable payment for MA providers serving dually eligible beneficiaries. We project that our requirement as finalized will result in increased bid costs for the MOOP for some MA plans. A portion of those higher bid costs will result in increased Medicare spending of \$3.9 billion over 10 years. That cost is partially offset by lower Federal Medicaid spending of \$2.7 billion and the portion of Medicare spending paid by beneficiary Part B premiums, which totals \$600 million over 10 years. The net Federal 10-year cost estimate for the finalized requirement is \$614.8 million.

6. Special Requirements During a Disaster or Emergency for Medicare Advantage Plans (§ 422.100(m))

In order to ensure enrollees have uninterrupted access to care, current regulations provide for special requirements at § 422.100(m) for MA plans during disasters or emergencies, including public health emergencies (PHEs), such as requirements for plans to cover services provided by non-contracted providers and to waive gatekeeper referral requirements. The timeframe during which these special rules apply can be very specific depending on the type or scope of the disaster or emergency, while other situations, like the PHE for COVID-19, may have an uncertain end date.

Currently, the regulation states that a disaster or emergency ends (thus ending the obligation for MA plans to comply with the special requirements) the earlier of when an end date is declared or when, if no end date was identified in the declaration or by the official that declared the disaster or emergency, 30 days have passed since the declaration. This has caused some confusion among stakeholders, who are unsure whether to continue special requirements during a state of disaster or emergency after 30 days, or whether those special requirements do not apply after the 30-day time period has elapsed. In this final rule, we clarify the period of time during which MA organizations must comply with the special requirements. Under this final rule, MA organizations must ensure access for enrollees to covered services throughout the disaster or emergency period, including when the end date is unclear and the period renews several times, so long as there is a disruption of access to healthcare.

7. Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application (§ 422.116)

We proposed to amend § 422.116 to require applicants to demonstrate that they meet the network adequacy standards for the pending service area as part of the MA application process for new and expanding service areas and to adopt a time-limited 10-percentage point credit toward meeting the applicable network adequacy standards for the application evaluation. Under our current rules, we require that an applicant attest that it has an adequate provider network that provides enrollees with sufficient access to covered services, and we will not deny an application based on the evaluation of the MA plan's network. Network adequacy reviews are a critical component for confirming that access to care is available for enrollees. As such, we believe that requiring applicants to meet network adequacy standards as part of the application process will strengthen our oversight of an organization's ability to provide an adequate network of providers to deliver care to MA enrollees. This change will also provide MA organizations with information regarding their network adequacy ahead of bid submissions, mitigating current issues with late changes to the bid that may affect the bid pricing tool. Finally, we understand that it may be difficult for applicants to have a full network in place almost 1 year ahead of the beginning of the contract as the proposed change for network adequacy rules will require. Therefore, the final rule includes a 10-

percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for new or expanding service area applicants. Once the contract is operational, the 10-percentage point credit will no longer apply and MA organizations will need to meet full compliance.

We are finalizing our proposal, with one modification; to allow applicants to utilize Letters of Intent (LOIs) to meet network standards in counties and specialty types as needed. Once the contract is operational, MA organizations must have signed contracts with providers and facilities to be in full compliance.

8. Part C and Part D Quality Rating System

Due to the scope and duration of the COVID-19 PHE, we adopted a technical change to the 2022 Star Ratings methodology for extreme and uncontrollable circumstances in the "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" published in the **Federal Register** and effective on September 2, 2020 (hereafter referred to as the "September 2nd COVID-19 IFC"),² (CMS-3401-IFC; 85 FR 54820) at 42 CFR 422.166(i)(11) to make it possible for us to calculate 2022 Star Ratings for MA contracts. We proposed making a technical change at § 422.166(i)(12) to enable CMS to calculate 2023 Star Ratings for three Healthcare Effectiveness Data and Information Set measures that are based on the Health Outcomes Survey (87 FR 1842, January 12, 2022). Specifically, these measures are Monitoring Physical Activity, Reducing the Risk of Falling, and Improving Bladder Control. Without this technical change, CMS will be unable to calculate measure-level 2023 Star Ratings for these measures for any MA contract. We are therefore finalizing § 422.166(i)(12) without modification. In this final rule, we also respond to comments we received on the Medicare Advantage and Part D Star Ratings provisions in the interim final rules titled "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" published in the **Federal Register** on April 6, 2020,

² www.federalregister.gov/documents/2020/09/02/2020-19150/medicare-and-medicare-programs-clinical-laboratory-improvement-amendments-clia-and-patient.

with a March 31, 2020 effective date (hereafter referred to as the “March 31st COVID–19 IFC”)³ (85 FR 19230) and the September 2nd COVID–19 IFC. As detailed in sections II.D.3. and II.D.4. of this final rule, we are finalizing most of the Star Ratings provisions from the March 31st COVID–19 IFC and the September 2nd COVID–19 IFC, but we are not finalizing several Star Ratings provisions in those interim final rules, regarding circumstances that did not happen, because they are moot. CMS will address other provisions from the interim final rules in other rulemakings.

9. Past Performance Methodology to Better Hold Plans Accountable for Violating CMS Rules (§§ 422.502 and 422.503)

In a previous rulemaking cycle, CMS modified the past performance methodology, revising the elements that are reviewed to determine if CMS should permit an organization to enter into a new contract or expand an existing contract. The current regulatory language prohibits an organization from expanding or entering into a new contract if it has a negative net worth or has been under sanction during the performance timeframe. In this final rule, we include an organization’s record of Star Ratings, bankruptcy issues, and compliance actions in our methodology going forward.

10. Marketing and Communications Requirements on MA and Part D Plans To Assist Their Enrollees (§§ 422.2260 and 423.2260, 422.2267 and 423.2267, 422.2274 and 423.2274)

CMS has seen an increase in beneficiary complaints associated with third-party marketing organizations (TPMOs) and has received feedback from beneficiary advocates and stakeholders concerned about the marketing practices of TPMOs who sell multiple MA and Part D products. In 2020, we received a total of 15,497 complaints related to marketing. In 2021, excluding December, the total was 39,617. We are unable to say that every one of the complaints is a result of TPMO marketing activities, but based on a targeted search, we do know that many are related to TPMO marketing. In addition, we have seen an increase in third party print and television ads, which appears to be corroborated by State partners. Through this final rule, we will address the concerns with TPMOs by means of the following three

updates to the communications and marketing requirements under 42 CFR parts 422 and 423, subpart V: (1) We define TPMOs in the regulation at §§ 422.2260 and 423.2260 to remove any ambiguity associated with MA plans/Part D sponsors responsibilities for TPMO activities associated with the selling of MA and Part D plans; (2) we add a new disclaimer that will be required when TPMOs market MA plans/Part D products (§§ 422.2267(e) and 423.2267(e)); and (3) we update §§ 422.2274 and 423.2274 to require additional plan oversight requirements associated with TPMOs, in addition to what is already required under §§ 422.504(i) and 423.505(i) if the TPMO is a first tier, downstream or related entity (FDR).

CMS’ January 2021 final rule, entitled “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) did not require notice and taglines, based on the HHS Office for Civil Rights repeal of certain notice and tagline requirements associated with section 1557 of the Affordable Care Act. In the months since the publication of this rule, CMS gained additional insight regarding the void created by the lack of these notification requirements. Based on the significant population (12.2 percent) of those 65 and older who speak a language other than English in the home and complaints CMS received through our Complaint Tracking Module, in this final rule we are finalizing a requirement that MA and Part D plans create a multi-language insert that will inform the reader, in the top fifteen languages used in the U.S., as well as any additional non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area, that interpreter services are available for free. As a note, CMS provides plans a list of all languages that are spoken by 5 percent or more of the population for every county in the U.S. As part of the finalized requirement, plans will be required to include the multi-language insert whenever a Medicare beneficiary is provided a CMS required material (for example, Evidence of Coverage, Annual Notice of Change, enrollment form, Summary of Benefits) as defined under §§ 422.2267(e) and 423.2267(e). We further note that existing statutes, including Section 504 of the Rehabilitation Act and 1557 of the

Affordable Care Act, require the provision of any auxiliary aids and services required for effective communication for individuals with disabilities at no cost to the individual.

Finally, in this final rule we are codifying a number of current sub-regulatory communications and marketing requirements that were inadvertently not included during the previous updates to 42 CFR parts 422 and 423, subpart V.

11. Greater Transparency in Medical Loss Ratio Reporting (§§ 422.2460 and 423.2460)

To improve transparency and oversight concerning the use of Trust Fund dollars, we reinstate the detailed medical loss ratio (MLR) reporting requirements that were in effect for contract years 2014 to 2017, which required reporting of the underlying data used to calculate and verify the MLR and any remittance amount, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, and regulatory fees. In addition, the new MLR reporting templates will require additional details regarding plan expenditures so we can better assess the accuracy of MLR submissions, the value of services being provided to enrollees under MA and Part D plans, and the impacts of recent rule changes that removed limitations on certain expenditures that count toward the 85 percent MLR requirement.

12. Pharmacy Price Concessions to Drug Prices at the Point of Sale (§§ 423.100 and 423.2305)

The “negotiated prices” of drugs, as the term is currently defined in § 423.100, must include all network pharmacy price concessions except those contingent amounts that cannot “reasonably be determined” at the point-of-sale. Under this exception, negotiated prices typically do not reflect any performance-based pharmacy price concessions that lower the price a sponsor ultimately pays for a drug, based on the rationale that these amounts are contingent upon performance measured over a period that extends beyond the point of sale and thus cannot reasonably be determined at the point of sale. We proposed to eliminate this exception for contingent pharmacy price concessions (87 FR 1842, January 12, 2022). We proposed to delete the existing definition of “negotiated prices” at § 423.100 and to adopt a new definition for the term “negotiated price” at § 423.100, which we proposed to define as the lowest amount a pharmacy could

³ www.federalregister.gov/documents/2020/04/06/2020-06990/medicare-and-medicaid-programs-policy-and-regulatory-revisions-in-response-to-the-covid-19-public.

receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor's intermediary (that is, the amount the pharmacy will receive net of the maximum negative adjustment that could result from any contingent pharmacy payment arrangement and before any additional contingent payment amounts, such as incentive fees). We proposed to allow plans the flexibility to determine how much of the pharmacy price concessions to pass through at the point of sale for applicable drugs in the coverage gap phase of the benefit. After consideration of the comments, we are modifying our proposal to apply the new definition of "negotiated price" to all phases of the

Part D benefit, including the coverage gap phase. We are also amending the definition of "negotiated price" at § 423.2305 by revising paragraphs (1) and (2) of the definition of "negotiated price" for the Coverage Gap Discount Program to be consistent with the definition of "negotiated price" that we are adopting at § 423.100 (that is, the lowest possible reimbursement such network entity will receive, in total, for a particular drug). This policy takes effect 60 days after publication of the final rule and is applicable beginning on January 1, 2024. Part D sponsors will need to account for these changes in the bids that they submit for contract year 2024.

In this final rule, we add a definition of "price concession" at § 423.100. Although "price concession" is a term important to the adjudication of the Part D program, it had not yet been defined in the Part D statute, Part D regulations, or sub-regulatory guidance. We define price concession to include any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor.

C. Summary of Costs and Benefits

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Summary of Major Provisions of Rule	Description	Impact
1. Enrollee Participation in Plan Governance (§ 422.107)	We are finalizing a requirement that any MA organization must establish one or more enrollee advisory committees in each State where the organization offers a D-SNP to solicit direct input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.	There is on average an annual cost of \$1.0 million on MA organizations for establishing and maintaining these D-SNP advisory committees, with a wide range of variability.
2. Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessments (§ 422.101)	Building on CMS's experience with other programs and model tests, we are finalizing a requirement that all SNPs include questions on housing stability, food security, and access to transportation from a list of screening instruments specified by CMS in sub-regulatory guidance as part of their initial and annual health risk assessments beginning in contract year 2024.	For the initial year of implementation, there is a negligible impact on a portion of SNPs to update systems and HRA instruments.
3. Refining Definitions for Fully Integrated and Highly Integrated D-SNPs (§§ 422.2 and 422.107)	We are finalizing a requirement, for 2025 and subsequent years, that all FIDE SNPs have exclusively aligned enrollment, as defined in § 422.2, and cover Medicare cost-sharing and Medicaid home health, medical supplies, equipment and appliances, and behavioral health services through a capitated contract with the State Medicaid agency. We are also finalizing a requirement that each HIDE SNP's capitated contract with the State apply to the entire service area for the D-SNP for plan year 2025 and subsequent years. Finally, consistent with existing policy outlined in sub-regulatory guidance, we are codifying specific limited benefit carve-outs for FIDE SNPs and HIDE SNPs.	There is a negligible one-time impact to update contracts.

Summary of Major Provisions of Rule	Description	Impact
4. Additional Opportunities for Integration through State Medicaid Agency Contracts (§ 422.107)	We are codifying new pathways through which States can use the State Medicaid agency contracts to require that certain D-SNPs with exclusively aligned enrollment (a) apply and request to establish contracts that only include one or more D-SNP within a State, and (b) integrate materials and notices for enrollees. We are also finalizing mechanisms to better coordinate State and CMS monitoring and oversight of certain D-SNPs when a State has elected to require these additional levels of integration, including granting State access to certain CMS information systems.	There is a one-time \$1.1 million impact shared among the Federal Government, State governments, and MA organizations to create new contracts and to update systems to review the new materials.
5. Attainment of the Maximum Out-of-Pocket Limit (§§ 422.100 and 422.101)	We are finalizing that the maximum out-of-pocket limit in an MA plan (after which the plan pays 100 percent of MA costs) must be calculated based on the accrual of all cost-sharing in the plan benefit, whether that cost-sharing is paid by the beneficiary, Medicaid, other secondary insurance, or remains unpaid.	The policy will increase Medicare spending by \$3.9 billion over 10 years. That cost is partially offset by lower Federal Medicaid spending of \$2.7 billion and the portion of Medicare spending paid by beneficiary Part B premiums, which totals \$600 million over 10 years. The net 10-year cost estimate for the proposal is \$614.8 million.
6. Special Requirements during a Disaster or Emergency for Medicare Advantage Plans (§ 422.100(m))	We are clarifying the period of time during which MA organizations must comply with the special requirements to ensure access for enrollees to covered services during a disaster or emergency (including PHEs) period, including when the end date is unclear and the period renews several times, so long as there is a disruption in access to healthcare for enrollees in the plan service area.	None anticipated.

Summary of Major Provisions of Rule	Description	Impact
7. Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application (§ 422.116)	We are finalizing an amendment at § 422.116 to require an applicant to demonstrate compliance with network adequacy standards as part of the MA application process for new and expanding service areas and to adopt a time-limited 10 percentage point credit toward meeting the applicable network adequacy standards for the application evaluation. We are also finalizing a modification to our proposal to allow applicants to utilize Letters of Intent to meet network standards in counties and specialty types as needed.	In response to comments, we are allowing LOIs in lieu of full contracts during the application period to meet the network standards. This change will have negligible impact.
8. Part C and Part D Quality Rating System (§§ 417.472, 422.152, 422.164, 422.166, 422.252, 423.156, 423.182, 423.184, and 423.186)	We are finalizing a technical change at § 422.166(i)(12) without modification to enable CMS to calculate 2023 Star Ratings for three Healthcare Effectiveness Data and Information Set measures that are based on the Health Outcomes Survey. We also respond to comments and finalize certain Star Ratings provisions adopted in the March 31 st COVID-19 IFC and the September 2 nd COVID-19 IFC in sections II.D.3. and II.D.4. of this final rule.	None anticipated.
9. Past Performance Methodology to Better Hold Plans Accountable for Violating CMS Rules (§§ 422.502 and 422.503)	We are finalizing the inclusion of Star Ratings, bankruptcy issues, and compliance actions in our methodology going forward.	None anticipated.

Summary of Major Provisions of Rule	Description	Impact
<p>10. Marketing and Communications Requirements on MA and Part D Plans to Assist Their Enrollees (§§ 422.2260 and 423.2260, 422.2267 and 423.2267, 422.2274 and 423.2274)</p>	<p>We are finalizing several updates to the communications and marketing requirements under 42 CFR parts 422 and 423, subpart V, to define MA plans/Part D sponsors responsibilities for TPMO activities associated with the selling of MA and Part D plans.</p> <p>We are finalizing a requirement that MA and Part D plans use a multi-language insert that will inform the reader, in the top fifteen languages used in the U.S., that interpreter services are available for free. We are also finalizing a requirement to include the multi-language insert whenever a Medicare beneficiary is provided a CMS required material as defined under §§ 422.2267(e) and 423.2267(e).</p> <p>Lastly, we are codifying a number of current sub-regulatory communications and marketing requirements.</p>	<p>There is an annual impact of \$0.3 million on plans to print the multi-language insert.</p>
<p>11. Greater Transparency in Medical Loss Ratio Reporting (§§ 422.2460, 422.2490, and 423.2460)</p>	<p>To improve transparency and oversight concerning the use of Trust Fund dollars, we are reinstating the detailed MLR reporting requirements that were in effect for contract years 2014–2017, which required reporting of the underlying data used to calculate and verify the MLR and any remittance amount. In addition, we are finalizing the collection of additional details regarding plan expenditures so we can better assess the accuracy of MLR submissions, the value of services being provided to enrollees, and the impacts of recent rule changes.</p>	<p>MA organizations and Part D sponsors are expected to pay an additional \$268.6 million in remittances to the Treasury over a 10-year period. There is an annual additional \$2.3 million administrative cost to MA organizations and Part D sponsors for complying with these provisions, as well as a \$0.2 million cost to the government for Federal contractors.</p>

Summary of Major Provisions of Rule	Description	Impact
<p>12. Pharmacy Price Concessions to Drug Prices at the Point of Sale (§§ 423.100 and 423.2305)</p>	<p>We are eliminating the exception for pharmacy price concessions that cannot reasonably be determined at the point of sale for all phases of the Part D benefit. We are also deleting the existing definition of “negotiated prices” at § 423.100 and adopting a new definition for the term “negotiated price” at § 423.100, which we define as the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor’s intermediary. We are also modifying the definition of negotiated price in the coverage gap at § 423.2305 to align with the new definition of negotiated price at § 423.100. Lastly, we are adding a definition of “price concession” at § 423.100.</p>	<p>Requiring pharmacy price concessions in the negotiated price is expected to reduce total beneficiary costs by \$26.5 billion between 2024 and 2032, or approximately 2 percent. In addition, the policy is estimated to have \$46.8 billion in Part D costs for the government between 2024 and 2032 due to increases in direct subsidy and low-income premium subsidy payments, which represents a 3 percent increase. Manufacturers will save about \$16.8 billion over the same period. We expect a one-time cost to plan sponsors of \$0.1 million to update systems and ongoing costs of \$0.1 million for added PDE transmission costs.</p>

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D. Background

We received approximately 6,179 timely pieces of correspondence containing one or more comments for the provisions addressed in this final rule from the proposed rule titled “Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs” which appeared in the **Federal Register** on January 12, 2022 (hereafter referred to as the January 2022 proposed rule, 87 FR 1842). Comments were submitted by MA health plans, Part D sponsors, beneficiaries, MA enrollee and beneficiary advocacy groups, trade associations, providers, pharmacies and drug companies, States, telehealth and health technology organizations, policy research organizations, actuarial and law firms, MACPAC, MedPAC, Members of Congress, and other vendor and professional associations.

The proposals we are finalizing in this final rule range from minor clarifications to more significant modifications based on the comments received. Summaries of the public comments received and our responses to those public comments are set forth in

the various sections of this final rule under the appropriate headings.

We received an overarching comment related to the proposed rule, which we summarize in the following paragraphs:

Comment: A commenter expressed a concern about the timing of the provisions included in the proposed rule related to the deadline for bid submissions, especially related to proposals with contract year 2023 effective dates. The commenter noted that several proposals would require operational and technical changes for MA organizations as well as additional resource allocations, and, as such, welcomed additional time for implementation. The commenter suggested it could better align and collaborate with CMS in the future if given more time to fully understand and implement proposed changes.

Response: We understand and appreciate the commenter’s concerns and MA organizations and Part D sponsors’ willingness to work to meet the implementation date timeframes. In response to comments, we are modifying the date on which some of the new and amended regulations in this final rule become applicable. We describe these modifications in further

detail in the respective sections of the rule.

We also note that some of the public comments received for the provisions implemented in this final rule were outside of the scope of the proposed rule. As such, these out-of-scope public comments are not addressed in this final rule. The following paragraphs summarize the out-of-scope public comments.

A commenter noted that long-term care provider-led institutional special needs plans (I-SNPs) offer a strong additional solution to States in integrated efforts, especially for long-term care services uses with complex, high risk needs.

We received a few comments related to D-SNP look-alikes, which are addressed at § 422.514(d). A commenter requested that CMS consider reducing the threshold for a D-SNP look-alike from the current 80 percent of dually eligible individuals enrolled to 50 percent and requiring the Medicare program to inform individuals that they are enrolling in a non-integrated model where an integrated model exists. Without such action, this commenter expressed that D-SNP look-alikes could undermine progress on integration,

leading to the erosion of D–SNP enrollment over time and additional beneficiary confusion. Another commenter requested that CMS reconsider its current policy for States without a D–SNP option for partial-benefit dually eligible individuals by either allowing these individuals to enroll in FIDE SNPs or excluding them from the 80-percent threshold calculation used to determine D–SNP look-alikes in these States.

A few commenters encouraged CMS to consider applying other MMP design elements to D–SNPs. These included extending contract management teams to HIDE SNPs and FIDE–SNPs, D–SNPs with exclusively aligned enrollment, and/or D–SNPs with a meaningful proportion of enrollees who receive Medicaid benefits from a managed care plan affiliated with the D–SNP; requiring D–SNPs to develop single case agreement policies to enable enrollees to see out-of-network providers; applying MMP program audit rules and protocols to D–SNPs with exclusively aligned enrollment; and allowing beneficiaries to enroll in integrated plans on a monthly basis rather than the roughly quarterly enrollment opportunities under MA.

MACPAC noted that while the provisions in the proposed rule promote integration in existing products, they do not necessarily increase the availability of integrated models or enrollment in integrated plans and urged CMS to look for ways to expand policies to promote integration beyond D–SNPs with exclusively aligned enrollment in future rulemaking.

A commenter encouraged CMS to reconsider its approach to setting separate requirements for D–SNPs and Medicaid managed care plans and to align Federal regulations for FIDE SNPs with those that already exist for Medicaid managed care.

A commenter recommended that CMS take steps to reduce limitations on data sharing between plans and States and provide additional guidance on creating a standardized and electronic method to integrate information in model materials.

A few commenters recommended that CMS take steps to ensure that quality measurement is appropriately targeted to the populations served by each product and that measurement and related financial incentives do not disproportionately penalize D–SNPs for serving populations with greater risk factors. Other commenters urged CMS to require all States to adopt standardized, disability-informed quality measurement tools so that measures are

collected and reported in a uniform format.

A few commenters expressed concern related to quality measurement for D–SNPs more broadly. A commenter stated that because of the challenges inherent to serving younger dually eligible beneficiaries with disabilities who represent the most complex and at-risk Medicare members with the most social risk factors, plans serving this population have less quality bonus funding available to support supplemental benefits tailored to the population.

A commenter suggested CMS consider revising the requirement that the D–SNP and Medicaid managed care plan contract holder must be the same legal entity in order to qualify as a FIDE SNP; instead, the commenter recommended using the same requirement that is used for HIDE SNPs that the contract holder is the same parent organization or another entity that is owned and controlled by its parent organization.

A few commenters requested CMS consider additional financial policies. A commenter encouraged CMS to require States to ensure that the capitated payments for HIDE SNPs and FIDE SNPs are documented in the State Medicaid agency contract. Another commenter noted that the existing risk adjustment methodology is not sensitive to pick up all of the nuances for D–SNPs that largely serve populations with more complex care. A commenter requested that CMS consider clarifying elements of the cost-sharing billing process during an enrollee's Medicare deeming period, including prohibiting Medicare cost-sharing being billed to dually eligible individuals during the Medicare deeming period.

A commenter requested guidance on how to handle cost-sharing for supplemental benefits that may overlap with what is provided by Medicaid.

A commenter expressed concern regarding the complaint resolution process for dually eligible individuals, noting that it is fragmented and confusing when some issues are handled by State Medicaid agencies or plans while others are handled by CMS or MA plans. The commenter noted that “no wrong door” policies for enrollee concerns are critical to ensuring complaints are addressed.

A commenter urged CMS to consider the limited availability of transportation options in rural communities when finalizing the proposed rule.

A commenter expressed interest in additional research to better understand fluctuations within dual eligibility and what may cause a partial-benefit dually eligible individual to become a full-

benefit dually eligible individual and encouraged CMS to assess whether integrated models can help prevent partial-benefit dual eligible individuals from necessitating full-benefit status.

A commenter suggested that another approach to improving integrated care is to establish a single program that would provide dually eligible beneficiaries with their medical, long-term care, behavioral, and social needs. They further suggested the program allow States to contract with the administering entities, which would bear two-sided risk to ensure accountability and eliminate incentives for cost-shifting.

A commenter expressed concerns about the MA program overall, including inadequate care provided to MA enrollees, low payments to providers, and high MA payment rates compared to the original Medicare fee-for-service (FFS) program.

CMS received a number of comments regarding extending the COVID–19 disaster adjustments that all contracts received for the 2022 Star Ratings for measures other than HEDIS–HOS measures and reducing the weight applied to the patient experience/complaints and access measures for the 2023 Star Ratings.

CMS received many comments regarding network adequacy requirements and policies that are outside of the scope of this rule. Some commenters indicated that CMS should consider reinstating previous network adequacy standards including returning to the 90 percent rate of beneficiary requirements within time and distance standards for micro, rural and counties with extreme access considerations, as well as including dialysis facilities as a specialty type evaluated for network adequacy under § 422.116(b). Many commenters recommended that CMS add criteria to our current network adequacy standards. For example, commenters recommended that CMS add new provider and facility specialty types, including sub-specialty types, to our list of those which are evaluated for network adequacy standards under § 422.116(b). Some commenters suggested that CMS increase the frequency in which network adequacy formal reviews are conducted or align the triennial network adequacy review timelines with the application timeline. A commenter suggested that CMS integrate network adequacy into Star Ratings measures. A few commenters suggested that CMS consider how increased use of telehealth-provided services will impact network adequacy, and that CMS should consider expanding the telehealth credit in certain county types such as rural

counties. A few commenters recommended CMS establish policies to enhance information available in MA plan network directories. A commenter suggested that CMS consider changes and improvements to the network adequacy exceptions and criteria process. A commenter provided recommendations regarding how network adequacy standards should recognize and address the unique needs of enrollees in I-SNPs. A commenter recommended CMS develop network standards specific to the D-SNP population. Additional topics out of scope of this rule include requests to update timelines for release of the Reference and Sample Beneficiary Files, make MA organizations' network adequacy review data publicly available, and limit organization's ability to make changes to network providers throughout the contract year.

CMS received some comments regarding special requirements during emergency and disasters that are out of scope for this rule. A commenter asked CMS to provide guidance about online or point-of-sale processing of Part B out-of-network claims during a disaster or emergency. Another commenter expressed concerns that these requirements do not apply to Part D drugs.

A commenter suggested that we take a more holistic approach to past performance. The commenter suggested we review all contracts for past performance and not just applicants.

We received several out-of-scope comments related to the provision on applying all pharmacy price concessions to the negotiated price at the point of sale. A few commenters urged CMS to address pharmacy benefit managers' (PBMs') formularies, specifically the preference for brand medications over generics due to the rebates and with respect to the use of biosimilars as they launch. Many commenters asked that CMS address the "reasonable and relevant" contracting terms and conditions between MA organizations/plan sponsors and pharmacies. A few commenters expressed concern with vertical integration of PBMs and pharmacies. A few commenters were concerned about the costs of COVID-19 tests and treatments. Some commenters stated that CMS should not make the changes associated with this Pharmacy Price Concessions rule when it should instead be working to wind down or officially incorporate policies put in place during the COVID-19 PHE. Some commenters stated that the proposal failed to address the root cause of high drug prices and offered recommendations for regulating

the pharmaceutical industry. A few commenters stated that PBMs should not set drug prices and encouraged CMS to make sweeping reforms including a patient bill of rights and a pharmacy bill of rights. A few commenters stated that PBMs cannot engage in sub-capitation arrangements that require pharmacies to bear risk. Some commenters requested CMS re-evaluate its policy on U.S. Food and Drug Administration (FDA)-approved anti-obesity medications. Other commenters recommended that CMS do more to improve access to the Part D Low-Income Subsidy (LIS) program, noting the program's importance to improving health equity and the nearly three million beneficiaries who are eligible for the program but not enrolled. This commenter also requested that CMS track and report on the number of complaints received regarding Part D plans charging individuals enrolled in the full LIS program the higher plan copayment rather than the established LIS copayment.

Unless otherwise noted, cites to regulations are to title 42 of the CFR.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

A. Improving Experiences for Dually Eligible Individuals

1. Overview and Background

Over 11 million people are concurrently enrolled in both Medicare and Medicaid. Beneficiaries who are dually eligible for both Medicare and Medicaid can face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in: (1) Missed opportunities to provide appropriate, high-quality care and improve health outcomes; and (2) undesirable outcomes, such as avoidable hospitalizations and poor beneficiary experiences. Advancing policies and programs that integrate care for dually eligible individuals is one way in which we seek to address such fragmentation.⁴

"Integrated care" refers to delivery system and financing approaches that—

⁴ For example, see chapter 1 of Medicaid and CHIP Payment and Access Commission, *Report to Congress on Medicaid and CHIP*, June 2021, and chapter 12 of Medicare Payment Advisory Committee, *June 2019 Report to the Congress: Medicare and the Health Care Delivery System*.

- Maximize person-centered⁵ coordination of Medicare and Medicaid services, across primary, acute, long-term, behavioral, and social domains;
- Mitigate cost-shifting incentives, including total-cost-of-care accountability across Medicare and Medicaid; and
- Create seamless experiences for beneficiaries.

We described at 87 FR 1849 through 1850 of the proposed rule a range of approaches to integrating Medicare and Medicaid benefits or financing for dually eligible individuals, including through demonstrations and existing programs. The most prevalent forms of integrated care use capitated financing, including capitation of health plans to cover the full range of Medicare and Medicaid services. The number of dually eligible individuals in integrated care or financing models or both has increased over time, now exceeding 1 million beneficiaries, but it remains the exception rather than the rule in most States.⁶

An increasing number of dually eligible individuals are enrolled in managed care plans. The broader trend toward managed care presents opportunities for integrated care. It also presents risks for further fragmentation and complexity. In fact, while enrollment in integrated care has increased, it is also becoming increasingly likely that dually eligible individuals are in one sponsor's Medicaid managed care organization (MCO) and a competitor's D-SNP. The result: Duplicative health risk assessments (HRAs); multiple ID cards, handbooks, and provider and pharmacy directories; strong incentives for cost-shifting where possible; multiple care coordinators; more complex billing processes for providers; and similar other fragmented care, burdens, or increased costs.

Section 2602 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) (Affordable Care Act) established the Medicare-Medicaid Coordination Office (MMCO) within CMS to better align and integrate benefits for dually eligible individuals.

⁵ "Person-centered care" typically refers to focusing care on the needs of the individual and ensuring that a person's individual preferences, needs, and values guide care decisions. This is in contrast to approaches to care in which the specific diagnosis or illness drives care and treatment decisions. See the National Center on Advancing Person-Centered Practices and Systems for additional information: <https://ncapps.acl.gov/home.html>.

⁶ CMS Medicare-Medicaid Coordination Office FY 2020 Report to Congress, available at: <https://www.cms.gov/files/document/reporttocongressmmco.pdf>.

Section 50311(b)(2) of the Bipartisan Budget Act (BBA) of 2018 amended that provision to also charge MMCO with—

- Developing regulations and guidance related to the integration or alignment of policy and oversight under Medicare and Medicaid regarding D-SNPs; and

- Serving as the single point of contact for States on D-SNP issues.

At 87 FR 1850 of the proposed rule, we described recent MA/Part D rulemaking to enhance D-SNPs. Despite this recent work, additional actions are needed to maximize the potential of D-SNPs to deliver person-centered integrated care—and ultimately better health outcomes and independence in the community—for dually eligible older adults, people with disabilities, and people with end stage renal disease. We are working to improve and increase options for more integrated care in a variety of ways, including through D-SNPs.

a. Dual Eligible Special Needs Plans

Special needs plans (SNPs) are MA plans created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Under section 1859(b)(6) of the Act, SNPs restrict enrollment to certain populations. The most common type of SNP is a dual eligible special needs plan, or D-SNP, in which enrollment is limited to individuals entitled to medical assistance under a State plan under title XIX of the Act.

D-SNPs are intended to integrate or coordinate care⁷ for dually eligible individuals more effectively than standard MA plans or the original Medicare fee-for-service (FFS) program by focusing enrollment and care management on this population. As of January 2022, approximately 4.0 million dually eligible individuals (more than 1 of every 4 dually eligible individuals) were enrolled in 729 D-SNPs.⁸

⁷ “Care coordination” typically refers to the managing of care and sharing of information among medical and non-medical providers and supports across the spectrum primary, acute, behavioral health, long-term services and supports. See, for example, <https://www.ahrq.gov/ncepcr/care/coordination.html>, and Barth, S., Silow-Carroll, S., Reagan, Russell, M., Simmons, T. (2019) Care Coordination in Integrated Care Programs Serving Dually Eligible Beneficiaries—Health Plan Standards, Challenges and Evolving Approaches. Report to the Medicaid and CHIP Payment and Access Commission. <https://www.macpac.gov/wp-content/uploads/2019/03/Care-Coordination-in-Integrated-Care-Programs-Serving-Dually-Eligible-Beneficiaries.pdf>.

⁸ Centers for Medicare & Medicaid Services. *SNP Comprehensive Report* (January 2021). Retrieved

Federal statute and implementing regulations have established several requirements for D-SNPs in addition to those that apply to all MA plans to promote coordination of care, including HRA requirements as described in section 1859(f)(5)(A)(ii)(I) of the Act and at 42 CFR 422.101(f)(1)(i), evidence-based models of care (MOCs) as described in section 1859(f)(5)(A)(i) of the Act and at 42 CFR 422.101(f), and contracts with State Medicaid agencies as described in section 1859(f)(3)(D) of the Act and at 42 CFR 422.107. The State Medicaid agency contracting requirement allows States to require greater integration of Medicare and Medicaid benefits from the D-SNPs in their markets.

Most recently, section 50311(b) of the BBA of 2018 amended section 1859 of the Act to add new requirements for D-SNPs, beginning in 2021, including minimum integration standards, coordination of the delivery of Medicare and Medicaid benefits, and unified appeals and grievance procedures for integrated D-SNPs, the last of which we implemented through regulation to apply to certain D-SNPs with exclusively aligned enrollment, termed “applicable integrated plans.” These requirements, along with clarifications to existing regulations, were codified in 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” final rule (84 FR 15696 through 15744) (hereinafter referred to as the April 2019 final rule).⁹

For a more comprehensive review of D-SNPs and legislative history, see the proposed rule titled “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” (85 FR 9018 through 9021), which appeared in the **Federal Register** on February 18, 2020.¹⁰

b. Medicare-Medicaid Plans

To test additional models of integrated care, we established the

from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDENrolData/Special-Needs-Plan-SNP-Data.html>.

⁹ See <https://www.govinfo.gov/content/pkg/FR-2019-04-16/pdf/2019-06822.pdf>.

¹⁰ See <https://www.govinfo.gov/content/pkg/FR-2020-02-18/pdf/2020-02085.pdf>.

Medicare-Medicaid Financial Alignment Initiative (FAI) in July 2011 with the goal of improving outcomes and experiences for full-benefit dually eligible individuals while reducing costs for both States and the Federal Government. This State-Federal partnership is tested using authority under 1115A of the Act (as added by section 3021 of the Affordable Care Act) and further described below. Although the FAI includes two models, the model with the largest number of States participating is a capitated model through which CMS, the State, and health plans (called Medicare-Medicaid Plans or MMPs) enter into three-way contracts to coordinate the full array of Medicare and Medicaid services for members. Our proposed rule at 87 FR 1851 through 1854 summarized the key elements offered by MMPs under the capitated model demonstrations.

As discussed in the proposed rule at 87 FR 1851, CMS and States partnered with MMPs to create a seamless experience for beneficiaries, but MMPs operate as both MA organizations offering Medicare Advantage Prescription Drug (MA-PD) plans and Medicaid managed care organizations. As such, unless waived by CMS, MMPs are required to comply with Medicaid managed care requirements under 42 CFR part 438, with MA (also known as Part C) requirements in title XVIII of the Act as well as 42 CFR part 422 and, with regard to the Medicare prescription drug benefit, Part D requirements in title XVIII of the Act and 42 CFR part 423. Section 1115A of the Act (as added by section 3021 of the Affordable Care Act) authorizes waiver of certain Medicare provisions and CMS used that authority to waive several Medicare requirements for the FAI. For States participating in the capitated model, CMS typically uses authority under section 1115(a), 1915(b), 1915(c), or 1932(a) of the Act to waive or exempt the State from certain provisions of title XIX of the Act or establish the authority to deliver Medicaid services through managed care.

As of January 2022, there are 39 MMPs in nine States serving approximately 424,000 members.¹¹

As summarized at 87 FR 1851 through 1854 in our proposed rule, while an independent evaluation of the FAI is still underway, we have already gleaned several lessons regarding integrated,

¹¹ MMP enrollment as of January 2022. See CMS *Monthly Enrollment by Contract Report* (January, 2022). Retrieved from <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenrolldata/monthly-enrollment-contract-2022-01>.

managed care from the capitated financial alignment model:

- Enrollee participation in governance helps identify and address barriers to high-quality, coordinated care;
- Assessment processes are a vehicle for identifying and addressing unmet needs, particularly those related to social determinants of health;
- Medicare-Medicaid integration correlates with high levels of beneficiary satisfaction;
- Carving in Medicaid behavioral health benefits helps promote better coordination of behavioral health and physical health services;
- Integrated beneficiary communication materials can enhance the beneficiary experience;
- Effective joint oversight of integrated managed care products is possible;
- Integrated care and joint oversight provide a platform for quality improvement;
- There is potential for market distortions in areas with multiple options targeting the same population; and
- State investment is critical to successful implementation of integrated care either through MMPs or D-SNPs.

Since the outset of the FAI, our shared goal with State partners has been to develop models that promote greater Medicare-Medicaid integration that, if successful, could be implemented on a broader scale. We proposed to incorporate into the broader MA program many of the MMP practices that successfully improved experiences for dually eligible individuals.

2. Summary of D-SNP Proposals Related to MMP Characteristics

Many of the proposals in the proposed rule would incorporate certain MMP policies into the regulations governing D-SNPs or, in several cases, certain types of D-SNPs. We included a table (87 FR 1854) summarizing how our proposals relate to MMP policies. Section II.A.14 of this final rule includes an updated version of that table to reflect the policies adopted in this final rule.

Comment: Several commenters, including MACPAC, described the challenges dually eligible individuals and their providers and families experience navigating separate and fragmented Medicare and Medicaid delivery systems. A commenter noted suboptimal care coordination can compromise patient care and increase overall program spending. A commenter noted younger dually eligible individuals face health inequities

caused by institutional racism and other systematic disadvantages. A few commenters encouraged full integration and MACPAC cited recent Bipartisan Policy Center reports¹² urging full integration of Medicare and Medicaid services for all full-benefit dually eligible individuals. Another commenter emphasized that coverage of medical, behavioral health, and long-term services and supports should be aligned and integrated care should be grounded in the diversity of dually eligible enrollees, tailored to individuals' needs and preferences, prioritize care coordination, simplify eligibility and enrollment processes, minimize administrative burdens, and honor enrollee choice of plan and providers.

Response: We appreciate the comments and we agree that a fragmented delivery system raises major issues, as we discussed in the proposed rule (87 FR 1849 through 1850). We are committed to maximizing opportunities for integration through the proposals finalized in this rule and will continue to explore additional ways to better align the Medicare and Medicaid programs in the future. We acknowledge the comment about dually eligible individuals experiencing health inequities caused by institutional racism and other systematic disadvantages. Addressing such inequity is a major focus of CMS and other Federal agencies, based in part on Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021).

Comment: Numerous commenters supported the overall focus of the proposals to better integrate Medicare and Medicaid services, incrementally strengthen and improve integration for D-SNPs, advance health equity, and improve the beneficiary experience for older adults and people with disabilities. A few commenters indicated these proposals improve the potential for D-SNPs to provide person-centered care and support enrollees to remain independent and manage their health and daily activities. A few commenters indicated the proposals provide States with greater D-SNP coordination and oversight opportunities.

A few commenters believed the proposals would tighten and clarify requirements for D-SNPs. A commenter indicated the proposals would help

simplify D-SNP offerings, and another commenter noted support for the proposed rule's goal of strengthening consumer protections to ensure dually eligible individuals have access to accurate and accessible information about health plan choices and benefits. A few commenters believed the proposals would help engage enrollees in designing and participating in care. Another commenter indicated the proposals offer the potential for both administrative and clinical integration at the plan level.

A commenter encouraged CMS to couple implementation of the final rule with guardrails to mitigate against potential unintended consequences. Another commenter encouraged CMS to quickly adopt regulations that reflect stakeholder recommendations in light of the rapid growth of D-SNPs.

Several commenters expressed support for the package of D-SNP proposals as useful incremental steps toward furthering integrated care via D-SNPs. A commenter encouraged CMS to consider how steps taken now build towards a broader long-term vision for integrated care. Another commenter acknowledged that CMS did not want to be prescriptive but encouraged CMS to provide sufficient detail with regard to the array of D-SNP proposals when finalizing the rule given the recent growth in the D-SNP landscape.

Response: We appreciate the widespread support for our proposals. As discussed in the proposed rule (87 FR 1850), these proposals build on two recent MA/Part D rulemakings and our experiences with MMP policies. We believe this final rule will further the potential of D-SNPs to deliver person-centered integrated care—and ultimately better health outcomes and independence in the community—for dually eligible older adults, people with disabilities, and people with end stage renal disease.

As we discuss later in this section under specific proposals, we will provide technical assistance, monitor implementation of the finalized provisions, and consider future rulemaking as needed to address any identified areas of concern. For example, information from CMS audits will help us monitor the extent to which MA organizations are meeting the enrollee advisory committee requirements at § 422.107(f), and we may consider more prescriptive requirements, as needed, based on implementation experience.

We acknowledge the request for additional detail related to some of the D-SNP proposals. As we discuss in response to comments on specific

¹² Bipartisan Policy Center, *Guaranteeing Integrated Care for Dual Eligible Individuals* (2021) and *A Pathway to Full Integration of Care for Medicare-Medicaid Beneficiaries* (2020).

proposals later in this section, we aim to strike a balance between providing MA organizations with flexibility in implementing various finalized requirements versus being more prescriptive. We explain our rationale further in responses to comments, including related to requirements for enrollee advisory committees at § 422.107(e), SDOH questions in SNP HRAs at § 422.101(f)(1)(i), and limited carve-outs of Medicaid behavioral health services and long-term services and supports (LTSS) at § 422.107(g) and (h).

Comment: A number of commenters commended CMS for applying lessons learned from MMPs to D-SNPs and providing a long-term strategy for D-SNPs as an integrated plan option. A few commenters stated that the MMP demonstrations created a gold standard for integrated care and have given beneficiaries avenues for providing input on plan operations through beneficiary advisory committees; enhanced the beneficiary experience through integrated communications materials; scaled up person-centered care planning and care coordination including effectively combining medical and behavioral health benefits; and delivered a platform for incentivizing innovation and investment to improve quality of care for dually eligible individuals. Several commenters noted the achievements of particular States and MMPs in the FAI and expressed appreciation for the CMS goal of establishing a more permanent mechanism to sustain integrated programs beyond the demonstrations.

MACPAC expressed support for CMS for proposals to promote integration by applying features of the MMPs operating under the FAI to D-SNPs. MedPAC encouraged CMS to extend some of the proposals that promote integration to HIDE SNPs too. A few commenters acknowledged the role of nonmedical benefits in providing care to complex populations and expressed appreciation for flexibilities in payment and benefit design.

Response: We thank the commenters for the support for the proposals that incorporate many of the early lessons learned from the MMP experience into the broader MA program. We believe doing so will improve experiences for dually eligible individuals.

Comment: A few commenters expressed support for the work of the CMS Medicare-Medicaid Coordination Office (MMCO) to improve care for dually eligible individuals, address needs around integration of care, focus on social determinants of health, and promote equity, while another

commenter noted appreciation for MMCO efforts to lower health care costs for beneficiaries, States, and Federal Government.

Response: We thank commenters for their support.

Comment: Several commenters noted that Federal support would be an important component to helping States implement the necessary changes and to facilitate further integration of D-SNPs. These commenters noted that State officials often struggle with competing priorities, limited Medicare knowledge, and limited staff capacity to develop and implement integrated care initiatives for dually eligible individuals relative to their other responsibilities. A few commenters acknowledged the wide range of technical assistance that CMS has provided to date to help navigate the complexities of the policy environment and expand State ability to integrate and encouraged CMS to continue to bolster these resources for States should the proposals in this rule become final. Other commenters recommended that States would need additional Federal funding to enhance State capacity and to further incentivize integration.

Response: We thank the commenters for this feedback and agree that States are an important partner in implementing many of the D-SNP proposals in this rule. We are committed to continue working closely with States to support their integration efforts and intend to utilize and build from the technical assistance resources we already have in place, including the Integrated Care Resource Center (see <https://integratedcareresourcecenter.com>).

Comment: A few commenters noted the importance of robust oversight to ensure that policies do not lead to higher spending without actually benefiting people with Medicare and supported the increased oversight of D-SNPs contained within the proposed rule. A commenter expressed concern as to whether there was sufficient demographic data, especially on disability and on social, racial, and economic status, or data on MA supplemental benefit spending, access, and eligibility for such oversight. Another commenter expressed concern that the Federal Government lacks the capacity to conduct adequate oversight without sharing responsibility with States.

Response: We thank the commenters for these comments. We agree that oversight is an important component of providing person-centered, high quality care and will continue to work with stakeholders to ensure integrated

programs do just that. We will consider opportunities for improving the types and quality of available data necessary to support such oversight in the future. We address issues related to expenditure data on MA supplemental benefits as part of MLR reporting in section II.G of this final rule.

Comment: A few commenters supported the focus on the D-SNP model for deepening integration, pointing out the widespread availability and growing enrollment in D-SNPs and the ongoing investments by plans and States in supporting infrastructure. The commenter indicated the provisions included in the proposed rule were a logical alternative to other more radical integration proposals. A commenter specifically appreciated CMS's focus on the experience of D-SNP enrollees given the large number of enrollees in D-SNPs in certain States and the health care needs of these individuals.

Response: We thank the commenters for this feedback. As we discussed in the proposed rule at 87 FR 1888, the integrated care landscape has changed substantially over the last 10 years. Key changes include Congress making D-SNPs permanent, establishing new minimum integration standards, and directing the establishment of unified appeals and grievance procedures. Changes in MA policy have also created a level of benefit flexibility that did not previously exist outside of the capitated model demonstrations, with MA plans increasingly offering supplemental benefits that address social determinants of health and LTSS. These changes make D-SNPs an attractive vehicle for integration for dually eligible individuals.

Comment: A few commenters stated that the proposals do not go far enough to further integrated care. A commenter stated that the proposed changes do not address the main factors that determine long-term beneficiary satisfaction with integrated care, such as access to providers, easily understood marketing or other materials to help inform beneficiaries of their choices, and access to supplemental benefits. Another commenter stated that while the proposed policy changes promote integration in existing products, they do not necessarily increase the availability of integrated models or enrollment in integrated plans.

Response: We appreciate the feedback from these commenters. We believe several of our proposals address factors that determine beneficiary satisfaction—see, for example, our proposal at § 422.107(e) related to using specified integrated materials—but we appreciate that there remain many other

opportunities to improve experiences for dually eligible beneficiaries. We will consider whether there are additional opportunities to address these issues in the future.

Comment: A few commenters supported the overall effort to promote care integration for dually eligible individuals but expressed concern about the potential for increased administrative burden for State Medicaid agencies, disruptions in care for members, and other operational challenges. A commenter expressed concern that some of the proposals would significantly curtail States' ability to customize programs that meet the specific needs of their State programs and constituents. Another commenter noted that the proposals are likely to be most impactful for States that are relatively far along in their integrated care strategies and recommended CMS continue its efforts through the Medicare-Medicaid Coordination Office and the Integrated Care Resource Center to promote integration for States newer to this policy area. A commenter was concerned that the operational aspects of some of the provisions would disadvantage new entrants to the MA market, particularly those that target underserved populations. Another commenter emphasized that CMS has an opportunity to ensure States do not use the proposed changes to hinder new market entrants who may offer more and better service to beneficiaries.

Response: We thank the commenters for these comments and acknowledge the concerns they raise. It is important to note that none of the provisions in the proposed rule would impose new requirements on States; rather, States may choose whether or not to take advantage of any of the proposals finalized here. We are committed to continue working closely with States to support their integration efforts, regardless of how far along they are, and intend to utilize and build from the technical assistance resources we already have in place, including the Integrated Care Resource Center. While some proposals would impose new requirements of D-SNPs, we think on balance, the advantages of increasing the overall level of integration outweigh the potential downsides.

Comment: A commenter recommended allowing MA organizations to offer D-SNPs without holding a Medicaid contract either directly or between the parent company and the State Medicaid agency.

Response: We note that while State contracting policies may have prevented sponsors from offering D-SNPs in some

markets, section 1859(f)(3)(D) of the Act requires a D-SNP to have a contract with the applicable State Medicaid agency. States are authorized to determine which D-SNPs they will contract with, as described in section 164 of the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110-274), which amended section 1859(f) of the Act to add the requirement for D-SNPs to have a contract with the State.

Comment: A commenter recommended that CMS further define terms such as care coordination, person-centered care, and integrated care. This commenter believes further definition of these terms is important to gain trust among dually eligible individuals, especially those between the ages of 21 and 65 years old.

Response: An important theme of our proposals is to improve experiences for dually eligible beneficiaries who are enrolled in D-SNPs. As part of that, we aim to streamline and simplify operations, including the terminology we use. We appreciate these suggestions and will consider them for the future. We believe that the terms care coordination, person-centered care, and integrated care are sufficiently clear in this final rule that additional regulatory definitions are not necessary.

3. Enrollee Participation in Plan Governance (§ 422.107)

We believe managed care plans derive significant value from engaging enrollees in defining, designing, participating in, and assessing their care systems.¹³ By soliciting and responding to enrollee input, plans can better ensure that policies and procedures are responsive to the needs, preferences, and values of enrollees and their families and caregivers. One of the ways managed care plans can engage dually eligible individuals is by including enrollees in plan governance, such as establishing enrollee advisory committees and placing enrollees on governing boards. Engaging enrollees in these ways seeks to keep enrollee and caregiver voices front and center in plan operations and can help plans achieve high-quality, comprehensive, and coordinated care.¹⁴ As described at 87

¹³ Centers for Medicare & Medicaid Services. (n.d.). *Person & Family Engagement Strategy: Sharing with Our Partners*. Retrieved from <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Person-and-Family-Engagement-Strategy-Summary.pdf>.

¹⁴ Resources for Integrated Care and Community Catalyst, "Listening to the Voices of Dually Eligible Beneficiaries: Successful Member Advisory Councils", 2019. Retrieved from: https://www.resourcesforintegratedcare.com/Member_

FR 1855 through 1856 of the proposed rule, Federal regulations for other programs, such as the Programs of All-Inclusive Care for the Elderly (PACE) and Medicaid managed care plans that cover LTSS include requirements for stakeholder engagement and committees, including input from beneficiaries.

As required by the three-way contracts between CMS, States, and MMPs, all MMPs established enrollee advisory committees. As described at 87 FR 1854 through 1855 of the proposed rule, these enrollee advisory committees provide a mechanism for MMPs to solicit feedback directly from enrollees, assisting MMPs in identifying and resolving emerging issues, and ensuring they meet the needs of dually eligible individuals.

We believe that the establishment and maintenance of an enrollee advisory committee is a valuable beneficiary protection to ensure that enrollee feedback is heard by D-SNPs and to help identify and address barriers to high-quality, coordinated care for dually eligible individuals. Therefore, we proposed at § 422.107(f) that any MA organization offering one or more D-SNPs in a State must establish and maintain one or more enrollee advisory committees to solicit direct input on enrollee experiences. We also proposed at § 422.107(f) that the committee include a reasonably representative sample of individuals enrolled in the D-SNP(s) and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.

We proposed to establish the new paragraph at § 422.107(f) under our authority at section 1856(b)(1) of the Act to establish in regulation other standards not otherwise specified in statute that are both consistent with Part C statutory requirements and necessary to carry out the MA program and our authority at section 1857(e) of the Act to adopt other contract terms and conditions not inconsistent with Part C as the Secretary may find necessary and appropriate. We believe that a requirement for an MA organization offering one or more D-SNPs to establish one or more enrollee advisory committees is not inconsistent with either the Part C statute or administration of the MA program. While current law does not impose such a requirement, our experience with existing requirements for MMPs and PACE demonstrates that the use of

advisory committees improves plans' ability to meet their enrollees' needs by providing plans with a deeper understanding of the communities the plans serve and the challenges and barriers their enrollees face, as well as serving as a convenient mechanism to obtain enrollee input on plan policy and operational matters. Our experience also suggests that advisory committees complement other mechanisms for enrollee feedback—such as surveys, focus groups, and complaints—with most advisory committees featuring longer-term participation by enrollees who can share their lived experiences while also learning how to best advocate over time for broader improvements for all enrollees. We believe the performance of all D–SNPs would benefit from this new requirement and that this requirement is therefore necessary and appropriate.

While we described the proposed advisory committee at § 422.107(f) as an enrollee advisory committee consistent with the use of the term “enrollee” in MA regulations, we noted that “enrollee” under the proposed § 422.107(f) requirement for D–SNPs has the same meaning as “member” under the § 438.110 requirement for Medicaid plans to have a member advisory committee when LTSS are covered under a Medicaid managed care plan's contract.

First, we proposed that the MA organization offering one or more D–SNP(s) in a State must have one or more enrollee advisory committees that serve the D–SNP(s) offered by the MA organization in that State. As proposed, an MA organization would be able to choose between establishing one single enrollee advisory committee for one or multiple D–SNPs in that State or by establishing more than one committee in that State to meet proposed § 422.107(f).

Second, we proposed that the advisory committee must have a reasonably representative sample of enrollees of the population enrolled in the dual eligible special needs plan or plans, or other individuals representing those enrollees. At 87 FR 1856 of the proposed rule, we explained that, by using the phrase “representative sample” in the regulation text, we intended that D–SNPs incorporate multiple characteristics of the total enrollee population of the D–SNP(s) served by the enrollee committee, including but not limited to geography and service area, and demographic characteristics. For MA organizations that offer separate D–SNPs serving full-benefit dually eligible individuals and partial-benefit dually eligible

individuals in the same State, we explained that our proposal would provide flexibility for MA organizations to solicit enrollee input through one or more committees where separate committees might represent specific eligibility groups.

Finally, we proposed that the advisory committee must, at a minimum, solicit input on ways to improve access to covered services, coordination of services, and health equity among underserved populations, which is a CMS priority aligned with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021). Our proposal did not specify other responsibilities or obligations for the committee, but we encouraged D–SNPs to solicit input from enrollees on other topics would be part of the committee's responsibilities.

At 87 FR 1857 of the proposed rule, we described how our proposal would relate to the requirement at § 438.110 for Medicaid managed care plans that cover long-term services and supports and how some organizations may satisfy our proposed requirement at § 438.110 with the same advisory committee.

Citing our belief that D–SNPs should work with enrollees and their representatives to establish the most effective and efficient process for enrollee engagement, we did not propose Federal requirements as to the specific frequency, location, format, participant recruiting and training methods, or other parameters for these committees beyond certain minimum requirements. However, we solicited comments on whether we should include more prescriptive requirements on how D–SNPs select enrollee advisory committee participants, training processes on creating and running a successful committee, the committee responsibilities, additional committee topics, and whether we should limit the enrollee advisory committee proposed at § 422.107(f) to a subset of D–SNPs. We also solicited comments on whether our approach to allow MA organizations to meet the requirements in proposed §§ 422.107(f) and 438.110 through one enrollee advisory committee could dilute the § 438.110 requirement by detracting from the focus on LTSS enrollees. We noted that, if our proposal were finalized, we would update the CMS audit protocols for D–SNPs to request documentation of enrollee advisory committee meetings.

Comment: Numerous commenters expressed strong support for our proposal to require that an MA organization offering one or more D–

SNP(s) in a State have one or more enrollee advisory committees that serve the D–SNP(s) offered by the MA organization in that State. Many of these commenters noted direct input from enrollees helps to improve plan quality, operations, and care coordination to better serve its enrollees and can help advance health equity among dually eligible individuals. A number of commenters stated that their support for our proposal was informed by their experience with enrollee advisory committees implemented by MMPs, Medicaid managed care plans, and D–SNPs. Numerous commenters suggested that engagement of enrollees representing the diversity of the dually eligible population in a State is essential to providing meaningful person-centered care and effectively coordinating and integrating care across Medicare and Medicaid services in a manner that reflects individual's needs and preferences. A commenter shared their experience implementing D–SNP enrollee advisory committees, noting these committees are a chance to build trust with enrollees, improve plan processes, address health equity barriers, and empower enrollees as active contributors and co-designers of programs and policies. Some commenters appreciated that our proposal builds on existing Federal regulations that require enrollee advisory processes among Medicaid LTSS managed care plans and PACE and similar requirements for MMPs, which would create fewer differences for State staff managing multiple integration efforts and preserve flexibility in the design of these committees. MACPAC expressed its support for the proposal and welcomes CMS modeling the structure after the MMP committees to include beneficiaries, families, and other caregivers. Some commenters viewed the proposed committee requirement as an opportunity for States to cross-pollinate committee input and activities across D–SNPs that operate in their State. Other commenters appreciated the proposed requirement for the committee to encompass a representative sample of D–SNP enrollees within a State and noted that, because of this requirement, plans constructing these committees would take efforts to recruit participants from the diverse backgrounds of their enrollees.

Response: We appreciate the widespread support we received for our proposal. These comments bolster our belief that the establishment and maintenance of an enrollee advisory

committee is a valuable beneficiary protection to ensure that enrollee feedback is heard by managed care plans and to help identify and address barriers to high-quality, coordinated care for dually eligible individuals. We agree that the requirement that D-SNPs include a reasonably representative sample of members will incentivize them to consider diversity when recruiting for their enrollee advisory committees.

Comment: A commenter applauded CMS's effort to create more mechanisms for enrollee input in plan operations and consult enrollees on issues related to health equity. But, this commenter believed requiring each SNP to establish and maintain a separate advisory committee could be redundant and duplicative with existing efforts. The commenter offered the example that, in many regions, coalitions or community groups already exist that can provide input on enrollee needs and stated that in some cases the existing coalitions or community groups are already prepared to inform plans about the challenges that impact their enrollees. This commenter recommended that CMS require all SNPs to have a mechanism to obtain diverse and representative enrollee input on plan policy and operations rather than requiring all D-SNPs to use the specific mechanism of enrollee advisory committees. Further, the commenter suggested that where community groups do not already exist, plans could then establish their own enrollee advisory committees.

Response: We thank the commenter for this perspective. We would like to take the opportunity to clarify that our proposal would not apply to all SNPs but MA organizations with one or more D-SNPs in a State. While C-SNPs and I-SNPs could benefit from enrollee advisory committees and the type of engagement described by the commenter, and we encourage them to do so, we are not requiring it at this time. Our experience with such committees has been concentrated on plans exclusively or mainly enrolling dually eligible individuals, so we have chosen to apply this requirement to D-SNPs. Based on the D-SNP experience with such committees, we may consider future rulemaking to consider such a requirement for C-SNPs and I-SNPs.

We recognize that coalitions and groups serving local communities can offer helpful perspectives to MA organizations and D-SNPs and our proposal does not preclude MA organizations and D-SNPs from engaging with other parties to gather feedback. But, our experience with existing requirements for MMPs and

PACE demonstrates that the use of advisory committees improves plans' ability to meet their enrollees' needs by providing plans with a deeper understanding of the communities the plans serve and the challenges and barriers their enrollees face, as well as serving as a convenient mechanism to obtain enrollee input on plan policy and operational matters. Our experience also suggests that advisory committees complement other mechanisms for enrollee feedback—such as surveys, focus groups, and complaints—with most advisory committees featuring longer-term participation by enrollees who can share their lived experiences while also learning how to best advocate over time for broader improvements for all enrollees. We believe the performance of all D-SNPs would benefit from this new requirement, which is consistent with the existing requirement at § 438.110 for Medicaid plans to establish member advisory committees when those Medicaid managed care plans cover LTSS.

Comment: Several commenters requested technical assistance for MA organizations and D-SNPs to help establish the proposed enrollee advisory committees. A few of these commenters stated that establishing robust enrollee advisory committees can be challenging. A commenter emphasized that the existence of an advisory committee is not itself a demonstration of enrollee input, but that these committees must be intentionally designed, integrated into overall program structures to be considered true enrollee engagement, and have decision-making authority. Another commenter requested that CMS provide technical assistance and guidance documents and/or training to plans, States, and consumer advocates on effective and standardized practices for these committees. A commenter suggested CMS leverage two existing resources on the topic of consumer engagement in enrollee advisory committees as technical assistance for plans regarding how to build a meaningful advisory committee.¹⁵

Response: We welcome this feedback and agree that technical assistance to support the design and implementation of enrollee advisory committees is

¹⁵ Community Catalyst, "Meaningful Consumer Engagement: A Toolkit for Plans, Provider Groups and Communities," March 2014. Retrieved from <http://www.advancingstates.org/hcbs/article/meaningful-consumer-engagement-toolkit-plans-provider-groups-and-communities>; and Community Catalyst, "Supporting Meaningful Engagement through Community Advisory Councils," August 2020. Retrieved from: <https://www.healthinnovation.org/resources/publications/supporting-meaningful-engagement-through-community-advisory-councils>.

important. CMS's contractor Resources for Integrated Care partnered with Community Catalyst, a non-profit advocacy organization, and offered a series of webinars and other written technical assistance to help enhance MMPs' operationalization of these committees in 2019.¹⁶ In the proposed rule at 87 FR 1855, we outlined some of the best practices leading to successful enrollee advisory committees. We also noted in the proposed rule (87 FR 1888) that we intend to continue—focusing now on D-SNPs—many of the technical assistance and quality improvement activities that we initially developed for MMPs, including—

- Learning communities;
- Direct work with beneficiary advocates and other stakeholders;
- Targeted efforts to improve outcomes and reduce disparities; and
- Capacity building on topics like person centeredness, disability-competent care, dementia, and behavioral health.

We expect these topics to also include a focus on enrollee advisory committees.

Comment: We received numerous comments in favor of more prescriptive requirements and numerous comments in favor of a less prescriptive approach consistent with our proposal.

Among those in favor of more prescriptive requirements, numerous commenters requested that we provide clarification or further requirements on selection processes for enrollee advisory committees and what we consider to be a reasonably representative sample of the population enrolled in the D-SNP. Several commenters suggested that a reasonably representative sample should include enrollee characteristics such as race, ethnicity, language, disability status, sexual orientation and gender identity, receipt of LTSS or behavioral health services, geography and service area. A few commenters suggested that we establish percentage thresholds, such as a majority of committee participants are dually eligible individuals or a majority of participants are non-white or non-English speaking. A commenter recommended that enrollee advisory committees be composed of a majority of participants based on the proportional representation of enrollees with lived experiences and demographic identities, including disability, while other commenters requested we provide specific

¹⁶ Resources for Integrated Care and Community Catalyst, "Member Engagement in Plan Governance Webinar Series", 2019. Retrieved from: <https://www.resourcesforintegratedcare.com/article/member-engagement/>.

parameters on how D-SNPs might meet the definition of “representative sample”. Some commenters requested that we specify a minimum number of participants for the enrollee advisory committees. A commenter recommended that CMS establish a threshold for volume of D-SNP enrollees that a single committee could represent, suggesting one committee per D-SNP or per a certain number of D-SNP enrollees across plans (for example, 20,000). This commenter also recommended that D-SNPs be required to notify eligible enrollees of the opportunity to participate. Another commenter suggested we relax the representative sample requirement, as it is difficult for D-SNPs to engage all populations enrolled to include representation on advisory committees.

Another commenter requested that CMS direct MA organizations to work with stakeholders, such as patient advocacy groups, to ensure enrollee advisory committees include a diverse and comprehensive patient population. MACPAC expressed that these committees should be developed by plans in partnership with advocates and should be representative of the people served by integrated programs. A few commenters noted that CMS should require D-SNPs to allow caregivers, personal care attendants, interpreters, and others to attend to help enrollees participate.

In making its case for more prescriptive requirements, a commenter remarked that an analysis of MMP advisory committees indicates that, despite requirements in most States that committee membership reflects the diversity of the member body, the lack of guidance on what diversity means or how to properly recruit leads to underrepresentation of minority enrollees in committees. According to the commenter, not defining “reasonable sample” of individuals enrolled in D-SNPs increases the risk that the committee does not adequately represent the D-SNP enrollees.

Response: We appreciate the commenters’ suggestions for additional specificity in requirements for establishing enrollee advisory committees for MA organizations with one or more D-SNPs in a State. Given the variation in State Medicaid program, D-SNPs, and dually eligible populations across States and localities and the existence of enrollee advisory committees established under § 438.110, we continue to believe that D-SNPs should work with enrollees and their representatives to establish the most effective and efficient process for enrollee engagement.

We appreciate comments regarding the need for more prescriptive requirements with respect to enrollee advisory committee diversity, and the need to more specifically define a reasonable sample of D-SNP enrollment such that committee representation is an accurate reflection of overall enrollment. We recognize that a key finding from the 2019 report “The Role of Consumer Advisory Councils in the Financial Alignment Initiative”¹⁷ was the need for improved diversity of enrollee advisory committee participation. The first annual report for the Massachusetts Financial Alignment Initiative demonstration found that attracting and retaining diverse stakeholder participation in the Implementation Council was a challenge.¹⁸ The second annual report indicated the Implementation Council was able to recruit additional members, and one Implementation Council member noted that “the resulting diversity was both exciting and challenging”.¹⁹ While we are choosing to be nonprescriptive in how a reasonable sample is defined for the purposes of our new requirement, we may consider more prescriptive requirements based on information regarding how MA organizations implement committees and comply with the requirement that the D-SNP enrollee committees be reasonably representative of the enrolled population. Future technical assistance will include promising practices for how plans can build a diverse committee membership.

Comment: We received some comments from organizations requesting that we specify how often the enrollee advisory committees must meet. A few of these commenters encouraged CMS to establish minimum frequency requirements but did not specify a meeting interval. Several commenters recommended that we require enrollee advisory committees to meet at least twice per year, and a commenter suggested quarterly convenings. A few of these commenters expressed concern

¹⁷ Center for Consumer Engagement in Health Innovation, “An Exploration of Consumer Advisory Councils within Medicare-Medicaid Plans Participating in the Financial Alignment Initiative”, 2019, Retrieved from: <https://www.healthinnovation.org/resources/publications/an-exploration-of-consumer-advisory-councils-within-medicare-medicaid-plans>.

¹⁸ RTI, “Financial Alignment Initiative Annual Report: One Care: MassHealth Plus Medicare, First Annual Report,” September 2016 (updated July 2017). Retrieved from: <https://innovation.cms.gov/files/reports/fai-ma-firstevalrpt.pdf>.

¹⁹ RTI, “Financial Alignment Initiative: Massachusetts One Care Second Annual Report,” April 2019. Retrieved from <https://innovation.cms.gov/files/reports/fai-ma-secondevalrpt.pdf>.

that, without a minimum required frequency, plans would opt for annual meetings, which the commenters indicated would have limited value.

A few commenters encouraged CMS to set training requirements for MA organizations and D-SNPs as they establish these committees. A commenter emphasized that CMS require D-SNPs to establish a process to train D-SNP staff on collecting and incorporating advisory committee feedback into plan operations and informing participants how enrollee feedback was used. We also received a comment that States should be given the authority to specify and require training components as part of their contracting with plans.

Some commenters encouraged CMS to provide more specifics related to training for enrollee advisory committee participants. A few of these commenters recommended requirements to ensure MA organizations educate enrollee advisory committee participants about the responsibilities of these committees and ways to meaningfully engage in them, including providing an understanding of D-SNP program design and organizational structure. A commenter suggested that CMS include a requirement that the enrollee advisory committee receives training on key health and health care disparity concerns that affect the population served by the D-SNP and a robust module be provided on disability inclusion in health care, emphasizing intersectional identities. This commenter also suggested that D-SNPs provide the committee basic information about the right to request reasonable accommodations and policy modifications, an overview of the D-SNPs’ transparency and accountability mechanisms, and local and State agencies and commissions with overlapping responsibilities and interests. A few of the commenters suggested that CMS create standards for training processes but did not provide further details.

A few commenters suggested that CMS require enrollee advisory committees to incorporate other parameters. A commenter recommended that enrollees, not State authorities, should lead the committee process. Another commenter stated that CMS should consider other required feedback mechanisms for enrollee input beyond the proposed committee structure, which—in their view—could have a limited number of participants or may not include those who have voiced concerns about the plan. Another commenter suggested that CMS require MA organizations to implement best

practices to ensure enrollee advisory committee participant retention and equity.

A few commenters urged CMS to issue additional sub-regulatory guidance concerning its expectations of MA organizations and D-SNPs in establishing these enrollee advisory committees.

Some commenters suggested specific topics the committee should be required to focus on beyond the health equity topic included in the proposed rule. A few commenters recommended that the committees focus on concerns and priorities of the enrollees themselves. A commenter supported additional topics be shared with committee participants for their input but did not name any particular topics. Another commenter did not specify any additional topics but suggested that the D-SNPs provide information to alert the enrollee advisory committee participants of the scope of potential topics, such as through a non-exhaustive list of topics other advisory committees have tackled. A few additional commenters identified specific topics for consideration, such as medication adherence, D-SNP collection of self-identified functional limitation data, and addition of self-identified functional limitation data fields to electronic patient records.

Response: We appreciate the commenters' suggestions for additional specificity in requirements for establishing enrollee advisory committees. We continue to believe that giving D-SNPs flexibility in structuring the enrollee advisory committees will permit D-SNPs—and the enrollees participating on the advisory committees—to tailor these committees based on the local needs of enrollees. As we stated in the proposed rule, our experience with MMPs establishing and maintaining enrollee advisory committees demonstrates that these plans have found the committees useful and carefully consider feedback provided by enrollees to inform plan decisions without prescriptive Federal requirements for the committees. We expect the evolution and adoption of telecommunications technology, including as experienced during the COVID-19 public health emergency, will mean that the most effective modalities for enrollee input may change over time. Therefore, we are not finalizing any additional Federal requirements as to the specific frequency, location, format, participant recruiting and training methods, or other parameters for these committees beyond certain minimum requirements; however, we may consider more prescriptive requirements in future

rulemaking based on D-SNP experience with enrollee advisory committees.

Comment: Numerous commenters emphasized the importance for transparency of these enrollee advisory committees and ensuring D-SNPs are held accountable for adhering to established requirements. Several commenters suggested that MA organizations create a feedback loop for advisory committees to see how their feedback is being considered and implemented and to share this information with enrollee advisory committee participants. A few commenters welcomed information on how CMS would evaluate the effectiveness of the enrollee advisory committees, including any expected measurable outcomes, to better understand how well the committees are achieving policy goals. Another commenter requested that CMS consider whether there may be additional Federal and State benefits to compiling the findings of these enrollee advisory committees since this information may help inform future policy duration for not only MA plans and SNPs but also for the original Medicare FFS program.

Response: We appreciate the request for monitoring of enrollee advisory committees against the requirements outlined at § 422.107(f) and the interest in information gathered through these convenings. We are not requiring that MA organizations publicly distribute enrollee advisory committee meeting agendas or materials since these committees will be addressing challenging topics related to plans and their enrollees, including potentially market-sensitive information related to potential changes in future plan benefits. We are concerned that requiring plans to make these agendas and materials publicly available could interfere with committee effectiveness. We noted in the proposed rule that, if our proposal were finalized, we would update the CMS audit protocols for D-SNPs to request documentation of enrollee advisory committee meetings. Information from CMS audits will help us monitor the extent to which MA organizations are meeting the enrollee advisory committee requirements at § 422.107(f), and we may consider more prescriptive requirements, as needed, based on implementation experience.

Comment: Numerous commenters supported the flexibility CMS offered in the structure of the proposed enrollee advisory committees and urged CMS to require a less prescriptive approach to the enrollee advisory committees, consistent with the proposed rule. Many of these commenters favored a minimum set of requirements to give D-

SNPs the flexibility to implement and manage enrollee advisory committees that best meet the needs of the local population and obtain meaningful input. Several commenters stated that the design flexibilities encourage the development of enrollee advisory committees to best reflect the different types of D-SNPs (that is, fully integrated dual eligible (FIDE) SNPs, highly integrated dual eligible (HIDE) SNPs, coordination-only D-SNPs²⁰) currently in place and the complexity of the dually eligible populations enrolled, which can differ from one locale to another. Some commenters noted that this flexibility would allow plans that currently offer D-SNPs in multiple States to build a foundation for an advisory committee that can be modeled and then refined to address specific needs of populations represented in each committee. Several commenters urged CMS not to be prescriptive with enrollee advisory committee requirements, especially for plans that already have such committees in place. These commenters emphasized that flexible enrollee advisory committee requirements would allow plans to build on experience and existing enrollee feedback approaches to best reflect the nuance and complexity of the D-SNP plans offered and populations served by those plans. Other commenters noted that this flexibility allows MA organizations already implementing such committees to continue existing operations without major changes, and the flexibility would allow plans to avoid overlapping or duplicative requirements from CMS and States as well as avoid beneficiary confusion. In supporting this perspective, a commenter explained that its experience offering FIDE SNPs, HIDE SNPs, and coordination-only D-SNPs across multiple States suggested wide variation in the specific benefits covered and populations served. Another commenter expressed concern that an overly prescriptive approach would reduce the flexibility for innovation and could stifle some of the positive strides already underway among managed care plans.

Response: We thank the commenters for their perspectives. Based on our experience with enrollee advisory committees operated by MMPs and PACE, we believe that D-SNPs should work with enrollees and their representatives to establish the most effective and efficient process for the enrollee advisory committees.

²⁰ Coordination-only D-SNPs are D-SNPs that neither meet the FIDE SNP nor HIDE SNP definitions at § 422.2.

Permitting flexibility for the enrollee advisory committees gives MA organizations—and enrollees themselves—more opportunity to establish committees that best meet the needs of enrollees.

State Medicaid agencies have broad authority to include more prescriptive parameters for enrollee advisory committees in their contracts with D-SNPs and could adopt some of the commenters' suggestions appropriate to their State through these State Medicaid agency contracts. As discussed in the proposed rule at 87 FR 1857, some State Medicaid agencies already do this in applying § 438.110.

Though we are choosing to be nonprescriptive on meeting frequency, location, format, enrollee recruitment, training, and other parameters, we encourage D-SNPs to adopt identified best practices²¹ to ensure advisory committee meetings are accessible to all enrollees, including but not limited to enrollees with disabilities, limited literacy (including limited digital literacy), and lack of meaningful access technology and broadband. We note that compliance with Federal law related to accessibility and effective communications for persons with disabilities is a requirement under other statutes such as Section 504 of the Rehabilitation Act. We also clarify that the enrollee advisory committees are not meant to preclude MA organizations and D-SNPs from gathering enrollee feedback through other means. As we discussed at 87 FR 1856, our experience with existing requirements for MMPs and PACE suggests that advisory committees complement other mechanisms for enrollee feedback—such as surveys, focus groups, and complaints—with most advisory committees featuring longer-term participation by enrollees who can share their lived experiences while also learning how to best advocate over time for broader improvements for all enrollees.

Comment: Some commenters requested that CMS clarify what documentation we will request as part of CMS audit protocols with respect to enrollee advisory committees. Other commenters suggested we audit enrollee advisory committees on the accuracy of committee representation of the D-SNP enrollee membership, meeting frequency and committee feedback to the D-SNP.

²¹ Resources for Integrated Care and Community Catalyst, "Engaging Members in Plan Governance", 2019. Retrieved from: <https://www.resourcesforintegratedcare.com/article/member-engagement/>.

Response: Information requested as part of the CMS audit protocols may be similar to that reported by MMPs as part of the reporting requirement (for example, dates of meetings held, number of enrollees invited, number of enrollees in attendance). As described in section IV.B.1.b., prior to implementation of new audit protocols (under OMB control number 0938-1395; CMS-10717), we will make them available to the public for review and comment under the standard PRA process, which includes the publication of 60- and 30-day **Federal Register** notices.

Comment: Several commenters questioned whether D-SNPs could delegate the facilitation or operation of enrollee advisory committees to first tier, downstream, or related entities.

Response: There is nothing in rule that precludes a D-SNP from delegating the facilitation or operation of an enrollee advisory committee to a first tier, downstream, or related entity. Notwithstanding any relationship(s) that the D-SNP has with first tier, downstream and related entities, the MA organization maintains the ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS, per § 422.504(i). All requirements with respect to the enrollee advisory committee are still applicable in the event a D-SNP delegates facilitation or operation of the enrollee advisory committee.

Comment: In addition to D-SNP enrollee advisory committees, some commenters recommended CMS require States to create centralized, cross-plan advisory councils, similar to the implementation councils currently in place for the Massachusetts and Rhode Island demonstrations under FAI. Commenters suggested these councils be comprised of majority of D-SNP enrollees and their caregivers, and expressed that such councils could provide additional transparency and insight into D-SNP policy and operations. A commenter suggested CMS provide Federal funding for these State-level advisory councils, and another commenter suggested an implementation council was best positioned to liaise and collaborate with other similar health services and LTSS/HCBS (home and community-based services) county and State-level committees including *Olmstead* committees, Money Follows the Person advisory committees, and Medicaid advisory committees.

Response: While we acknowledge the utility of a centralized advisory council, and commend the important work of the

Massachusetts One Care Implementation Council in particular, we defer to States to decide whether to implement broader advisory councils in order to solicit feedback more broadly on their Medicaid managed care programs and the D-SNPs that operate in the State.

Comment: A commenter opposed the approach of allowing MA organizations to meet the requirements proposed in §§ 422.107(f) and 438.110 through one enrollee advisory committee, acknowledging that, although there is overlap in the enrollees served, there are important distinctions in the populations and topics relevant for each stakeholder group.

Response: While we appreciate the commenter's perspective that there are important distinctions in the populations served, and that there may be distinct topics for each group, there may also be instances in which populations align and therefore separate enrollee advisory councils may be duplicative. We believe the best approach is to be nonprescriptive and allow one enrollee advisory committee to satisfy both requirements in the instances in which the minimum requirements for §§ 422.107(f) and 438.110 are both met. States may choose to apply distinct requirements via their State Medicaid agency contracts and their Medicaid managed care contracts, such that plans would need distinct enrollee advisory committees for different plan populations.

Comment: Many commenters suggested we delay the implementation of the enrollee advisory committee provision to contract year 2024 or suggested a phased-in approach that would require FIDE and HIDE SNPs to implement the enrollee advisory committees starting in contract year 2023, with less integrated D-SNPs implementing in contract year 2024. Commenters indicated the need for additional time to develop outreach strategies, coordinate with States, and develop reasonable representation recruitment strategies. A commenter noted D-SNPs will need more than a few months to ensure membership represents the different enrollee perspectives impacted by access, infrastructure, clinical needs, economic status, and prevalence of social supports.

Response: While we acknowledge commenters concerns around potential operational challenges to establishing and convening an enrollee advisory committee, we are nonprescriptive on meeting committee frequency, location, format, participant recruitment and training methods. For this reason, we do

not believe a contract year 2023 implementation timeframe is unreasonable. Given the implementation timing of this rule, D-SNPs will have approximately 6 months prior to the effective date of January 1, 2023, to develop an enrollee advisory committee, and we are nonprescriptive regarding when in calendar year 2023 the committee must meet, as well as the number of meetings and meeting frequency. Further, the regulation permits use of one committee per State, allowing for D-SNPs to start with a single committee and develop more nuanced committees over time. Additionally, while we have committed to providing technical assistance to D-SNPs in this area, a number of resources on establishing meaningful enrollee advisory committees are currently available via the Resources for Integrated Care.²²

Comment: Numerous commenters requested clarification on how D-SNPs could reimburse enrollee advisory committee members for their time and expertise, and suggested D-SNPs be able to offer stipends, transportation or transportation reimbursement for in-person meetings, and food and drink.

Response: We acknowledge the advantages of reimbursing enrollee advisory committee participants for their time and expertise, and prior technical assistance in this area²³ has cited incentives as a best practice to recruit and retain enrollee advisory committee members. We clarify that enrollee participation in an advisory committee is neither a marketing activity nor a personal enrollee health-related activity that would fall under § 422.134, so the authorities and limits that are specific to those activities under MA regulations would not apply. However, MA organizations are prohibited from providing cash, gifts, prizes, or other monetary rebates as an inducement for enrollment or otherwise by sections 1851 and 1854 of the Act. D-SNPs should ensure that any incentives be structured to avoid an inadvertent impact on enrollee eligibility for public benefits. In addition, the provision of stipends, transportation reimbursement, or anything else of value to D-SNP enrollees serving on the enrollee advisory committee potentially implicates the Federal Anti-kickback

Statute (AKS), found in section 1128B(b) of the Act. Whether any particular arrangement violates the AKS would be based on the specific facts and circumstances. D-SNPs must ensure that the provision of reimbursement to these members complies with the AKS and other applicable law. We will provide future technical assistance to D-SNPs on this issue to help avoid unintended consequences related to plan compliance or enrollee eligibility for public programs.

Comment: A number of commenters expressed concerns about operationalizing an enrollee advisory council for a D-SNP that has low enrollment. Commenters cited concerns about D-SNPs' ability to meet the reasonably representative sample if overall plan enrollment is too small, particularly for a newly established plan or a plan operating in a rural service area. These commenters suggested CMS either set a minimum enrollment threshold or allow for advisory committees to cross geographies (for example, via multi-State consumer advisory councils). A few commenters recommended we set the minimum D-SNP enrollment threshold at 1,000 enrollees for the establishment of enrollee advisory committees. A commenter requested we consider exempting new plans from this requirement, while another recommended small plans be able to meet the requirement via focus groups, surveys, or other methods.

Response: While we appreciate the commenters' recommendations with respect to low-enrollment D-SNPs and the challenges low D-SNP enrollment might present in operationalizing a consumer advisory committee, we do not agree that the reasons cited create a significant barrier for MA organizations to meet the new requirement. First, we would like to clarify that an MA organization offering one or more D-SNP(s) in a State must have one or more enrollee advisory committees that serve the D-SNP(s) offered by the MA organization in that State. As proposed and finalized here, an MA organization would be able to choose between establishing a single enrollee advisory committee for one or more D-SNPs in that State or by establishing multiple committees in that State to comply with § 422.107(f). Thus, in situations where an MA organization operates more than one D-SNP in a State, the MA organization can, unless State Medicaid agency contracts dictate otherwise, establish one or more committees that encompass multiple D-SNPs in a State, which should help to address concerns related to low enrollment in any given

D-SNP. Second, a number of MMPs that participated in FAI had low enrollment (that is, fewer than the suggested 1,000 enrollee threshold) and were able to operationalize meaningful enrollee advisory committees. Third, we are nonprescriptive in this requirement regarding how an MA organization recruits committee membership, the timing, frequency or number of advisory meetings an MA organization must conduct in a calendar year, and the meeting's format (for example, in person or virtual). The reasonably representative requirement is also sufficiently flexible that small plans can meet the standard. With this level of flexibility, we believe it is reasonable for D-SNPs that may have low enrollment to meet the requirements finalized at § 422.107(f).

Comment: Some commenters asked us to clarify or confirm whether D-SNPs have the flexibility to convene their advisory councils virtually. A commenter noted current use of digital platforms, while other commenters suggested virtual meetings may encourage greater enrollee participation. A few commenters specifically welcomed the flexibility in committee format (that is, in-person vs. virtual). A commenter explained that while in-person meetings remain the gold-standard for engagement, providing flexibility in how a D-SNP advisory committee engages with enrollees would help maximize enrollee engagement and provide flexibility for the D-SNP to evolve its processes as new effective methods become available.

Response: We are not proposing Federal requirements regarding the means by which enrollee advisory committees or committee meetings convene (either in-person or virtually). We confirm that MA organizations can meet the minimum requirements at § 422.107(f) by convening meetings virtually, provided they are not restricted from doing so via their State Medicaid agency contract. However, we reiterate our encouragement of D-SNPs to adopt identified best practices to ensure advisory committee meetings are accessible to all enrollees, including where lack of meaningful access to internet technology and broadband may limit involvement.

Comment: In the proposed rule, we solicited comments on whether we should limit enrollee advisory committees to a subset of D-SNPs. A few commenters agreed that the new requirement should apply to all D-SNPs, noting it to be the most comprehensive approach to soliciting feedback from dually eligible enrollees,

²² Resources for Integrated Care "Engaging Members in Plan Governance", Retrieved From: <https://www.resourcesforintegratedcare.com/article/member-engagement/>.

²³ Resources for Integrated Care "Engaging Members in Plan Governance", Retrieved From: <https://www.resourcesforintegratedcare.com/article/member-engagement/>.

while acknowledging some D-SNPs may already have enrollee advisory councils that meet the new requirement. A commenter noted that while it had encouraged applying enrollee advisory committees to FIDE SNPs in the past, it also supported applying this approach more broadly to all D-SNPs.

Response: We appreciate the comments of support and we agree that applying an enrollee advisory committee requirement to D-SNPs broadly, rather than a subset, is the better mechanism to solicit feedback directly from enrollees and assist D-SNPs in identifying and resolving emerging issues. We believe applying this requirement to all D-SNPs, including those with a low level of integration, is the best approach to elevate the voice of dually eligible enrollees across a wider array of States and circumstances.

Comment: To increase transparency, oversight, and accountability, a few commenters urged State Medicaid agency participation in D-SNP enrollee advisory councils, or to give States access to the proceedings and recommendations of the committees on at least a quarterly basis. In contrast, a commenter suggested the inclusion of State participation on enrollee advisory councils would add unnecessary complexity.

Response: Nothing in the proposed rule precludes State Medicaid agencies from requiring, via the State Medicaid agency contracts required by § 422.107, D-SNPs to include State representatives in their enrollee advisory council meetings. Additionally, through these State Medicaid agency contracts, States could require D-SNPs to provide additional reporting on D-SNP advisory councils as a means for additional transparency, accountability, and oversight.

Comment: A few commenters suggested CMS allow MA organizations to establish enrollee advisory committees on a regional or multi-State basis, to overcome barriers to enrollee participation or when D-SNP enrollment is small in any single State. A commenter suggested the MA-PD's enrollee advisory committee within a State include enrollee representatives of the plans' other Medicare products as another means to encourage enrollee participation, while another requested to include Medicaid-only participants on the advisory committee to meet the existing Medicaid managed care advisory requirement at § 438.110.

Response: Due to the variations in State Medicaid agency contracts and Medicaid, we believe there is value in keeping enrollee advisory councils

specific to a State. This offers operational simplicity to MA organizations to meet any State-specific advisory committee requirements and would improve the effectiveness of an enrollee advisory committee without combining committee membership across States, where services, eligibility, and geography could vary greatly. While we intend this new requirement to generate feedback based on the unique experience of dually eligible enrollees via a D-SNP enrollee advisory committee, we recognize that committees may not always be made up solely of dually eligible enrollees, as organizations can use a single advisory committee to meet the Medicaid managed care advisory committee requirement at § 438.110. However, we do not agree that the enrollee advisory committee should include representatives from Medicare products that do not focus on dually eligible enrollees. In meeting the requirement proposed at § 422.107(f), there is nothing precluding MA organizations from establishing sub-committee arrangements to established enrollee advisory committees. Also, the proposed requirement does not preclude non-SNP MA plans from establishing separate enrollee advisory committees.

Comment: Many commenters indicated that the minimum of a single Statewide enrollee advisory committee across potentially multiple D-SNP products was an insufficient approach in larger States, where D-SNPs may have very large enrollment as well as geographically and demographically diverse service areas. Commenters noted that a combined enrollee advisory council in a large State would dilute the value of the committee. A commenter suggested CMS require each D-SNP to establish its own committee, and a few commenters requested flexibility for States to further direct committee geographic scope, composition, and other factors beyond the Federal minimum requirements, including the ability to require multiple committees for specific enrollee populations. Several other commenters asked CMS to clarify whether enrollee advisory committees need to be at the plan benefit package (PBP) level. Finally, a commenter expressed that even within a State and D-SNP parent organization, many D-SNPs have similar plan names and cover different benefits, which could lead to potential enrollee confusion if an advisory committee is established Statewide across D-SNP products.

Response: The new requirement established at proposed § 422.107(f) does not preclude States from using

their State Medicaid agency contracts (as required by § 422.107) to impose more prescriptive requirements for D-SNP enrollee advisory committees based on D-SNP enrollment, service area geography, or any other characteristic. The new proposal does not require D-SNPs to implement enrollee advisory committees at the PBP level, although they could choose to do so. States could also require each D-SNP to develop its own committee, either at the contract or the PBP level. Additionally, organizations that operate multiple D-SNPs in a State could elect to establish and maintain multiple enrollee advisory committees that best represent their eligibility populations (for example, full- or partial-benefit dually eligible beneficiaries) and/or service areas. We believe this regulation sets a floor from which States and D-SNPs may work to craft enrollee advisory committees that best meet local population and plan needs without committee duplication or significant disruption of current enrollee advisory committee operations, as required either by States or § 438.110.

Comment: Many commenters questioned whether D-SNPs could use existing plan enrollee advisory committees—either FIDE SNP or committees representing Medicaid managed care plans that cover long term services and supports—to meet the new proposed requirement at § 422.107(f). A few commenters asked us to clarify that one enrollee advisory committee could be used to meet the new requirements in §§ 422.107(f) and 438.110, noting that competing advisory committees would be inefficient. Another commenter requested we provide clarity on how the proposal should be implemented with respect to LTSS and non-LTSS enrollee participants and corresponding council topics. Other commenters recommended the use of subcommittees (either D-SNP enrollee advisory committees specific to MLTSS or MLTSS advisory committee with a subcommittee specific to dually eligible enrollees) as a potential means to solicit more precise feedback on unique plan subpopulations.

Response: We acknowledge some D-SNPs, or their affiliated Medicaid managed care plans covering LTSS, are currently operating enrollee advisory committees to meet existing State requirements; these existing committees may satisfy the requirements at § 422.107(f). As we noted in the proposed rule, our proposal at § 422.107(f) would permit an organization that operates a D-SNP that is affiliated with a Medicaid managed care plan to use one enrollee advisory committee to meet both the requirement under § 438.110 and the requirement

proposed at § 422.107(f), when all the criteria in both regulations are met. However, a State may limit the ability of a D-SNP to use one committee to meet both regulatory requirements. Finally, nothing in our proposed requirement would preclude the use of subcommittees with respect to unique D-SNP subpopulations. As discussed earlier in this section, we are nonprescriptive on topics (for example, with respect to LTSS) covered by enrollee advisory committees so long as the minimum topics specified in the regulation (ways to improve access to covered services, coordination of services, and health equity for underserved populations) are addressed; however, we encourage D-SNPs and their advisory committees to choose topics most relevant to the populations served.

Comment: Numerous commenters requested we encourage or require D-SNPs to operate their enrollee advisory committees with accessibility, accommodations, and communications access in mind for enrollees with disabilities, as well as enrollees with limited literacy, limited digital literacy, lack of meaningful access to technology and broadband and limited English proficiency. Other commenters recommended CMS require D-SNPs provide interpretation and accommodation for individuals with hearing and vision disabilities and impairments. Another commenter recommended CMS require D-SNPs to conduct enrollee advisory committee meetings in the preferred language of the region/county, when that region's primary language preference is not English. A commenter noted the need for committee meeting materials in alternate formats, while another commenter urged CMS to require D-SNPs to provide accommodations to committee enrollees who lack transportation or access to the technology necessary to facilitate robust virtual participation. Finally, a commenter recommended that CMS provide parameters regarding the importance of D-SNPs facilitating access to enrollee advisory committees via training, recruitment, and location and timing of meetings that reflect the community and population to create a process that allows enrollees to meaningfully participate in the committee.

Response: We agree with the commenters that it is vitally important for MA organizations to facilitate meaningful enrollee access to their enrollee advisory committees through accommodations for their enrollees' needs in order to achieve a

representative sample of enrollee perspectives and meaningful feedback from the enrollee advisory committees. Although we are choosing to be nonprescriptive on meeting frequency, location, format, enrollee recruitment and training methods, and other parameters, we encourage D-SNPs to adopt identified best practices to ensure advisory committee meetings are accessible for all enrollees. Ensuring that the enrollee advisory committee has a reasonably representative sample of the covered population should include taking steps to ensure access for enrollees with disabilities, limited literacy (including limited digital literacy), and lack of meaningful access to technology and broadband, particularly to the extent that these considerations are also relevant to improving access to covered services and health equity. Where D-SNPs serve enrollees with disabilities, limited literacy or limited English proficiency, we expect those characteristics to be reflected in the D-SNP's enrollee advisory committee membership. D-SNPs must comply with any applicable civil rights law. We note that existing Federal civil rights authorities such as Section 504 of the Rehabilitation Act of 1973, HHS' implementing regulation at 45 CFR part 84, and Title VI of the Civil Rights Act of 1964 and the implementing regulation at 45 CFR part 80 would likely apply to an MA organization's administrative functions, such as enrollee advisory committees. We encourage D-SNPs to also consider virtual accessibility and transportation accessibility for in person meetings for their enrollee committee membership.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposed requirement for D-SNPs to establish and maintain enrollee advisory committees at § 422.107(f).

4. Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessments (§ 422.101)

Section 1859(f)(5)(A)(ii)(I) of the Act requires each SNP to conduct an initial assessment and an annual reassessment of the individual's physical, psychosocial, and functional needs using a comprehensive risk assessment tool that CMS may review during oversight activities, and ensure that the results from the initial assessment and annual reassessments conducted for each individual enrolled in the plan are addressed in the individual's individualized care plan. We codified

this requirement at § 422.101(f)(1)(i) as a required component of the D-SNP's MOC. In practice, we allow each SNP to develop its own HRA, as long as it meets the statutory and regulatory requirements.²⁴ 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 referred to as the January 2021 final rule), we noted that integrated D-SNPs (by which we mean D-SNPs or their affiliates under the same parent organization also receiving capitation for Medicaid services) may combine their Medicare-required HRA with a State Medicaid-required HRA so long as the applicable requirements for the HRA under § 422.101(f) are met, to reduce assessment burden (86 FR 5879).

Certain social risk factors can lead to unmet social needs that directly influence an individual's physical, psychosocial, and functional status.²⁵ This is particularly true for food insecurity, housing instability, and access to transportation. As summarized in our proposal rule at 87 FR 1858, CMS in recent years has addressed social risk through the identification and standardization of screening for risk factors, including finalizing several standardized patient assessment data requirements for post-acute care providers²⁶ and testing the Accountable

²⁴ In the CY 2016 Call Letter (an attachment to the Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies) released on April 6, 2015, CMS encouraged SNPs to adopt the components in the CDC's "A Framework for Patient-Centered Health Risk Assessments" tool but did not mandate their use. Specifically, CMS encouraged the use of elements that identify the medical, functional, cognitive, psychosocial and mental health care needs of enrollees.

²⁵ Hugh Alderwick and Laura M. Gottlieb, "Meanings and Misunderstandings: A Social Determinants of Health Lexicon for Health Care Systems: Milbank Quarterly," Milbank Memorial Fund, November 18, 2019, <https://www.milbank.org/quarterly/articles/meanings-and-misunderstandings-a-social-determinants-of-health-lexicon-for-health-care-systems/>.

²⁶ See the "Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements" final rule (84 FR 39151 through 39161) as an example. In the interim final rule with comment period (IFC) "Medicare and Medicaid Programs, Basic Health Program and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program" (85 FR 27550 through 27629), CMS delayed the compliance dates for these

Health Communities (AHC) model under section 1115A of the Social Security Act. The AHC model tests whether systematically screening for health-related social needs and referrals to community-based organizations will improve health care utilization and reduce costs, and includes a CMS Innovation Center-developed AHC Health-Related Social Needs (HRSN) Screening Tool.²⁷

As discussed in the proposed rule at 87 FR 1858 through 1859, many dually eligible individuals contend with multiple social risk factors such as food insecurity, homelessness, lack of access to transportation, and low levels of health literacy.²⁸ We posited that requiring SNPs to include standardized questions about social risk factors would be appropriate in light of the impact these factors may have on health care and outcomes for the enrollees in these plans and that access to this information would better enable SNPs to design and implement effective models of care.

We proposed to amend § 422.101(f)(1)(i) to require that all SNPs (chronic condition special needs plans, D-SNPs, and institutional special needs plans) include one or more standardized questions on the topics of housing stability, food security, and access to transportation as part of their HRAs. We noted that these questions would help SNPs gather the necessary information to conduct comprehensive risk assessments of each individual's physical, psychosocial, and functional needs as required at § 422.101(f)(1)(i) and would inform the development and implementation of each enrollee's

standardized patient assessment data under the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP), Long-Term Care Hospital (LTCH) QRP, Skilled Nursing Facility (SNF) QRP, and the Home Health (HH) QRP due to the public health emergency. In the "CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID-19 Reporting Requirements for Long-Term Care Facilities" final rule (86 FR 62240 through 62431), CMS finalized its proposals to require collection of standardized patient assessment data under the IRF QRP and LTCH QRP effective October 1, 2022, and January 1, 2023, for the HH QRP.

²⁷ CMS Innovation Center, "The Accountable Health Communities Health-Related Social Needs Screening Tool." Retrieved from: <https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf>.

²⁸ Medicaid and CHIP Payment and Access Commission, "Report to Congress on Medicaid and CHIP," June 2020. Retrieved from: <https://www.macpac.gov/wp-content/uploads/2020/06/June-2020-Report-to-Congress-on-Medicaid-and-CHIP.pdf>.

comprehensive individualized plan of care as required at § 422.101(f)(1)(ii). Rather than include the specific questions in regulation text, we proposed that the questions be specified in sub-regulatory guidance. This would afford us some flexibility to modify questions to maintain consistency with standardized questions that are developed for other programs while still providing MA organizations with clear requirements; we expressed our intent to provide ample notice to MA organizations of any changes in the questions over time. As discussed in the proposed rule, SNPs would comply with the new requirement added to § 422.101(f) by including in their HRAs the standardized questions on these topics that we would specify in sub-regulatory guidance. We described in the proposed rule our intent to, at a minimum, align selected questions with the Social Determinants of Health (SDOH) Assessment data element²⁹ established as part of the United States Core Data for Interoperability Standard (USCDI) v2, when finalized and where applicable.

While we proposed that the regulation text specify that the wording of individual questions would be established through sub-regulatory guidance, we provided examples in the proposed rule of the questions on these topics used in other Medicare contexts to provide better context on the proposed requirement and to solicit public comment. These examples included the transportation question in the post-acute care patient/resident instruments³⁰ and the housing and food insecurity questions from the AHC Model HRSN Screening Tool.³¹

As discussed in the proposed rule at 87 FR 1859, our proposal would result in SNPs having a more complete picture for each enrollee of the risk factors that may inhibit accessing care and achieving optimal health outcomes and independence. We believe that these questions are sufficiently related to and provide information on enrollees' physical, psychosocial, and functional needs to be appropriate to include the HRAs. Having knowledge of this information for each enrollee would better equip MA organizations to develop an effective plan of care for

²⁹ For more information, see: <https://www.healthit.gov/isa/taxonomy/term/1801/uscdi-v2>.

³⁰ For more information, see: <https://prapare.org/the-prapare-screening-tool>.

³¹ For the Accountable Health Communities Health-Related Social Needs Screening Tool, see <https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf>. The PAC assessment utilized the same transportation question as the AHC HRSN Tool.

each enrollee that identifies goals and objectives as well as specific services and benefits to be provided. Our proposal would also equip SNPs with person-level information that would help them better connect enrollees to covered services and to social service organizations and public programs that can help resolve housing instability, food insecurity, transportation needs, or other challenges. Coordinating care along these lines is consistent with the obligations under § 422.112(b)(3) for MA organizations that offer coordinated care plans.

We did not propose that SNPs be accountable for resolving all risks identified in these assessment questions, but § 422.101(f)(1)(i) requires that the results from the initial and annual HRAs be addressed in the individualized care plan. As explained in the proposed rule at 87 FR 1859, results of the HRAs would not require SNPs to provide housing or food insecurity supports, but having the results means that SNPs would need to consult with enrollees about their unmet social needs, which may include homelessness and housing instability, for example, in developing each enrollee's care plan. We explained that a SNP could demonstrate this in several ways, consistent with its MOC, including making referrals to appropriate community partners and taking steps to maximize access to covered services that meet the individual's needs.

By standardizing certain data elements, our proposal would make those data elements available for collection by CMS from the SNPs for all enrollees. (States can also use their contracts with D-SNPs at § 422.107 to require reporting of these data elements in the HRAs to the State or its designee.) In the proposed rule at 87 FR 1859, we explained that, while we continue to consider whether, how, and when we would have the SNPs actually report data to CMS, we believe having such information could help us to better understand the prevalence and trends in certain social risk factors across SNPs and further consider ways to support SNPs in promoting better outcomes for their enrollees. We believe standardizing these data elements could also eventually facilitate better data exchange among SNPs (such as when an individual changes SNPs).

We understand that some States may separately require that Medicaid managed care plans collect similar information, potentially creating inefficiencies and added assessment burden on dually eligible individuals who are asked similar, but not identical,

questions in multiple HRAs. As we explained in the proposed rule, we believe that the benefit gained by all SNPs having standardized information about these social risk factors outweighs this potential risk. Where States are interested in requiring assessment questions, we recommended that States consider conforming to the standardized questions we implement for use under this final rule and, for integrated care programs, ensuring that plans do not need to ask the same enrollees similar or redundant questions. However, we also solicited input from States about what questions they are using and how we can best minimize assessment burden while ensuring that SNPs and States are capturing actionable information on social risk factors.

As discussed in the proposed rule at 87 FR 1860, we considered several alternatives to our proposal. We considered requiring fewer or more assessment questions on additional topics related to social risk factors or different combinations of questions, including questions on health literacy and social isolation. We considered soliciting comment on different examples of questions on housing, food, and transportation other than the examples included in the proposed rule. We considered simply proposing that all HRAs address certain domains (for example, housing), without authorizing CMS to specify the standardized questions to be used. We also considered specifying that the new questions only apply to certain enrollees and not others. We explained our rationale for not including these alternatives in the proposed rule at 87 FR 1860.

Finally, due to the processes associated with developing HRA tools, approval of MOCs, and MOC implementation, we discussed applying our proposed requirement beginning contract year 2024. However, we also considered whether to have our proposed requirement take effect at a later date, such as contract year 2025, to allow MA organizations more time to work our proposed new questions into their existing SNP HRAs. We solicited comments on our proposal and these potential alternatives. We also solicited comments on when CMS would need to issue sub-regulatory guidance providing the specific questions to be included in the HRAs to ensure that MA organizations would have sufficient time to incorporate the required questions.

We received the following comments on this proposal and respond to them below:

Comment: Most commenters expressed support for our proposal to require all SNPs to include questions on housing stability, food security, and access to transportation as part of their HRAs. Some commenters noted that inclusion of questions on these topics in HRAs would improve insight into enrollee needs. Several commenters stated that collection of information related to the SDOH can also better inform plans of enrollees' challenges and reduce barriers to optimal care and quality of life. A few commenters noted the importance of SDOH-related information in the development of an individualized, person-centered care plan. Some commenters expressed appreciation that CMS's proposal acknowledged the influence of the SDOH on health outcomes. Several commenters noted that social risk factors have a significant impact on health outcomes for the SNP population in particular. Several commenters noted that capturing social risk factors in SNP HRAs can help plans develop targeted interventions and connect enrollees to available supplemental benefits. A commenter believed health plans are best suited to collect this information and have the necessary resources to connect beneficiaries to social support services. Another commenter believed awareness of SDOH information improves care and lowers long-term costs. Other commenters noted that identifying unmet social needs among SNP enrollees could help reduce health disparities and advance health equity. A few commenters stated that that answers to HRA questions help capture information on social risk factors that is not only useful for individual enrollees, but also can be curated for evaluation at the population level in a way that can inform policy changes like payment reform. Another commenter believed HRA data on social risk factors have the potential to inform SNP supplemental benefit design and could be useful for incorporating social risk factors into future risk adjustment.

Response: We appreciate the widespread support for inclusion of questions on housing stability, food security, and access to transportation as part of SNP HRAs. We agree that requiring SNPs to collect information on these topics can allow SNPs to better understand enrollees' needs and challenges. As we noted in the proposed rule, our proposal would result in SNPs having a more complete picture of the risk factors that may inhibit enrollees from accessing care and achieving optimal health outcomes and independence. We also appreciate the

commenters' support for reducing health disparities and advancing health equity more broadly. We agree that better identifying the needs of SNP enrollees can be an important first step toward these larger goals.

Comment: A number of commenters expressed support for the three question topic areas included in the proposed rule (housing stability, food security, and access to transportation). A commenter recommended CMS require all three categories be added to the HRAs. A few commenters noted these three topics are important indicators of social needs that are linked to individual health outcomes. A commenter noted that these three risk factors are issues that SNPs are well-positioned to address. Another commenter noted they supported the proposal and were already implementing an assessment tool that covered these three topics. Other commenters expressed support for all three topics, but noted transportation in particular. A commenter noted that problems with transportation can seriously impact access to care, and that advocates and beneficiaries report that these problems are widespread. Another commenter noted the importance of transportation for rural populations that may need to travel significant distances to providers. A commenter stated that SNPs armed with the knowledge that, for example, many of their members are experiencing access barriers due to a lack of transportation may wish to expand the availability of transportation benefits.

A commenter expressed support for all three proposed topics, but noted particular support for the inclusion of one or more questions about food security. The commenter believed that requiring screening for food insecurity will allow plans to better understand the important interplay between food insecurity and chronic illness in their enrollee populations, and will better equip plans to connect enrollees to critical responsive services such as medically tailored meals.

Response: We appreciate the support for our proposed HRA question topics. As we outlined in the proposed rule, we focused on housing stability, food security, and access to transportation because there is a large evidence base suggesting they have a particularly significant influence on the physical, psychosocial, and functional needs of the enrollees. These comments reinforce our belief that these three topics are the most important factors for which SNPs should be screening their enrollees.

Comment: Some commenters expressed support for the three topic

areas included in the proposed rule but recommended that CMS include questions on additional topics as well. Several commenters recommended adding a question about family and unpaid caregiver support. A commenter noted that understanding how much support a SNP member has at home—or the caregiving responsibilities they may have—has direct connections to health outcomes of SNP enrollees and may provide information on the prevalence of family caregivers and the need to better support them to help ensure members can continue to live in the community. Another commenter believed that addressing this topic and expanding supports for caregivers could reduce future reliance on Medicaid-funded LTSS and limit growth in LTSS expenditures. A few commenters suggested adding questions about caregiver burden in particular, noting that early recognition of caregiver burden can lead to targeted supports, and a lack of recognition of caregiver burden can prompt an emergency department visit or hospitalization. A commenter also suggested CMS add an assessment question about symptom burden, noting that the SNP assessment can be a powerful opportunity to identify poorly managed pain and symptoms and avoid crises like potentially preventable emergency department visits. The commenter recommended that, at minimum, questions about symptom burden as well as caregiver burden be required for SNP enrollees with certain serious illnesses, but also believed there are benefits to including those two topics in HRAs for all SNP enrollees.

Another commenter recommended multiple additional domains such as such as functional status, frailty, spoken language, and health literacy. Several other commenters encouraged CMS to include one or more questions on health literacy. A commenter noted that a question related to health literacy gets at the individual's ability to understand and ask questions about health information they receive, which the commenter suggested could have a significant impact on health outcomes.

Some commenters recommended CMS include questions on both health literacy and social isolation. A commenter noted that these two health-related social needs are prevalent among SNP populations and have direct impacts on health outcomes and behaviors, and expressed support for validated, concise screening tools on these topics, such as the Single Item Literacy Screener and AHC Model HRSN Screening Tool. Another commenter pointed to research showing

that low health literacy is associated with nonadherence to treatment plans and puts patients at higher risk for hospitalization and mortality, and noted disparities in health literacy among different racial and ethnic groups. The commenter also believed the COVID-19 pandemic has highlighted weaknesses in the social support systems of older adults and at-risk populations, and noted that social isolation is associated with increased risk for premature mortality and significantly influences physical, mental, and cognitive health outcomes. A few commenters suggested CMS include a question on social isolation. A commenter recommended CMS include a question on social isolation rather than one on access to transportation. The commenter believed transportation has not been as high on the list of observed needs for SNP enrollees—they noted this was perhaps because many SNPs provide transportation as a supplemental benefit.

A few commenters recommended CMS include questions related to disability and functional limitations. These commenters believed that information related to the SDOH is not enough and that, without information on disability status, the assessment is incomplete and will perpetuate the disparities it seeks to uncover. Another commenter recommended including questions about interpersonal violence and its subdomains intimate partner violence and elder abuse, as well as utilities insecurity, and noted that the AHC HRSN screening tool includes these topics.

A commenter expressed support for CMS's three proposed topic areas, but noted some populations may not have those specific needs depending on individual circumstances or geographic location. The commenter believed an exclusive focus on these three social needs could miss other critical social needs that are more relevant, and noted that the relevance of different social needs questions will vary depending on individual circumstances, geographic location, populations served, and resource availability, among other factors. Another commenter noted that once the proposed HRA questions have been implemented successfully, CMS could consider adding new questions or expanding to other social needs topics, such as social isolation and access to telehealth.

Response: We appreciate the commenters' suggestions and acknowledge that the domains these commenters suggested are all important indicators of unmet enrollee needs. However, we maintain that the three

topics we proposed have the strongest currently available evidence base³² suggesting they have a particularly significant influence on health outcomes, and we still value parsimony in establishing new HRA requirements. Furthermore, the three topics on which SNP HRAs will be required to solicit information align with other efforts in this arena, such as the National Committee for Quality Assurance (NCQA) proposed Social Need Screening and Intervention HEDIS measure, which measures the percent of enrollees who were screened for unmet food, housing, and transportation needs, and received a corresponding intervention if they screened positive.³³ As we discuss in more detail later in this section, the requirement we are finalizing at § 422.101(f)(1)(i) allows SNPs flexibility to include questions from a list of screening instruments specified by CMS in sub-regulatory guidance on housing stability, food security, and access to transportation. The amendment we are finalizing to § 422.101(f)(1)(i) does not preclude SNPs from including additional questions in their HRAs as appropriate for their enrollee populations. The broad language at section 1859(f)(5)(A) of the Act and at § 422.101(f) provide SNPs a great deal of flexibility in developing their HRA tools to gather information about the unique physical, psychosocial, and functional needs of their enrollee populations in order to better meet those needs and coordinate care for the specific special needs population enrolled in the plan. Additionally, we may consider adding more, specific question topics in future rulemaking. We note that current regulations do not contain any specific requirements similar to what we are adopting in this rule, and we believe it is appropriate to first assess experiences implementing the change we are finalizing in this rule before proposing to require questions on other topics.

Comment: Some commenters recommended that CMS require collection of patient demographic information as part of the HRA, including a variety of factors, such as race, ethnicity, sex, gender, gender identity, sexual orientation, language, disability, and others. A few of these commenters noted collecting this information is important to understanding how demographic

³² See, for example, Kushel M.B., Gupta R., Gee L., Haas J.S. Housing instability and food insecurity as barriers to health care among low-income Americans. *J Gen Intern Med.* 2006;21(1):71–7. doi: 10.1111/j.1525-1497.2005.00278.x.

³³ <https://www.ncqa.org/blog/hedis-public-comment-period-is-now-open/>.

characteristics interact with each other intersectionally as well as with health outcomes, and is important to identifying disparities within a plan and in the SNP population more broadly. A commenter noted that collecting demographic information should be accompanied by quality improvement initiatives to reduce health disparities, such as improving a plan's ability to provide primary care in a culturally and linguistically appropriate manner. A commenter noted that demographic information can help facilitate a culturally sensitive care planning process for SNP enrollees. Another commenter expressed support for the proposal, but urged CMS to add safeguards to ensure the questions are framed and presented, and the answers are received, in respectful and culturally competent ways. The commenter encouraged all such questions to be posed only by people who have had training to combat implicit bias.

A commenter recommended ensuring that SDOH data standards are inclusive so there is not exclusion and further marginalization of populations due to limited definitions such as gender being defined as binary male or female, excluding individuals of other genders including nonbinary, agender, and transgender. Another commenter believed there is a need to move beyond individual SDOH factors to incorporate factors at the neighborhood, community, and zip code level, such as housing discrimination, to identify systematic and institutionalized forms of discrimination that may affect health.

A few commenters recommended that CMS include an option for an enrollee to choose not to respond to the proposed HRA questions to protect enrollee choice and privacy.

Response: We appreciate the commenters' input and agree that collecting enrollee demographic and other information can provide the plan with a more complete picture of the enrollee. We believe that many SNPs are already collecting demographic and other information as described in the comments, and therefore we have chosen to focus on the three topics we proposed for parsimony. The amendment we are finalizing at § 422.101 requires SNPs to include one or more questions on housing stability, food security, and access to transportation using questions from a list of screening instruments specified by CMS in sub-regulatory guidance. We believe this approach allows SNPs enough flexibility to choose questions that are the most appropriate for their enrollee populations while still maintaining some of the benefits of

standardization. We encourage SNPs to ensure HRAs are conducted in a culturally sensitive manner. We also clarify that enrollees always have the option to refuse to answer an HRA question if they choose.

Comment: Some commenters suggested CMS require alternative or additional questions from those discussed in the proposed rule at 87 FR 1859 that cover the same three proposed topics or closely related topics. A commenter suggested CMS consider the National Comprehensive Cancer Network's Distress Thermometer assessment, a well-known screening tool among oncology providers, that includes housing, food security, and transportation among other topics. Another commenter noted examples of questions covering these three topics that are required for D-SNPs in the commenter's State. A commenter believed the examples in the proposed rule provided a good starting point for the subsequent sub-regulatory guidance, but also offered additional questions for consideration on topics related to those in the proposed rule, including questions about fall risk in the home, barriers to shopping for healthy food, and whether lack of access to transportation is persistent or infrequent, among other questions. Another commenter recommended CMS require SNPs to include in their HRAs questions across three specific housing specific domains, not just the proposed topic of housing stability: Homelessness, housing instability, and inadequate housing, noting that the AHC HRSN screening tool identifies all three housing topics. A commenter cautioned CMS against utilizing questions from the PAC assessment instruments. The commenter noted the patient assessment instruments used in each of the PAC settings are based on a "medical" model designed to determine medical care needs and associated resource use, and believed the information collected in the PAC assessments is insufficient to address ongoing social or medical needs.

Response: We appreciate the commenter's suggestions. As discussed in more detail later in this section, we are finalizing language at § 422.101(f)(1)(i) to require SNPs to include one or more questions from a list of screening instruments specified by CMS sub-regulatory guidance that complies with the Paperwork Reduction Act on housing stability, food security, and access to transportation (rather than requiring that all SNPs use the same specific standardized questions on these topics as proposed). We recognize that a variety of HRA questions on these

topics could allow SNPs to collect meaningful information on their enrollees' needs. The requirement we are finalizing in this rule provides SNPs with some flexibility to select the specific questions on these topics that are most appropriate for their enrollees from the list of screening tools specified by CMS in sub-regulatory guidance. We remind SNPs that they may also choose to include additional questions that are related to the three required topics, but not exactly the same, such as fall risk in the home, for example.

Comment: A number of commenters expressed concern that the addition of the proposed questions to HRAs would make the assessments too long and burdensome. Several commenters suggested that CMS limit the number of questions SNPs must include in their assessments. A commenter recommended CMS limit the number of required questions to one question on each of the three proposed domains. A few commenters stated CMS should start with just a few questions and/or interoperable codes relating to housing, food, and transportation. Other commenters believed adding the proposed questions could reduce HRA completion rates.

Response: We appreciate the commenters' perspective on this issue. We believe that the potential benefit of SNPs having a more complete picture their enrollees' physical, psychosocial, and functional needs as required at § 422.101(f)(1)(i) outweighs the potential burden of including these questions in an assessment. Furthermore, because the requirement we are finalizing allows SNPs some flexibility to choose questions on housing stability, food security, and access to transportation from a list of screening tools specified by CMS in sub-regulatory guidance, SNPs can potentially continue using existing questions on these topics they already include in their HRAs if they are from the CMS-specified list, reducing the potential for administrative burden. We anticipate that the list of tools included in the CMS sub-regulatory guidance will likely include screening tools that are widely used in the industry and that SNPs may already be using for their HRAs. We will seek input on the list of screening instruments and comply with the Paperwork Reduction Act.

Comment: A commenter suggested that, instead of questions on the three proposed domains, CMS use a one-to-two-question pre-screener that asks enrollees their needs or challenges across a wider range of social needs (such as social isolation, employment, safety, legal needs, assistance with

utilities, issues with a person's living or home environment, material security, and digital access, in addition to housing, food and transportation). While the commenter recognized that social needs pre-screeners have not been widely used or vetted, the commenter believed pre-screeners could allow for a more holistic assessment of enrollee needs, which can then be followed up by additional questions if needed and be used to better inform care.

Response: We appreciate the commenter's suggestion; however, as the commenter noted, this approach has not been widely used or vetted. We prefer that SNPs use questions from validated or otherwise widely used assessment instruments (including any required by States), because we believe they will allow SNPs to collect high-quality, actionable information on their enrollees—at the individual level as well as at the population level—to more holistically understand the barriers to care enrollees face. While we are not familiar with exactly what type of questions would be included in such a pre-screener, we do not believe that a question that asks enrollees about their needs across such a wide range of domains is likely to receive useful responses. Because we believe using validated or otherwise widely used assessment instruments is important to understanding and addressing enrollee needs, we are finalizing a requirement at § 422.101(f)(1)(i) that SNPs include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on housing stability, food security, and access to transportation.

Comment: A few commenters opposed requiring questions about social risk factors as part of SNP HRAs. A commenter recommended CMS give health plans the choice to include these questions on their HRAs to preserve assessment completion rates. Another commenter suggested CMS consider providing a list of standardized optional HRA questions, and noted that States could choose to require D-SNPs to include one or more optional questions in their HRAs, and individual plans could decide to include them as well. The commenter noted that plans using the optional questions could provide feedback to CMS on ease of use to help inform a future CMS decision about requiring these additional questions.

Response: We disagree with the recommendation to make questions about social risk factors optional for SNPs. We believe it is necessary to require SNPs to include questions about housing stability, food security, and access to transportation in order to have

a more complete understanding of enrollees' physical, psychosocial, and functional needs. Though we are aware that many SNPs may already be asking their enrollees various questions related to SDOH, we want to ensure that, at minimum, SNPs are collecting information on these three key topics that are among the most influential to an enrollee's health outcomes. We remind commenters that SNPs currently have the option to include questions about social risk factors on their HRAs; making the proposed questions optional would not necessarily expand the screening of SNP enrollees for social risk factors from the level of screening that SNPs are doing currently.

Comment: A significant number of commenters expressed support for requiring standardized questions on the proposed topics. A commenter noted that standardized questions would streamline and facilitate ease in reporting, leading to improved data collection and higher quality data that more reliably measures impact and progress across populations. Another commenter believed that a lack of standardized data has impaired the ability of policymakers to fully understand the links between social risk factors and health inequities. Other commenters believed standardization would better ensure beneficiary needs are systematically identified and enable SNPs to develop and implement models of care to address those needs.

Several commenters noted standardized questions could improve SNPs' ability to understand prevalence and trends in social risk factors among enrollees. Several commenters also noted that standardized questions would enhance both SNPs' and CMS's ability to collect, analyze, and publicly report disparity- and equity-related data. Another commenter noted that developing standards for collecting and sharing SDOH-related data can result in actionable insights into disparities while improving data sharing across sectors. A commenter noted the importance of standardized data on food security in particular, stating that the use of standardized screening questions would provide data needed to better understand the impact of food insecurity and chronic illness across SNPs as a whole. A few commenters noted the importance of standardized assessment questions to data exchange between SNPs.

A commenter noted that there is a key need for standardized data on SDOH for interoperability purposes, the importance of which has been further amplified during the COVID-19 pandemic. A few commenters

applauded CMS's intent to align the selected HRA questions with the SDOH data elements established as part of the USCDI v2. A commenter noted, however, there is still clarification needed to make certain the USCDI v2 questions would integrate seamlessly with traditional health information and result in successful interoperability.

A few commenters stated that implementing standardized questions such as those from the AHC Model screening tool would ensure that plans are using screening questions that have been tested for validity and reliability and to maximize opportunities to compare data across settings. Another commenter stated that SDOH-related information should be standardized across plans and Medicare programs to ensure the screening tools health plans are utilizing to capture this information are uniformly adopted across SNP, MA, Health Exchange and Medicaid plans.

A health plan commenter noted that they are already utilizing questions from the AHC HRSN screening tool to assess their enrollees and track their needs. The commenter noted that using this standardized tool has informed how they invested in internal capabilities and formed community partnerships to meet enrollee needs and improve their health. A few commenters stated that standardized questions would support plans' ability to address enrollee needs directly or to make referrals to social service organizations and programs. Another commenter believed that SNPs are in a unique position to meet enrollee needs because they have the flexibility to create unique benefit packages which can get to the root of many of the most important SDOH.

A commenter noted that they did not have a preference to which questions are specified (that is, from which standardized screening tool), but they strongly encouraged CMS to include standardized questions in sub-regulatory guidance and recommended that CMS coordinate with other HHS agencies to require the same set of standardized questions.

A commenter requested that CMS consider standardizing all questions on SNP HRAs to increase care coordination. Another commenter suggested CMS should provide clear definitions of housing, food, and transportation insecurity and word questions in a way to limit any ambiguity of the responses to increase the probability that MA plans get quantifiable, actionable data. They encourage CMS to reference existing tools and assessment questions when developing the standardized questions so that there is consistency with

screening tools already in use by providers and social services organizations.

Response: We appreciate the commenters' support for our proposal to require standardized questions, and the commenters' perspective that standardizing the collection of information on SNP enrollees' social risk factors would improve SNPs' ability to understand their enrollees' needs, track those needs over time, and improve interoperability and data exchange between plans as well as between plans and CMS, should CMS require the SNPs to report this data. We are finalizing an amendment at § 422.101(f)(1)(i) to require SNPs to include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on housing stability, food security, and access to transportation in their HRAs. However, we are not finalizing the part of our proposal that required SNPs to use specific standardized questions identified by CMS. We believe this middle-ground approach will retain some of the benefits of standardization while mitigating the potential downsides of using standardized questions, such as possibly (and unintentionally) limiting the opportunity to adopt questions that maximize cultural competence, potential increases in administrative burden and cost, and the potential for redundancy in States that have similar (but not fully aligned) requirements in their Medicaid programs. Requiring questions on the three topics from a CMS-specified list of screening tools, rather than specific standardized questions, will allow SNPs to choose questions from the specified tools on these topics that are most relevant to their enrollee populations.

We considered concerns about the administrative burden associated with modifying an HRA, as discussed in response to comments later in this section. We recognize that it could be burdensome for a SNP that is already asking questions on these topics in its current HRA to replace those questions with new ones from a CMS-specified list of screening tools. However, we believe that some degree of standardization helps ensure that SNPs are using validated questions and gathering high-quality, actionable responses from enrollees. Therefore, we are finalizing a requirement at § 422.101(f)(1)(i) for SNPs to include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on housing stability, food security, and access to transportation in their HRAs.

In response to commenters who expressed support for standardization because of its potential for improved data collection and exchange, we recognize there is a need for greater interoperability in this area. Though we are not limiting SNPs to specific questions identified by CMS, we are requiring SNPs to use questions from a list of screening instruments specified by CMS in sub-regulatory guidance. While this provides a measure of flexibility for SNPs, by limiting the scope of available questions on these three domains to specified instruments, we expect there will be some degree of standardization. We anticipate including validated, health IT-enabled assessment tools on the CMS-specified list in order to maximize opportunities for standardized data collection and analysis. We also anticipate our sub-regulatory guidance will include screening instruments that have been developed with clear definitions of housing stability, food security, and access to transportation and that word questions in a way to limit any ambiguity of the responses and increase the probability that SNPs gather quantifiable, actionable data. As we develop the CMS-specified list in sub-regulatory guidance, we will consider existing requirements in other HHS programs, and will coordinate with agency partners to identify opportunities for burden reduction. In addition, the sub-regulatory guidance will include the option to use State-required Medicaid screening instruments that include questions on these domains.

In response to the commenter who requested that CMS consider standardizing all HRA questions, we note that we do not currently require any specific questions on SNP HRAs, and implementing such a large-scale requirement is outside the scope of this rulemaking.

We clarify that this requirement only applies to SNP HRAs, though other MA plans are free to include questions on these topics on the one-time HRAs they are required to make a best effort to complete within 90 days of enrollment under § 422.112(b)(4)(i).

Comment: Numerous commenters opposed the requirement to include standardized questions specified by CMS. A number of commenters recommended that CMS instead set more flexible guidelines that allow plans to select their own assessment questions, such as requiring questions on certain topics rather than dictating the questions themselves. Some commenters asked CMS to consider allowing SNPs that are already

collecting information on the proposed topic areas in their HRAs to continue using their existing questions. Another commenter believed flexibility to select and customize assessment instruments and questions is the best approach to encourage screening for a broad array of needs and identifying an enrollee's most salient needs.

A commenter believed that requiring standardized questions would be expensive and cumbersome to change HRA questionnaires to match the CMS-specified question wording for plans that already actively work with SDOH assessment software vendors. Another commenter noted there is already a robust data collection environment in this area, and that payers and providers may have existing interoperable systems with their own definitions and language that encode social needs questions in HRAs and electronic health records (EHRs). The commenter believed the CMS proposal could require multiple organizations to modify data collection and IT systems and have significant spillover impacts into provider EHRs. Another commenter believed that prescriptive HRA elements would disrupt SNP operations and have an adverse impact on overall HRA completion rates. The commenter did not believe that the HRA questions themselves must be standardized in order for SNPs to have a more complete picture of their enrollees' risk factors.

A few commenters noted concerns about continuity in HRA data. A commenter expressed concern that, in the case of States and SNPs that have already been collecting this information, existing and baseline data could be lost or marginalized. Another commenter expressed concern that changes to their existing HRA would prevent them from doing effective historical data analysis.

Several commenters believed that requiring standardized questions would be burdensome for SNP enrollees, citing that enrollees may already be answering similar but slightly different questions in other assessments, such as in Medicaid programs. A commenter noted that most D-SNPs actively work with State partners to simplify data collection tools so that beneficiaries do not have to answer multiple questions with similar responses, and suggested that this proposal could get in the way of that coordination and lead to assessment burden among enrollees. A commenter expressed concern that beneficiaries would be required to answer multiple related questions solely as a result of this requirement.

Other commenters believed SNPs should be able to continue using their own assessment questions on topics

related to social risk factors because they tailored them to their specific enrollee populations and developed them over time to obtain more detailed information from enrollees. A commenter believed that standardized questions can lead to enrollees not feeling comfortable sharing information. Another commenter believed that CMS's proposal would prevent organizations from using validated questions they have determined work best to elicit information that is most effective in developing individualized plans of care for their enrollees. Another commenter believed plans are in the best position to review and revise their current HRAs to ensure collection of information and avoid overlap or unnecessary burden on enrollees.

A few commenters expressed concern about standardized assessment questions needing to be translated. A commenter stated that expectations of enrollees may differ in certain SNP service areas due to a range of cultural, linguistic, social, geographic, and economic factors, and believed that CMS should consider giving plans flexibility so that information on housing stability, food security, and access to transportation can be sought in a manner that is culturally and linguistically appropriate.

Response: We appreciate the commenters' concerns about requiring standardized questions in SNP HRAs. We recognize the challenge that CMS-specified standardized questions can pose to SNPs in terms of plan administrative burden and to enrollees in terms of potentially being asked multiple similar questions, and we acknowledge the commenters' perspective that SNPs are best-suited to develop questions that are most appropriate to their specific enrollee populations. We are also particularly sensitive to concerns about cultural and linguistic competence in HRAs. We agree with the commenter who stated that enrollee expectations may differ in different SNP service areas, and understand that an assessment question that is appropriate for one group of enrollees may be irrelevant or insensitive to another group. As discussed earlier in this section, we believe that the downsides of requiring specific standardized questions, including the potential administrative burden and duplication of existing efforts, outweigh the potential benefits of requiring specific standardized questions. However, we believe some degree of standardization helps ensure that SNPs are collecting high-quality, actionable responses from enrollees. We also believe using questions from a

CMS-specified list of screening instruments increases the likelihood of SNP HRA data being shared in a meaningful way because the answers can be comparable across populations that are using the same questions. Therefore, we are finalizing language at § 422.101(f)(1)(i) that requires SNPs to include one or more questions from a list of screening tools specified by CMS in sub-regulatory guidance on housing stability, food security, and access to transportation in their HRAs. The sub-regulatory guidance will include the option to use State-required Medicaid screening instruments that include questions on these domains. We believe the requirement we are finalizing allows SNPs enough flexibility to choose questions that are appropriate for their enrollee population, given that they will be able to choose from a CMS-specified list of assessment tools. We also believe the requirement we are finalizing addresses commenters' concerns about the need to make burdensome changes to information technology (IT) and EHR systems to utilize CMS-specified standardized questions. We aim to include validated, widely available screening tools in our sub-regulatory guidance, similar to the tools included in the proposed NCQA Social Need Screening and Intervention HEDIS measure. We believe many plans may already be using questions from one or more of these types of screening tools. As a result, relative to our proposal, we believe there will be less need for systems, IT, and EHR changes.

Comment: Many commenters expressed concern that requiring standardized HRA questions would lead to duplication of efforts, given existing State and provider SDOH assessment requirements. A commenter noted that plans, providers, and States have been using a variety of different screening tools for years that focus on similar SDOH domains but with questions that may differ slightly. A few commenters stated they did not fully support the proposal because many providers are duplicating this work at the clinic level. A commenter cited work that has gone into building SDOH screening and navigation into provider offices. Another commenter noted that it is important to continue to have flexibility for providers to pursue more in-depth screening in the clinical setting as they deem appropriate.

A number of commenters noted concerns about how the SNP HRA requirement might overlap with existing efforts, particularly at the State level. A few commenters stated that dually eligible individuals may be asked similar, but not identical, questions in

Medicaid managed care and in statewide D-SNP HRAs, and believed that the proposal to require standardized questions could therefore be challenging to implement. A commenter believed most D-SNPs already incorporate questions addressing social risk factors into their HRAs and actively work with State partners to simplify data collection tools and ensure the process is not burdensome for beneficiaries. A commenter recommended CMS give SNPs a menu of potential questions to include in their HRAs to potentially reduce overlap with other assessments. A few other commenters believed States should work with CMS on the development of standardized HRA questions and that CMS's rules should allow States to require alternative, standardized, State-specific HRA questions in addition to those CMS may specify in sub-regulatory guidance. The commenter believed this would improve alignment across each State's Medicaid program and reduce duplication for enrollees. Another commenter expressed support for standardization, but recommended that CMS allow for exemptions in cases where a State already requires assessments for social risk factors for Medicaid beneficiaries through other means, such as Health Homes and other Medicaid programs. The commenter noted that, in cases where community-based organizations are conducting care coordination activities such as assessments, standard measures and systems for collection can create a barrier due to the cost of systems, including updates or changes to existing systems, to support standardized data collection. A commenter believed that States would like to retain the right to modify D-SNP HRA questions to complement Medicaid assessment questions through the State Medicaid agency contract with D-SNPs required by § 422.107, and expressed uncertainty about whether that option would remain available under CMS's proposal.

Another commenter recommended CMS consider how to use information on social risk factors that is already being collected by different providers to populate a SNP enrollee's HRA when the information came directly from the enrollee within a given timeframe, rather than asking the enrollee to answer multiple similar questions.

A few commenters suggested CMS allow health plans to leverage community or provider organizations to complete these assessments. A commenter believed HRAs have a greater likelihood of being completed when conducted in the community

rather than by a health plan. Another commenter supported requiring standardized questions as outlined in the proposed rule, but encouraged flexibility in how the information would be gathered. The commenter noted they already require the same information as part of their State's comprehensive LTSS assessments.

Response: We thank the commenters for their input on how we can best minimize assessment burden while ensuring SNPs and States are capturing actionable information on these three social risk factors. SNPs can choose to utilize community-based organizations or other entities as subcontractors to conduct HRAs or portions of an HRA, and we have seen successful examples of this both with SNPs and MMPs. SNPs and MMPs are responsible for ensuring that their subcontractors meet all CMS care coordination requirements. As described in Medicare Part C Plan Technical Specifications for D-SNPs, CMS will accept a Medicaid HRA that is performed within 90 days before or after the effective date of Medicare enrollment as meeting the Part C obligation to perform an HRA, provided that the requirements in § 422.101(f)(1)(i) are met. We appreciate the commenters' concerns about duplication of efforts. We recognize that some SNPs, particularly D-SNPs, may already include questions related to housing stability, food security, and access to transportation on their HRAs to meet State requirements for assessing social risk factors. We also recognize that States may require D-SNPs to use particular assessment tools or questions on these topics to align with other State Medicaid initiatives or priorities, and that requiring SNPs to also include similar but not identical CMS-specified questions could result in redundant assessment questions that do not necessarily add to SNPs' knowledge of their enrollees' needs. When considered in combination with other concerns we discuss earlier in this section, we believe the potential downsides of requiring specific standardized questions—including potential redundancy and duplication of effort—outweigh the potential benefits of requiring all SNPs to use the same standardized questions. However, we maintain that some level of standardization is necessary to ensure SNPs are using validated questions and collecting reliable, actionable responses from enrollees. Therefore, we are finalizing language at § 422.101(f)(1)(i) that requires SNPs to include one or more questions on housing stability, food security, and access to

transportation from a list of screening tools specified by CMS in sub-regulatory guidance in their HRAs but does not require SNPs to adopt standardized questions on these topics. We will consider State requirements in establishing the list of screening tools in sub-regulatory guidance. As a result, the sub-regulatory guidance will include the option to use any State-required Medicaid screening instruments that include questions on these domains. This modification to our proposal will allow SNPs to continue to use questions on social risk factors that States may already require and will prevent duplication of efforts.

Comment: Some commenters recommended CMS consider the use of standardized coding of responses rather than standardized responses. A commenter noted that with standardized data elements, assessment information would be interoperable to help plans, providers, States, and community-based organizations collectively identify and address social needs. Several commenters noted that standardized data elements would allow CMS to collect the assessment data and suggested that CMS specify a permissible set of SDOH screening tools to ensure the use of person-centered and validated tools without mandating specific standardized questions. A few of these commenters noted that requiring standardized data elements rather than standardized questions would be easier for SNPs to implement, potentially allowing them to continue to use their existing HRA questions that cover housing stability, food security, and access to transportation. A commenter noted this would allow SNPs to ensure HRA questions are culturally appropriate when translated across the many languages that SNP enrollees speak. The commenter also stated standardized coding would give plans the flexibility to ask questions in a way that accommodates the specific communication needs of enrollees, such as individuals with intellectual disabilities.

A commenter suggested CMS look to the Gravity Project for standardized value sets, interoperable codes, and HL7 technical standards to document standardized data on social needs. The commenter noted interoperable codes could include codes from ICD-10 Z codes, LOINC codes, and/or SNOMED code sets, among others.

Response: We appreciate the commenters' suggestions and will consider them as we develop the list of specified screening instruments in sub-regulatory guidance. We aim for SNPs to utilize questions from assessment tools

that have the capability to facilitate data exchange as well as systematic analysis of prevalence and trends in their enrollees' social risk factors.

Comment: A commenter suggested that CMS create a standardized data submission tool to collect social risk factor-related data in a way most compatible to how the MA plans currently collect and report that data. The commenter expressed concern that requiring a standardized reporting format would cause MA organizations already actively collecting this data to undertake a potentially costly adjustment to their HRA operations. Another commenter stated health plans consistently identify the lack of standardization in SDOH data definitions and lack of harmony in scaling and scoring between assessment instruments as challenges. The commenter noted that requiring a specific instrument across settings and providers could solve this issue, but noted that another solution would be to allow for multiple screening instruments where items and scoring are cross-walked to create a universal scale. Several commenters recommended CMS allow SNPs to capture the required SDOH data using their own methods, including but not limited to HRAs, then crosswalk the data to CMS-specified data elements in order to report it to CMS. A few commenters specifically recommended that CMS work with experts to conduct a cross-walk of SDOH risk factor items from validated instruments and then create an acceptable equivalence to harmonize, calibrate and connect the items, scaling, scores, and findings from the various instruments to one standardized universal scale for each SDOH risk item. A commenter believed multiple data sources would be able to feed into the SDOH data that CMS could collect.

Response: We thank the commenters for these suggestions. We remind the commenters that CMS does not currently collect information related to social risk factors from SNPs. CMS currently only collects information regarding the number of initial and annual HRAs conducted as part of the Medicare Part C Reporting Requirements and reviews a sample of HRAs conducted by SNPs during audits. We will consider this feedback as we continue to consider whether, how, and when we would have SNPs report data to CMS.

Comment: A commenter believed that focusing on the annual HRA only as a source of information on enrollees' social risk factors would miss opportunities to better understand enrollee needs and would have limited

impact. A commenter noted that allowing SNPs to capture SDOH data outside of the HRA process would be sensitive to the personal nature of questions about social risk factors and allow the care team member the enrollee trusts the most to ask the questions. Another commenter believed CMS should allow collection of social risk factor information through HRAs or through other screening processes, and that CMS should require use of that social risk factor data in risk assessment and navigation to supports.

A commenter suggested that, instead of requiring plans to incorporate specific questions in their HRAs, CMS could require plans to include a minimum number of social needs-related questions in their HRAs, the SNP Model of Care, or as part of the Managed Care Manual Chapter 5 requirements. The commenter believed this alternative approach would fulfill the intent of the proposed requirement while providing plans the flexibility to leverage existing social risk factor questions they have already incorporated into their HRAs, minimizing the need for edits to existing HRAs.

Response: We appreciate SNPs' efforts to address their enrollees' unmet needs through their models of care, quality improvement projects, and various touchpoints with enrollees. We clarify that the new requirement at § 422.101(f)(1)(i) does not say that SNPs are to use the HRA as the only source of information on enrollee social risk factors. In addition to HRAs, we encourage SNPs to use sources of information outside of the HRA process in order to ensure that SNPs have a complete picture of an enrollee's physical, psychosocial, functional, and social needs and their personal goals. This can include, but is not limited to, interactions between enrollees and providers, care coordinators, other members of the integrated care team, or community-based organizations. This information can assist with the development of and any updates to an enrollee's individualized care plan. Though SNPs may use a variety of sources of information to better understand their enrollees' needs, we are finalizing a requirement for SNP HRAs to include questions from a list of CMS-specified screening tools about housing stability, food security, and access to transportation because all SNPs are required at § 422.101(f)(1)(i) to conduct a comprehensive HRA. Making this requirement part of the HRA ensures all SNPs are universally collecting this information, at minimum, in their assessments,

regardless of any other sources of information on enrollee social risk factors they may use. As described elsewhere in this section, we have considered commenters' perspectives in coming to a final decision regarding a requirement to use CMS-specified standardized questions, and are instead finalizing language at § 422.101(f)(1)(i) that requires SNPs to include questions from a list of screening tools specified by CMS in sub-regulatory guidance on housing stability, food security, and access to transportation in their HRAs.

Comment: Many commenters recommended CMS gather further input from stakeholders, including enrollees, plans, SDOH assessment tool developers, and providers, to develop the proposed standardized HRA questions before releasing sub-regulatory guidance. A few commenters suggested CMS convene a technical expert panel to consider research on the comparative effectiveness of existing social needs screening tools and to develop and test a social needs prescreener. A commenter noted that the complexity of capturing social needs requires a thoughtful and multifaceted understanding of enrollee populations. Another commenter recommended CMS conduct a landscape review and align requirements to build off of what plans have already accomplished. A commenter suggested CMS initially gather information on one or two questions per SDOH topic so that plans can begin to incorporate standardized questions into their HRAs while continuing to use most of their own already-tested questions with enrollees. Another commenter believed CMS should not dictate specific questions without going through a consensus process for measure development, such as the National Quality Forum, and noted that SNPs should be able to incorporate CMS's required questions into their existing assessment tools.

A commenter urged CMS to seek provider feedback on the wording of standardized HRA questions. Several commenters suggested CMS incorporate direct enrollee input into any required HRA questions to ensure they are understandable and relevant to the intended audience. A commenter offered to provide CMS input into the development of the standardized questions that would work well across diverse enrollee populations. A commenter believed enrollees should have opportunities for feedback and oversight not only on screening questions, but also on any navigation and referral system a plan may use to meet the needs enrollees identify. Another commenter stated that CMS

should not rush to use questions that collect questionable, unreliable, or inconsistent data.

Response: We thank the commenters for their suggestions. We agree that the complexity of capturing social needs requires a thoughtful and multifaceted understanding of enrollee populations. We are not finalizing the proposed requirement that SNPs use standardized questions specified by CMS on these topics. Instead, we are finalizing a requirement that SNPs use questions on these topics from a list of screening tools specified by CMS in sub-regulatory guidance. In developing this sub-regulatory guidance, we will consider the extensive work that health plans, the Federal Government, tool developers, and other stakeholders have already done to research and validate screening instruments. We clarify that we did not propose to create new measures, nor did we intend to require that SNPs adopt new assessment tools wholesale. Rather, we proposed to require SNPs to incorporate CMS-specified standardized questions about housing stability, food security, and access to transportation into their HRAs; we had intended that existing standardized questions, from existing validated assessment tools, would be specified by CMS for use by SNPs. Although we are not finalizing a requirement for SNPs to use CMS-specified standardized questions, we are finalizing a requirement that SNPs use questions from a list of screening instruments specified by CMS in sub-regulatory guidance. We anticipate this list will include validated, widely used assessment tools that include questions on housing stability, food security, and access to transportation.

Comment: Several commenters supported CMS's proposal to apply this HRA requirement across all SNPs. A commenter noted that all SNP enrollees are at elevated risk of experiencing health-related social needs. A few commenters recommended that CMS apply a requirement to screen beneficiaries for social risk factors beyond SNPs. A commenter suggested that CMS consider how to encourage all MA plans to screen beneficiaries for social risk. Another commenter encouraged an even greater expansion of this type of data collection across the Medicare program, noting that data collection by MA plans could provide a model for other providers in better understanding gaps in health equity especially given that racial minorities make up a larger percentage of MA enrollees than Original Medicare enrollees. Other commenters recommended that CMS work to implement social risk screening

consistently across both the Medicare and Medicaid programs.

Response: We appreciate the commenters' support and suggestions for expanding our proposed requirement beyond SNPs. We agree that greater prevalence of screening for social risk factors can help providers better understand health disparities for all MA enrollees and will consider future rulemaking on this subject. In this final rule, we are limiting the new requirement to include questions on housing stability, food security, and access to transportation on HRAs to SNPs because we believe SNP enrollees are more likely than other MA enrollees to have particular challenges with unmet social needs.

Comment: A commenter encouraged CMS to consider excluding institutional special needs plans (I-SNPs) from the requirement to include questions on housing stability, food security, and access to transportation in SNP HRAs. The commenter noted that all I-SNP enrollees reside in nursing facilities, which provide housing, meals, and transportation. The commenter also noted that nursing facilities are required to conduct minimum data set assessments and meet other requirements, and believed that requiring I-SNPs to assess enrollees for social risk factors would add administrative burden for the plan and potential confusion for enrollees with no apparent benefit. Another commenter believed that the proposal to include questions about housing stability in SNP HRAs was equally important to enrollees who reside in congregate housing as those who live in the community. The commenter noted that some residents of congregate housing may be spending down resources and believed it would be helpful to understand if an individual's current housing arrangements are precarious, potentially allowing a plan to connect them with needed services or resources.

Response: We disagree that assessing nursing facility residents for social risk factors in HRAs provides no apparent benefit. An enrollee residing in a nursing facility or other congregate housing setting can have concerns about the stability of their living situation. And, as we noted in the proposed rule preamble at 87 FR 1860, people may move between settings, including from an institutional placement to the community. In addition, I-SNPs may enroll individuals living in the community who require an institutional level of care, for whom housing stability could be of particular concern. I-SNPs, like other SNPs, are required at

§ 422.101(f)(1)(i) to conduct an initial as well as annual comprehensive HRA. We believe that the benefit of better understanding enrollee needs outweighs any potential burden of adding a few questions to the required assessment. However, we recognize that the types of questions that may be relevant for community-dwelling SNP enrollees may be less relevant for I-SNP enrollees who reside in a nursing facility. Therefore, we are allowing some flexibility for SNPs by finalizing regulatory language at § 422.101(f)(1)(i) which requires SNPs to include questions from a list of CMS-specified screening instruments on these three topics in the initial and annual HRA.

Comment: Numerous commenters provided feedback on the timing for enforcement of the proposal. A few commenters recommended requiring HRA questions on social risk factors as quickly as possible rather than delaying until contract year 2025. A commenter noted that the three proposed question topics are already well-developed in 2022 and believed the questions are too important to delay beyond 2024. Other commenters expressed support for implementing the requirement in contract year 2024. Several commenters recommended CMS consider delaying implementation beyond 2024. A commenter requested that CMS make the effective date no earlier than 2025 to allow time for plans to design, test, evaluate, and operationalize the requirements. Another commenter recommended CMS provide sub-regulatory guidance on the specific standardized questions at least one year in advance of the required implementation to allow SNPs time for IT, system, and process changes. A few commenters suggested that CMS consider allowing flexibility in the time granted to implement standardized questions. Other commenters urged CMS to effectively communicate their requirements and implementation timeframe to States to allow time for States to remove any overlapping assessment requirements.

Some commenters stated they were supportive of a 2024 effective date only if CMS did not require standardized questions, and noted that, if CMS did require standardized questions, they requested an effective date no earlier than 2025 to allow SNPs sufficient time for implementation. A few of these commenters believed the implementation timeline should depend on the scope and complexity of the questions CMS ultimately requires.

A commenter encouraged CMS to give plans at least six months' notice of final requirements before the implementation

date. A commenter noted that any change of assessment questions could have implications for EHR vendors that would need to implement such changes within an 18- to 24-month cycle. A plan commenter stated they would require 90 days to implement additional HRA questions.

Response: We appreciate the commenters' input on the implementation timeline for our proposal. We are finalizing a requirement at § 422.101(f)(1)(i) that SNPs must include questions from a list of screening instruments specified by CMS in sub-regulatory guidance on housing stability, food insecurity, and access to transportation beginning contract year 2024. We will ensure compliance with the Paperwork Reduction Act as we strive to post the sub-regulatory guidance by the end of 2022. This would leave more than a year from publication of this final rule for SNPs to come into compliance. The comments we received suggested that many SNPs already include questions on these topics in their HRAs. We believe many of the SNPs that are already including questions on these topics are using certain validated, widely available screening instruments. In our sub-regulatory guidance, we anticipate including validated tools that are already widely in use. Because we believe many SNPs are already using these types of screening tools, and because we are not requiring the use of specific standardized questions, we believe it is reasonable for SNPs to implement this requirement in contract year 2024.

Comment: Many commenters expressed concern about SNPs' responsibility to address social risk factors identified through the HRA. Several commenters noted that the HRA should be used to inform the enrollee's individualized care plan as well as to connect enrollees to covered services and community resources. A commenter noted that developing the enrollee's plan of care invites the SNP to form community partnerships that will allow them to address enrollee needs. The commenter believed these partnerships were crucial to reducing health disparities. Another commenter believed that assessments must be paired with strong connections to community-based organizations, including innovative approaches to payment for these organizations.

A number of commenters recommended CMS take steps to ensure SNPs are acting on the information they receive in HRAs. A commenter encouraged CMS oversight to ensure that HRA results are included in

enrollees' individualized plan of care. Another commenter believed CMS should emphasize that HRA questions related to social risk factors would help inform, but not direct, a provider's plan of care. A commenter expressed concern with CMS's statement, described at 87 FR 1859, that CMS would not be explicitly requiring that SNPs be accountable for resolving all risks identified in the HRA questions. The commenter believed CMS should require this type of accountability for SNPs. A few commenters requested CMS consider going beyond requiring HRA questions and work with plans to ensure that plans are not only assessing and referring enrollees to services, but also confirming that needed social services have been received. A commenter believed there needs to be a clear level of understanding of who is responsible for connecting a patient to services, and that there is potential for doing more harm than good by frequently asking enrollees about their social risk factors but not addressing them. A few commenters believed that screening without a strong referral and navigation system is ineffective, disrespectful, and unethical, and it can undermine enrollee trust in providers. Another commenter suggested that assessments for social risk factors be conducted on a monthly basis and even more frequently based on an enrollee's needs.

A few commenters urged CMS to consider how it can encourage and support plans to use data collected in HRAs in meaningful ways, and what guidance and resources it can provide plans on meeting enrollees' social needs. Another commenter urged CMS to establish oversight mechanisms and standards to ensure that SNPs have systems in place to assist enrollees based on the needs identified in the HRA. A commenter encouraged CMS to track HRA data to identify trends and potentially compare to the supplemental benefit offerings and utilization. Another commenter urged CMS to provide not just standardized questions but also guidance around framing, an explanation of why the questions are being asked, and expectation setting about how the information will be used to ensure it is maximally actionable.

Other commenters expressed concern about increasing demand for community-based services. A commenter noted that, even with services in place, enrollees may face access challenges, especially in rural areas. Another commenter believed that increasing screening for social risk factors would create more demand for an already-taxed community-based

services infrastructure, which would inadvertently create new or exacerbate existing health disparities. The commenter recommended CMS work with the Administration for Community Living to continue to build community-based organizations' capacity to partner with health plans. The commenter also recommended CMS encourage financial investments in the community-based services infrastructure through value-based payments and flexible spending arrangements.

Response: We thank the commenters for their perspective on this issue. We agree that it is important for SNPs to not only assess their enrollees for social risk factors, but also connect them to needed services based on enrollee goals and preferences, whether such services are plan-covered benefits or referrals to community resources. We believe requiring all SNPs to include questions on enrollees' housing stability, food security, and access to transportation will help inform the comprehensive individualized plan of care required at § 422.101(f)(1)(ii); these individualized plans of care identify goals developed with the enrollee and measurable outcomes as well as describe specific services and benefits. At 87 FR 1859 in the proposed rule, we provided several examples of the ways in which SNPs could consult with enrollees about their unmet social needs as part of the development of individualized care plans, such as making a referral to an appropriate community partner. We appreciate the need for additional technical assistance on addressing the social needs of enrollees and will consider it in the future.

Comment: A commenter stated it is important to understand how the SDOH data that is collected through the new required questions is going to be used, including what the proposed output would be if those data elements are required to be reported to CMS.

Response: We clarify that the SDOH data collected as part of an HRA would be used to inform a SNP enrollee's individualized care plan based on the enrollee's goals. The language we are finalizing at § 422.101(f)(1)(i) does not require SNPs to submit HRA data to CMS. However, as we outlined in the proposed rule at 87 FR 1859, we continue to consider whether, how, and when we could have SNPs report this data to CMS under other regulations. If SNPs do submit this data to CMS in the future, we believe having such information could help us better understand the prevalence and trends in certain social risk factors across SNPs and consider ways to support SNPs in improving enrollee outcomes.

Comment: Several commenters suggested that CMS clarify that SNPs are not responsible for addressing all enrollee social risk factors identified during the HRA. A commenter requested clarification on whether CMS's expectation would be that these questions trigger care management outreach. Another commenter noted that plans often do not have the ability to address all the systemic barriers to achieving optimal health outcomes that may be identified in the HRA. A few commenters believed addressing social risk factors requires resources beyond what a SNP can offer, or may lie outside a SNP's control. A commenter believed that an organization's ability to address enrollee social needs depends on many factors, such as geographic location and resource availability in their communities, among others. Another commenter believed HRA questions about social risk factors could cause enrollee confusion, noting that an enrollee who indicates they are struggling to afford their rent may expect a health plan to provide a solution—perhaps a referral to a community housing resource—but then experience frustration and disappointment when a health plan is unable to do so.

A commenter expressed concerns about how SNP auditors may interpret this proposed requirement. The commenter believed that program auditors have demanded verification that such risks or needs are assessed and resolved. The commenter strongly encouraged CMS to include language in the SNP audit protocols emphasizing that the focus of this requirement, if finalized, is on assessment not resolution.

Response: We appreciate the commenters' perspectives on this issue. As stated at 87 CFR 1859, our proposal regarding the content of the HRA would not require SNPs to be accountable for resolving all risks identified in these assessment questions. The information gathered in the HRAs must be used to inform the development of the individualized care plan per § 422.101(f)(1)(i) and (ii). Section 422.101(f)(1)(i) requires the SNP to ensure that the results from the initial and annual HRAs are addressed in the individualized care plan. Section 422.101(f)(1)(ii) also provides that the individualized care plan must be developed and implemented in consultation with the beneficiary. The SNP must take steps to provide the services or connect the enrollee with appropriate services in order to accomplish the goals identified in the individualized care plan. The SNP can

take these social risk factors into account in the development and implementation of the individualized care plan, even if the SNP is not accountable for resolving all social risk factors. For instance, knowing that an enrollee is homeless or lacks reliable transportation could change how the SNP delivers covered services, such as by helping the enrollee find a primary care physician (PCP) that is more conveniently located or suggesting that the enrollee utilize a Federally Qualified Health Center (FQHC) in order to get multiple services delivered at the same time.

We remind the commenter who expressed concerns about how SNP auditors may interpret this proposed requirement that CMS welcomes stakeholder feedback on the audit protocols when the collection becomes available for public comment under the Paperwork Reduction Act of 1995. We also remind commenters of the requirement at § 422.503(b)(4)(vi) for MA organizations to adopt and implement an effective compliance program to prevent, detect, and correct non-compliance with CMS's program requirements, including the requirement at § 422.101(f)(1)(ii) that SNPs must develop and implement an individualized care plan.

Comment: Some commenters provided feedback on CMS's intent to provide the specific HRA questions through sub-regulatory guidance. Several commenters indicated they were supportive of this approach. A commenter agreed that it is important for CMS to retain the discretion to modify questions while still providing SNPs with clear requirements. Another commenter recommended CMS include a statement in sub-regulatory guidance to discourage States from adding their own questions and to encourage data sharing. A few commenters encouraged CMS to provide additional detail on how SNPs should implement this proposal.

Other commenters did not support CMS's intent to specify the questions in sub-regulatory guidance. A commenter believed this information should be standardized across plans and Medicare programs, rather than being specified in sub-regulatory guidance applicable to SNPs only. Another commenter strongly suggested CMS include any questions or specific requirements in regulation text because the commenter would like as much time as possible to implement changes, and believed the predictability of the regulatory cycle would allow them to better plan for policy changes.

Response: We appreciate the commenters' perspectives on use of sub-

regulatory guidance to specify standardized questions. We believe that specifying the topics in regulation while providing additional operational detail in sub-regulatory guidance strikes the appropriate balance between the need for stability and predictability for plans and the need to be able to revise the specific questions to stay aligned with similar assessment tools. Although we are not requiring SNPs to use specific standardized questions, we believe a degree of standardization is necessary to ensure that SNPs are gathering high-quality, actionable responses from enrollees on their social risk factors. We also believe that allowing SNPs to choose questions from a list of screening instruments may increase opportunities for alignment with other efforts in this area, including NCQA's proposed Social Need Screening and Intervention HEDIS measure, as discussed in more detail later in this section. Therefore, we are finalizing a requirement at § 422.101(f)(1)(i) that SNPs include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on each of these three topics. We believe the requirement we are finalizing addresses commenters' concerns about the lack of predictability involved in specifying required HRA questions in sub-regulatory guidance, since SNPs will be able to choose questions on these topics from the list of screening instruments in sub-regulatory guidance that best meet the need to assess housing stability, food insecurity, and access to transportation for the specific population they serve. We intend to issue the first sub-regulatory guidance on this issue by the end of 2022 and will revise and update the guidance as necessary in the future.

Comment: A few commenters recommended CMS consider privacy and confidentiality as part of this proposal. A commenter strongly urged CMS to provide adequate protection for and confidentiality of information collected through HRAs, noting that the collection and use of SDOH-related information should be held to the highest standard and that appropriate oversight and enforcement should restrict inappropriate use and access. Another commenter recommended CMS maintain high data security standards to ensure the collection of demographic information be conducted in a transparent, secure, and culturally sensitive manner for the targeted populations in question to reduce systemic bias. Another commenter asked for clarification as to whether the

HRA is intended to be delivered by and stored as part of the EHR.

Response: We appreciate the commenters' concerns for protecting enrollee privacy. At a minimum, all MA plans, including the SNPs that are subject to this new requirement, must ensure the confidentiality of enrollee records under § 422.118 and the Health Insurance Portability and Accountability Act (HIPAA) Security and Privacy Rules at 45 CFR part 164. Enrollee records that must be protected under § 422.118 include the information collected as part of health risk assessments, and we believe that information gathered through SNP HRAs is protected health information (as defined in 45 CFR 160.103) subject to protection under HIPAA rules. We agree that information related to social risk factors is particularly sensitive and should be handled accordingly. We do not intend to specify how SNPs store this information. We remind the commenters that CMS does not currently collect this type of information from SNPs. Should CMS collect this information in the future, we will protect enrollee privacy as we do more broadly when handling beneficiary data.

Comment: Several commenters noted related efforts within and outside of CMS that they recommended CMS leverage when determining what questions to include in the HRA. A few commenters noted the Social Need Screening and Intervention quality measure under development from NCQA. Several others noted the work of the Gravity Project, supported by the Office of the National Coordinator for Health Information Technology, including the USCDI v2. A commenter strongly encouraged alignment with USCDI v2. A few commenters supported leveraging and aligning with the work of the Gravity Project, as well as ensuring alignment with other programs. A commenter noted CMS's proposal is consistent with the February 1, 2022 National Quality Forum Measure Applications Partnership recommendations to CMS for screening for social drivers of health and public data on those screening positive for social drivers of health. Another commenter cited a proposal for a similar quality measure for use in the Merit-Based Incentive Payment System for physicians and Inpatient Quality Reporting program for hospitals. A commenter also encouraged an approach that utilizes publicly available tools, such as the AHC HRSN screening tool, and does not require use of any specific proprietary screening tool.

Response: We appreciate the additional information and have been closely reviewing other SDOH efforts both within the Federal Government and other parts of the industry, including NCQA's proposed new Social Need Screening and Intervention HEDIS measure and discussion in the contract year (CY) 2023 Rate Announcement about comments received on potential future use of that proposed measure in Star Ratings. We recognize that there are a number of well-developed validated assessment tools with questions on the three proposed topics already in use by plans. We agree that our efforts should align with other programs. As we discussed in responses to earlier comments, we are finalizing a requirement at § 422.101(f)(1)(i) that SNPs must include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance about housing stability, food insecurity, and access to transportation in their HRAs, rather than requiring specified standardized questions. We believe allowing some flexibility for SNPs to choose questions best suited to their enrollee populations is important; however, we also believe some degree of standardization is necessary to ensure SNPs are collecting high-quality, actionable responses from enrollees. Furthermore, we believe this approach better allows us to align with other programs and SDOH efforts and retains the potential for improved data exchange and interoperability. For example, in response to the 2023 Advance Notice, the vast majority of commenters supported the use of NCQA's proposed screening and referral to services for social needs measure in MA Star Ratings. We believe our requirement would align well with potential use of that measure in Star Ratings. The proposed NCQA measure does not require use of a specific tool or questions, but would allow use of questions from a list of selected validated assessment instruments, similar to the new requirement finalized here at § 422.101(f)(1)(i). We anticipate our list of screening instruments in sub-regulatory guidance will overlap with the list of screening instruments NCQA includes in the specifications for its proposed measure, which will provide the opportunity for SNPs to align their compliance with the new requirement at § 422.101(f)(1)(i) with data to be used for the proposed NCQA measure. We believe the result will still be an increased ability for interoperable data exchange among SNPs.

Comment: A commenter requested clarification on several aspects of our

proposal. The commenter questioned whether the HRA questions should be included on the initial, reassessment, and transition HRAs and whether each plan would be required to include the same questions on the HRA or whether it would be up to the individual plan to determine wording and how these new question sets fit into other existing domains.

Response: We appreciate the commenter's request for clarity. We clarify that the questions should be included in all HRAs used by SNPs. On the commenter's request for clarification about question standardization, we clarify that our original proposal would have required SNPs to use CMS-specified standardized questions. However, as discussed earlier in this section, we are instead requiring SNPs to use one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance in each of the three required domains. However, SNPs can determine how any new questions they add to their HRA in order to meet the new requirement fit into their existing assessment process.

Comment: A commenter requested CMS clarify how SDOH-related information may be used if an HRA identifies an issue that is not identified by a provider and asked how CMS intends to treat that information for other MA purposes.

Response: We thank the commenter for their questions and note that, per § 422.101(f)(1), the enrollee's providers should be included as part of the interdisciplinary care team (ICT) and the information from HRAs should be shared with the ICT as described in the SNP's MOC. As discussed in more detail in other comments and responses earlier in this section, the individualized plan of care for an enrollee must be developed in consultation with the enrollee and the care plan should address the results from HRAs. A provider is not required to independently identify a social health factor for it to be addressed in the care plan. As to the treatment of the information for other MA purposes, CMS does not currently intend to collect information about the responses on these newly required questions from SNPs. CMS may review HRAs and responses in order to determine compliance with the regulatory requirement.

Comment: A commenter encouraged CMS to allow for a wider range of providers who can conduct the HRA without the oversight of physicians and requested that CMS to continue to allow non-physician clinicians to conduct the HRA using telehealth under the

supervision of a physician. They asked CMS to provide additional resources to community advocates, who can facilitate remote provider-patient interactions. A commenter suggested that enrollees, especially those with nutrition-related chronic conditions, should receive a referral to registered dietician nutritionists when food insecurity is identified.

Response: We thank the commenters and note that § 422.101(f)(1)(i) does not stipulate that specific plan personnel must conduct the HRA. CMS does not require physicians to oversee providers or other staff when conducting an HRA and allows SNPs flexibility to determine the level of clinical expertise needed to conduct the HRA. CMS does not preclude the use of telehealth to conduct HRAs. SNPs must conduct their HRA in a manner that is consistent with the plan's approved MOC; approval of the MOC is required by § 422.101(f)(3). We appreciate the information on community resources for referrals provided by commenters and will consider providing additional education on resources available to fill enrollee's needs as determined by the HRA and ways to support community-based organizations.

Comment: A commenter urges CMS to require that these standardized questions be made available and accessible in the preferred languages of the enrollees. They noted that for individuals with limited English proficiency, the inability to communicate adequately with providers serves as a barrier to accessing care.

Response: We appreciate the commenter's perspective on this issue. In § 422.112(a)(8), we require that MA organizations that offer MA coordinated care plans ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse ethnic and cultural backgrounds. The HRAs conducted by SNPs are key to developing individualized care plans for enrollees and such care plans are the foundation for furnishing, coordinating, and managing covered services to the special needs individuals who are enrolled in SNPs. Further, § 422.2267(a)(2) requires that, for markets with a significant non-English speaking population, MA organizations translate required materials into any non-English language that is the primary language of at least five percent of the individuals in a plan benefit package (PBP) service area. As HRAs are required by § 422.101(f)(1), SNPs are obligated to comply with

§§ 422.112(a)(8) and 422.2267(a)(2) in performing these assessments.

Comment: A commenter requested that CMS review and rewrite the technical specifications of the existing SNP care management reporting measure. They stated that, as currently written, a plan is required to conduct two HRAs (an initial and a reassessment) in the same calendar year for members who did not complete an HRA the previous year. They believe that the “doubling up” of HRAs in the same year can create member abrasion.

Response: This comment is out of scope of this final rule; however, we will consider it in future reporting specifications.

Comment: A few commenters stated that, under current statutory authority, SDOH cannot be used as primary targeting criteria for Special Supplemental Benefits for the Chronically Ill (SSBCI), just as secondary criteria when the three-part eligibility criteria have been met. The commenters recommend that CMS provide additional flexibilities to equip plans with the ability to address the social needs for which standardized data collection is being proposed in this rule. They recommend CMS consider allowing plans to use indicators of SDOH need outside of low-income subsidy status as primary targeting criteria through the Value-Based Insurance Design demonstration under Center for Medicare and Medicaid Innovation authority. They stated that this demonstration can serve as a pilot for potentially expanding the eligibility criteria for SSBCI in the future.

Response: We appreciate the recommendations for using SDOH data for determining eligibility for SSBCI and will consider it in the future. With regard to the commenters’ recommendation that CMS provide additional flexibilities to equip plans with the ability to address social needs, we remind the commenter that, as discussed in more detail earlier in this section, SNPs must use the information gathered in the HRA to inform the development and implementation of the individualized care plan, and to ensure that the results of HRAs are addressed in the care plan per § 422.101(f)(1)(i) and (ii). We also remind the commenters that SNPs are not required to furnish housing, food, or transportation services. Changing the scope and criteria for SSBCI is outside the scope of this rulemaking.

Comment: A few commenters requested that CMS explore the potential use of standardized SDOH data more broadly in the Medicare Advantage program, such as in the Star

Ratings program and in the CMS–HCC (hierarchical condition category) risk-adjustment model. Another commenter noted that the adoption and optimization of EHR infrastructure in low-resource settings is vital to increasing interoperability, as providers in underserved communities typically have outdated systems unable to integrate with other sources. A commenter also stated that the software development community is missing important guidance that would allow them to promulgate consensus-based standards for the exchange of SDOH data with providers and community-based organizations. A commenter strongly supported efforts to promote greater flexibility and alignment of provider payment incentives for care that address social needs and outcomes that advance health equity, noting that such measures can include incentives to increase provider uptake of evidence-based, high-value, low-cost services known to improve patient health outcomes.

Response: We agree that the use of SDOH data can provide us with a better understanding of enrollees. We thank commenters for raising these important issues. However, addressing SDOH and social risk factors in the context of payment policy, interoperability and EHR standards, and quality rating programs is outside the scope of this rulemaking. We note that CMS has discussed SDOH and social risk factors in other contexts, such as in the CY 2023 Rate Announcement, which discussed comments received on MA risk adjustment payment policy and use of a health equity index in MA/Part D Star Ratings. We appreciate the commenter’s perspective on alignment of provider payment incentives for care to address social needs, but the topic is outside the scope of this rulemaking. Further, CMS is prohibited from requiring MA organizations to use particular payment arrangements with their contracted providers by section 1854(a)(6)(B) of the Act, but we will take these comments into consideration with regard to the Medicare FFS program and Innovation Center models.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing a requirement at § 422.101(f)(1)(i) for SNPs to include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on housing stability, food insecurity, and access to transportation in their comprehensive risk assessment tool. However, we are not finalizing the

proposal that SNPs use specific standardized questions.

5. Refining Definitions for Fully Integrated and Highly Integrated D–SNPs (§§ 422.2 and 422.107)

Dually eligible individuals have an array of choices for how to receive their Medicare coverage. Those choices vary by market, and not all dually eligible individuals may qualify for all options, but they include Original Medicare with a standalone prescription drug plan, non-D–SNP MA plans, FIDE SNPs, HIDE SNPs, coordination-only D–SNPs, and Programs of All-Inclusive Care for the Elderly. Those choices can be complex and, for some, overwhelming.

Our own terminology is complex too. While we have defined terms through rulemaking in § 422.2, there remains nuance and variation that may make it difficult for members of the public—and even the professionals who support them—to readily understand what may be unique about a certain type of plan or what a beneficiary can expect from any FIDE SNP, for example. We proposed several changes to how we define FIDE SNPs and HIDE SNPs, citing our belief that they would ultimately help to differentiate various types of D–SNPs and clarify options for beneficiaries.

Comment: Numerous commenters expressed support of CMS’s proposed changes to refine the definitions of FIDE SNPs and HIDE SNPs. MACPAC echoed this support and expressed the belief that CMS’s proposal furthers integration and clarifies the definitions of FIDE SNPs and HIDE SNPs. MedPAC supported the proposed changes to the FIDE SNP requirements, stating that it believed the changes will help ensure that those plans are fully integrated with Medicaid and make it easier for beneficiaries to understand how they differ from other, less integrated D–SNPs. MedPAC also supported the proposed changes to the HIDE SNP requirements as an incremental step towards greater integration. Others also believed that CMS’s proposal raises the standards for integration in SNP products. Several commenters agreed that the proposed refinements increase transparency of the options available for dually eligible beneficiaries. A commenter appreciated that CMS’s proposal may encourage more States and health plans to provide integrated care for dually eligible individuals. Another commenter expressed support that the proposal would allow standards for quality measures set to be set more accurately, services provided more effectively, and plans held more accountable. A commenter stated that

Minnesota Medicaid products continued to meet the proposed definitions. A commenter urged CMS to require plans to make their status as a FIDE SNP or HIDE SNP more transparent to ensure beneficiaries and their advocates can understand the level of alignment and integration they should expect from their current or potential plan.

MACPAC cautioned that some States may need support to implement the new requirements and that there is some risk that the new requirements may lead to fewer FIDE SNP or HIDE SNPs available in the market. MACPAC suggested that CMS work closely with States and plans to remove barriers to offering FIDE SNPs and HIDE SNPs to make these integrated plans more available. Another commenter expressed a similar concern that States may choose to have less integrated systems due to limited State capacity and challenges with conflicting timelines for Medicaid requests for proposal and procurements and for CMS and D-SNP contracts. The commenter recommended several proposals to ease the burden for States, including CMS developing educational materials on the benefits of integrated care and CMS working with Congress to develop formal requirements and strategies to integrate care and increase State funding. Another commenter suggested that CMS encourage States to use a request for proposals process for FIDE SNPs to ensure FIDE SNPs are best positioned to support State and CMS goals for integration.

Response: We appreciate the robust support for our proposed changes to the FIDE and HIDE SNP definitions. We agree with commenters that the changes to the definitions will ultimately help differentiate the types of D-SNPs, clarify options available to beneficiaries, and improve and increase integrated coverage options for dually eligible individuals.

We appreciate the comments about States needing support to take actions that make HIDE SNP or FIDE SNP designation attainable for D-SNPs that operate in the State. CMS will continue to engage with States to promote integration, directly as well as by providing education to States about this final rule through our technical assistance contract with the Integrated Care Resource Center, which provides a range of written and live resources targeted to State Medicaid staff, such as sample contract language for State Medicaid agency contracts with D-SNPs, tip sheets describing exclusively aligned enrollment and other operational processes that support Medicare and Medicaid integration,

educational materials and webinars about D-SNPs and highlighting State strategies for integrating Medicare and Medicaid, and one-on-one and small group technical assistance.

We acknowledge the suggestion for us to work with Congress on requirements and strategies to integrate care and increase State funding. While outside the scope of this rulemaking, we will consider whether there are additional opportunities to address this in the future. A Federal requirement for States to use a request for proposal process is outside the scope of this rulemaking, but nothing in this rulemaking prohibits States from using a request for proposal process to select the FIDE SNPs and affiliated organizations with which the State will contract.

Comment: A commenter recommended that in future rulemaking, CMS eliminate the distinction between HIDE SNPs and FIDE SNPs and that all D-SNPs in all States be required to meet a standard definition of full integration. The commenter also recommended limiting enrollment in full integration models, such as FIDE SNPs, to full benefit dual eligible individuals to improve integration in those models. Another commenter suggested that CMS should establish a glide path for phasing out HIDE SNPs to instead support FIDE SNPs. The commenter believes that lower tiers of integration are not sufficient to meet the needs of dually eligible individuals with disabilities.

Response: We appreciate the perspective shared by the commenters. We believe the distinction between HIDE SNPs and FIDE SNPs is meaningful and accounts for variation in State integration strategies, and therefore we are retaining HIDE SNPs. To clarify, in proposing that all FIDE SNPs have exclusively aligned enrollment, as discussed later in this section at II.A.5.a., all FIDE SNPs would be limited to full benefit dually eligible individuals beginning in 2025.

Comment: A few commenters expressed concern about State or Federal policies that may result in limiting the number or type of plan operating in a given market. A commenter requested that CMS continue to allow for HIDE SNPs and coordination-only D-SNPs to operate alongside FIDE SNPs required to have exclusively aligned enrollment as it promotes quality and value through competition and preserves freedom of choice. Another commenter recommended that CMS discourage any requirements that limit plan choice to a select few plans, particularly if these plans have limited or no experience servicing complex populations.

A few commenters expressed concern about the number of plan choices currently available to dually eligible beneficiaries. A commenter noted the number of plan choices and related information provided to beneficiaries results in a coverage landscape that is overwhelming to dually eligible individuals. The commenter further noted that more work is needed to increase awareness around integrated options and their potential value.

Response: We thank the commenters for sharing their perspectives. While our proposal makes changes to how we define FIDE SNPs and HIDE SNPs that we believe will ultimately help to differentiate various types of D-SNPs and clarify options for beneficiaries, we do not believe our proposal will directly limit the number or types of plans available for beneficiaries to choose from. We clarify that our proposal does not impact the ability for HIDE SNPs and coordination-only D-SNPs to operate alongside FIDE SNPs.

Comment: A commenter recommended that CMS revise the requirement that the MA organization offering the D-SNP and the Medicaid MCO contract holder must be the same legal entity in order to qualify as a FIDE SNP because, based on the experience of the commenter, there is no difference in a plan's ability to work with the State or integrate care for the members based on legal entity or parent organization status.

Another commenter expressed concern that the current definitions of HIDE and FIDE SNPs restrict plans that are operationally fully integrated from obtaining a FIDE SNP designation by requiring a Medicaid contract within the same legal entity that contracts with CMS to operate as a MA plan, while Medicaid contracts for HIDE SNPs only be provided by the same parent organization as that offering the MA plan. The commenter recommended that CMS amend the definition of FIDE SNPs to allow for the Medicaid contracts to be provided by the same parent organization that offers the MA plan because, in the commenter's view, this level of integration is sufficient to allow for full data sharing and coordination of benefits and is in keeping with the spirit of D-SNP regulations.

Response: We appreciate the comments but, because we did not propose to change that aspect of the definitions for FIDE SNPs and HIDE SNPs, we believe the suggestions are out of the scope of this rulemaking. We believe that providing coverage of Medicare and Medicaid benefits through a single legal entity constitutes the most extensive

level of integration, with the greatest potential for holistic and person-centered care coordination, integrated appeals and grievances, comprehensive beneficiary communication materials, and quality improvement. However, we will consider these comments in future rulemaking.

Comment: A few commenters encouraged CMS to strengthen its oversight on State Medicaid rate setting to ensure that Medicaid rates for the MCO contracts held by FIDE SNPs are adequate and appropriately reflect the scope of the Medicaid services covered. A commenter noted that in some cases a capitated contract with a State Medicaid agency is held by a D-SNP's parent company or sister company, while in other cases the D-SNP entity itself may hold the contract. The commenter stated that, in the latter situation, Medicaid rules are not clear about the application of the Medicaid actuarial soundness requirements at 42 CFR 438.4 to the Medicaid benefits covered by those capitated contracts. Specifically, 42 CFR 438.4 applies to MCOs with comprehensive Medicaid contracts, prepaid inpatient health plans, and prepaid ambulatory health plans. The commenter noted that neither that rule nor the current CMS Medicaid Managed Care Rate Development Guide refer to D-SNPs or provide guidance on the applicability of Medicaid actuarial soundness standards to Medicaid services provided by D-SNPs. The commenter therefore requests that CMS formally clarify that capitation rates developed pursuant to State Medicaid agency contracts with D-SNPs are subject to the actuarial soundness requirements of 42 CFR 438.4.

Response: We appreciate the commenter's perspective on this issue. We clarify that the phrase "capitated contract with the State Medicaid agency" may be a Medicaid managed care contract for coverage of Medicaid benefits by a Medicaid MCO, or, for a HIDE SNP, a prepaid inpatient health plan (PIHP) or prepaid ambulatory health plan (PAHP), depending on the scope of coverage of Medicaid services. All MCO, PIHP, and PAHP contracts are subject to the actuarial soundness requirements of 42 CFR 438.4. When the same legal entity as the MA organization that offers the D-SNP has the contract for coverage on a risk basis for Medicaid benefits—that is, when there is a capitated contract between the D-SNP and the State Medicaid agency—that contract may be an MCO, PIHP, or PAHP contract depending on the scope of benefits covered; in such cases, all of the applicable 42 CFR part 438 requirements for the MCO, PIHP, or

PAHP contract, including the requirement for actuarially sound capitation rates, must be met. For example, Medicaid PIHPs and PAHPs can serve as the affiliated Medicaid managed care plan for delivery of Medicaid behavioral health or LTSS for HIDE SNPs.

a. Exclusively Aligned Enrollment for FIDE SNPs

Section 422.2 defines the term "fully integrated dual eligible special needs plan". Under the current definition, FIDE SNPs are plans that: (i) 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 MCO contract under section 1903(m) of the Act with a State Medicaid agency, (ii) under the capitated Medicaid managed care contract (that is, the MCO contract), provide coverage, subject to some limited flexibility for carve-outs, of primary care, acute care, behavioral health, and LTSS, and coverage of nursing facility services for a period of at least 180 days during the plan year; (iii) coordinate delivery of covered Medicare and Medicaid benefits using aligned care management and specialty care network methods for high-risk beneficiaries; and (iv) employ policies and procedures approved by CMS and the State to coordinate or integrate beneficiary communication materials, enrollment, communications, grievance and appeals, and quality improvement.

The current definition of a FIDE SNP does not require that the MA contract limit enrollment to the individuals who are enrolled in the affiliated MCO. An MA plan designated as a FIDE SNP may qualify for a frailty adjustment as part of CMS's risk adjustment of its MA capitation payments under section 1853(a)(1) of the Act and § 422.308(c). Section 422.2 also defines the term "aligned enrollment" as referring to when full-benefit dually eligible individuals who are enrolled in a D-SNP also receive coverage of Medicaid benefits from the D-SNP or from a Medicaid MCO that is: (1) The same organization as the MA organization offering the D SNP; (2) its parent organization; or (3) another entity that is owned and controlled by the D SNP's parent organization. When State policy limits a D-SNP's membership to individuals with aligned enrollment, § 422.2 refers to that condition as exclusively aligned enrollment.

Exclusively aligned enrollment is an important design feature for maximizing integration of care for all the D-SNP's enrollees. As discussed on 87 FR 1861, it facilitates the use of integrated

beneficiary communication materials and clarifies overall accountability for outcomes and coordination of care. FIDE SNPs and HIDE SNPs with exclusively aligned enrollment are applicable integrated plans subject to the requirement to use (beginning January 1, 2021) unified grievance and appeals procedures for both Medicare and Medicaid benefits.

As explained at 87 FR 1861, the current regulatory definition of FIDE SNP permits certain forms of unaligned enrollment between Medicare and Medicaid coverage. That is, a beneficiary may be in one parent organization's FIDE SNP for coverage of Medicare services but a separate company's Medicaid managed care plan (or in a Medicaid FFS program) for coverage of Medicaid services.

We proposed to amend the definition of "fully integrated dual eligible special needs plan" at § 422.2 with a new paragraph (5) to require, for 2025 and subsequent years, that all FIDE SNPs have exclusively aligned enrollment. Requiring all FIDE SNPs to have exclusively aligned enrollment would allow all enrollees to have their Medicare and Medicaid benefits under the FIDE SNP and affiliated Medicaid MCO explained clearly, which is made more difficult when some enrollees are, but others are not, also enrolled in the affiliated Medicaid MCO. Our proposed change would promote higher levels of Medicare-Medicaid integration by ensuring that all FIDE SNPs can deploy integrated beneficiary communication materials and unify appeals and grievance procedures for all the Medicare and Medicaid benefits covered through the FIDE SNP and affiliated Medicaid MCO; such unified procedures are not feasible when some FIDE SNP enrollees do not receive their Medicaid benefits from the same organization.

Under our proposed definition, all FIDE SNPs would, by virtue of the same legal entity holding the MA and the Medicaid MCO contracts, (1) be capitated for Medicaid services, with some permissible exceptions proposed at §§ 422.107(g) and (h) and discussed later in this section, for all of their enrollees, and (2) based on meeting the definition of applicable integrated plans in § 422.561, operate unified appeals and grievance processes and continue delivery of benefits during an appeal.

As discussed in the proposed rule, absent a State Medicaid policy change in select States, our proposal would result in 12 current D-SNPs losing FIDE SNP status. However, our proposal would not prohibit those States and plans from operating as they currently

do but would simply mean that the affected plans would be HIDE SNPs rather than FIDE SNPs beginning January 1, 2025, and a consequence of this would be that the MA plans would not qualify for the frailty adjustment, as described in § 422.308(c)(4). States may also choose to require, through their State Medicaid agency contracts under § 422.107, that MA organizations create separate MA plan benefit packages (that is, separate D-SNPs), with one for exclusively aligned enrollment and the other for unaligned enrollment, the former of which would meet our proposed criteria and allow the organization to maintain FIDE SNP status for a share of its current FIDE SNP enrollment while using one or more new, separate D-SNPs for the unaligned enrollment. MA organizations would need to submit a request to CMS for a crosswalk exception under § 422.530(c)(4)(i), which we proposed in section II.A.6.a. of the proposed rule to redesignate from § 422.530(c)(4) without substantive change, for such enrollment transitions.

Finally, because the definition of aligned enrollment is specific to full-benefit dually eligible individuals, our proposal would also mean that D-SNPs enrolling new or continuing the enrollment of partial-benefit dually eligible individuals could not achieve FIDE SNP designation beginning in 2025. As discussed at 87 FR 1861 through 1862, we do not believe this would have any meaningful impact for plans currently operating as FIDE SNPs. Further we believe that the benefits to be achieved with FIDE SNPs having exclusively aligned enrollment for Medicare beneficiaries eligible for full Medicaid benefits, and the associated greater levels of integration in the provision and coverage of benefits and plan administration outweigh the potential negative effects of excluding partial-benefit dually eligible individuals. Partial-benefit dually eligible individuals would be limited to enrollment in HIDE SNPs, coordination-only D-SNPs, other MA plans, or the original Medicare FFS program.

Comment: Many commenters supported the proposal and noted that exclusively aligned enrollment advances full integration, strengthens care coordination between Medicare and Medicaid, improves enrollee communications, and better allows the FIDE SNP to unify processes that improve the beneficiary experience, such as through a single set of member materials and a unified appeals and grievances process. MACPAC commented that the proposal is consistent with its desire to move more

States toward exclusively aligned enrollment. A few commenters expressed that FIDE SNPs should represent the highest level of integration and that this change would help clarify the currently confusing levels of integration among D-SNP categories.

In supporting the requirement for FIDE SNPs to have exclusively aligned enrollment, other commenters expressed that the current FIDE SNP structure is not designed to address the needs of enrollees who receive Medicaid services through fee-for-service or a misaligned Medicaid MCO. In these cases, commenters noted that a current FIDE SNP might be required to coordinate with different Medicaid MCOs or Medicaid fee-for-service and that lack of exclusively aligned enrollment is inconsistent with the otherwise-integrated FIDE SNP model. A commenter indicated including beneficiaries in FIDE SNPs who receive their Medicaid services elsewhere diverts plan resources, and another commenter indicated it does not afford a meaningfully integrated experience for enrollees, providers, or payers.

A few commenters indicated that exclusively aligned enrollment enabled plans and providers to develop and implement care models that are payer-agnostic, and a commenter indicated a FIDE SNP may enable a provider to submit a single claim for all services and cost-sharing.

Some commenters expressed appreciation for CMS's proposal to provide a crosswalk exception that would allow current FIDE SNPs that operate in States that do not require exclusively aligned enrollment to create separate PBPs for aligned and unaligned enrollees to maintain access to the frailty adjustment for aligned enrollees. Several commenters asked CMS to provide more detail on how this crosswalk would be initiated and approved.

A commenter agreed with CMS's analysis that making exclusively aligned enrollment a criterion for FIDE SNP status would cause minimal disruption to existing arrangements and leave ample fallback options for HIDE SNP status for the small number of plans that would be impacted by this change.

Response: We appreciate the widespread support for requiring exclusively aligned enrollment for FIDE SNPs. We agree that this proposed requirement would encourage a deeper level of integration of Medicare and Medicaid, improve beneficiary communications about covered Medicare and Medicaid benefits and services, and promote unified appeals and grievances. As we noted in the

proposed rule at 87 FR 1861, we believe our proposal would clarify overall accountability for outcomes and coordination of care. We appreciate that it could also reduce provider administrative burden for contracting with FIDE SNPs. We agree that transitioning to HIDE SNP status is an option for existing FIDE SNPs in States where exclusively aligned enrollment is not in place by 2025 and that a small number of existing plans would be impacted by this change.

We clarify that the crosswalk exception being redesignated in this final rule to § 422.530(c)(4)(i) is available under current law. This crosswalk exception is available when a renewing D-SNP has another new or renewing D-SNP and the two D-SNPs are offered to different populations; the crosswalk exception permits within-contract movement of the enrollees who are no longer eligible for their current D-SNP into the other new or renewing D-SNP offered by the same MA organization if the enrollees meet the eligibility criteria for the new or renewing D-SNP and CMS determines the movement is in the best interest of the enrollees in order to promote access to and continuity of care for enrollees relative to the absence of a crosswalk exception. This existing crosswalk exception may be available to implement a State's requirement to separate exclusively aligned enrollment from unaligned enrollment in separate PBPs. Our proposal was only to redesignate the regulatory provision to a different paragraph. When we issue the additional information on timelines and procedures for requesting crosswalks and crosswalk exceptions in sub-regulatory guidance, we intend to consider current timeframes and procedures for submission of applications, bids, and other required material to CMS, in addition to the need for MA organizations to make business decisions in a timely manner.

Comment: Several commenters opposed our proposal. A few commenters indicated that finalizing the proposal would limit the ability of States that exclude coverage of certain Medicaid benefits from their Medicaid MCO contracts (that is, States with Medicaid carve-outs) from pursuing more integrated models, may require modification of State-specific Medicaid processes for managed care enrollment, and could restrict enrollee choice in coverage. Another commenter discouraged any requirements that limit FIDE SNP offerings to Medicaid managed care organizations with contracts under section 1903(m) of the Act. Another commenter noted that a

State Medicaid agency decision not to facilitate exclusively aligned enrollment could lead to loss of FIDE designation and impact the frailty adjustment for an MA organization.

Another commenter expressed concern that the proposal limits plan choice where a beneficiary wanted to maintain access to a trusted provider or case manager in one Medicaid plan, while selecting an alternative Medicare plan based on supplemental benefits.

MACPAC recognized potential burden on States with FIDE SNPs that do not have exclusively aligned enrollment (Arizona, Pennsylvania, and Virginia) to make this adjustment and suggested CMS work with States to ensure there is a glidepath for these States. A commenter encouraged CMS to ensure that unaligned individuals and impacted providers in FIDE SNPs receive notices and counseling about the change and have access to continuity of care protections in Medicaid.

Response: We thank the commenters. We agree that requiring FIDE SNPs to have exclusively aligned enrollment would, in the absence of State policy changes, impact 12 existing FIDE SNPs in a few States (we identified Arizona, Pennsylvania, and Virginia in the proposed rule). States may also choose to require—through their State Medicaid agency contracts under § 422.107—that MA organizations create separate plan benefit packages, with one for exclusively aligned enrollment and the other for unaligned enrollment, which would allow the organization to maintain FIDE SNP status for a share of the existing FIDE SNP enrollment, as discussed at 87 FR 1861. As discussed in the proposed rule, these affected plans would be designated as HIDE SNP, rather than FIDE SNPs, beginning January 1, 2025, if the plans were unable to meet the new FIDE SNP requirements, and as such, we disagree that the proposal would limit States pursuing integrated care options, restrict member choice, or restrict the ability of States to facilitate access to D-SNPs. States and MA organizations may continue to use other structures for D-SNPs where enrollment is not exclusively aligned; those other plans, however, would not be FIDE SNPs.

Unaligned beneficiaries transitioned to a separate PBP would receive that information in the Annual Notice of Changes. We do not anticipate all beneficiaries will be disenrolled from existing FIDE SNPs that do not have exclusively aligned enrollment since an existing FIDE SNP could become a HIDE SNP or create separate PBPs, with one for exclusively aligned enrollment and the other for unaligned enrollment. In

cases where an MA organization does transition unaligned beneficiaries to a separate PBP, we do not expect transitioning beneficiaries to encounter issues accessing providers since, in our experience, MA organizations tend to have the same provider networks across PBPs with overlapping service areas under the same contract. For these reasons, we disagree that we should require additional notification to enrollees in the affected plans.

The proposed rule did not ease the requirement in § 422.2 that FIDE SNPs provide coverage of comprehensive Medicaid benefits under a capitated contract between a Medicaid MCO and the State Medicaid agency under section 1903(m) of the Act. States may contract with HIDE SNPs and coordination-only D-SNPs if their Medicaid contracting strategies are not consistent with the new FIDE SNP requirements. We seek to move FIDE SNPs toward greater integration in the provision of Medicare and Medicaid benefits but this final rule does not eliminate less integrated approaches for other types of D-SNPs. We believe the benefits of exclusively aligned enrollment, including simplifying enrollee communication, allowing Medicare and Medicaid benefits to be explained more clearly, and unified appeal and grievance processes will differentiate FIDE SNPs from other plans. It will simplify the ways we, States, and benefit counselors communicate about FIDE SNPs by eliminating some of the confusing scenarios related to unaligned enrollment, as described in 87 FR 1861 of the proposed rule, and will allow FIDE SNPs to consistently and more clearly be the most integrated D-SNP option in the market. Exclusively aligned enrollment lays the groundwork for further integration of Medicare and Medicaid, giving States and plans the ability to improve the beneficiary experience such as through access to integrated beneficiary communication materials that describe available benefits, improve the enrollee experience, and decrease confusion by providing a simplified set of beneficiary materials.

Comment: A commenter recommended enrollee communications clearly articulate the features of integration and be communicated by a neutral party to support enrollee choice among coverage options. Another commenter asked CMS to assist States in understanding marketing materials.

Response: We appreciate the comments and we noted in the proposed rule that we believe the proposed changes to how we define FIDE SNP and HIDE SNP will help

differentiate the types of D-SNPs and clarify options for beneficiaries. We will continue to work with States, plans, advocates, beneficiaries, and providers to improve model MA plan materials that describe D-SNPs and ensure that the features enabled by exclusively aligned enrollment are clearly communicated to beneficiaries. We will also continue to work with States to help them develop State materials and educate State Health Insurance Assistance Program (SHIP) counselors and Medicaid choice counselors to assist beneficiaries in understanding their coverage options. States may also want to leverage their beneficiary support systems as described in § 438.71.

Comment: A commenter noted the Massachusetts Senior Care Options D-SNPs and MMPs also limit enrollment in the Medicaid managed care plan to those members enrolled for Medicare, explaining that it substantially improves integration for all enrollees.

Response: We appreciate the commenter's perspective on this issue and we agree with the commenter that Massachusetts has achieved a high level of integration through Senior Care Options and One Care. We did not propose regulations limiting enrollment in the Medicaid managed care plan. As proposed and finalized, the amendments to the definition of FIDE SNP do not require that the State limit enrollment in the capitated Medicaid MCO to only those enrollees in the FIDE SNP for Medicare. Rather, this amendment limits the FIDE SNP designation to D-SNPs with State contracts requiring exclusively aligned enrollment. However, our proposal to require all FIDE SNPs to have exclusively aligned enrollment would not preclude a State from choosing to replicate Massachusetts' approach.

Comment: Another commenter encouraged CMS to continue to allow HIDE SNPs and coordination-only D-SNPs to operate alongside FIDE SNPs.

Response: We thank the commenter and clarify that the proposal would not restrict a State from allowing HIDE SNPs and coordination-only D-SNPs to operate in the same market as FIDE SNPs.

Comment: Several commenters supported the January 1, 2025, proposed effective date of this provision, while several other commenters suggested a delay to 2025 was not required, particularly for newly qualifying FIDE SNPs. Another commenter acknowledged the benefits of full alignment but noted implementation would require plan operational, policy, and system changes that would be

burdensome to implement by contract year 2025.

Response: We thank the commenters for their perspectives on the January 1, 2025 effective date. We believe there is sufficient time for FIDE SNPs to implement exclusively aligned enrollment for January 1, 2025. Through the Integrated Care Resource Center and CMS Medicare-Medicaid Coordination Office, we will provide technical assistance to States and plans interested in facilitating exclusively aligned enrollment and we are actively planning for upcoming technical assistance opportunities. We reiterate that MA organizations that are not interested in offering FIDE SNPs that meet the new requirements applicable beginning January 1, 2025 are not required by the changes finalized in this rule to do so because such MA organizations may offer coordination-only D-SNPs or HIDE SNPs that are subject to lower integration standards. The new requirement for exclusively aligned enrollment applies only to FIDE SNPs.

Comment: A commenter requested that the crosswalk option not be limited to States requiring or requesting exclusively aligned enrollment, but that the crosswalk option also include MA plan-initiated implementation of exclusively aligned FIDE SNPs and the creation of separate MA contracts.

Response: While we appreciate the request for MA organizations to initiate separate contracts in order to facilitate exclusively aligned enrollment, we clarify that under § 422.107(e) the separate contract would only be provided after CMS receives a request from a State. Section II.A.6.a. of this final rule discusses the proposal regarding § 422.107(e) and the corresponding crosswalk exception in more detail. The existing crosswalk exception at § 422.530(c)(4)(i) (redesignated in this final rule) is not limited to situations where a State has required or requested exclusively aligned enrollment but is limited to specific situations described in the regulation text where a renewing D-SNP has another new or renewing D-SNP under the same overall contract and the two D-SNPs are offered to different populations. In such instances, enrollees who are no longer eligible for their current D-SNP may be crosswalked into the other D-SNP.

Comment: A few commenters expressed support for the proposal to limit FIDE SNP enrollment to full-benefit dually eligible individuals and allow separate D-SNP PBPs for partial-benefit dual eligible individuals. A few commenters indicated that partial-benefit dually eligible individuals'

characteristics are similar to full-benefit dually eligible individuals and that partial-benefit enrollees can benefit from access to stronger care coordination models not generally available in non-SNP MA organizations. The commenter believed this provision would allow the necessary distinctions in communications and enrollee materials describing access to Medicaid benefits for partial-benefit dually eligible enrollees compared to full-benefit dually eligible enrollees. A few commenters noted that separate PBPs based on whether enrollees are eligible for partial Medicaid benefits or full Medicaid benefits allows for targeting supplemental benefits to partial-benefit dually eligible individuals, and a commenter indicated it could potentially lead to some financial incentives for States to support D-SNP enrollment and possible shared savings opportunities.

Another commenter indicated any additional burden these changes may place on FIDE SNPs is preferable to disallowing enrollment of partial-benefit dually eligible individuals in D-SNPs as some policy makers have advocated and are far less restrictive than some other integration legislative proposals that have been promoted.

A few commenters expressed the proposal may create additional administrative burden for States, plans, and CMS for oversight and another commenter indicated that States may not have experience or processes to track PBPs, particularly when States may have a single MLTSS contract with a comprehensive benefit package with all enrollees included. The commenter indicated that having separate MA PBPs could create the need for additional Medicaid MCO contracts and additional rate-setting and contract review burdens both internally and with CMS. Another commenter asked CMS to provide technical assistance to States on procurement timing, contract support, full- and partial-benefit dually eligible individuals and applicability of unified appeals and grievances, and to encourage the use of crosswalks into PBPs for partial-benefit dually eligible individuals.

Response: We thank the commenters for the feedback. We noted at 87 FR 1861 through 1862 of the proposed rule that for contract year 2021, no FIDE SNPs enrolled partial-benefit dually eligible individuals. As such, we do not believe the preclusion of enrollment into FIDE SNPs by partial-benefit dually eligible individuals places additional burden on States, MA plans, or CMS for oversight or necessitates any new notifications to beneficiaries. We intend

to provide education and outreach to States about changes codified in this final rule. To the extent that this new requirement for exclusively aligned enrollment for FIDE SNPs causes concerns for MA organizations or States that wish to have a single PBP for all dually eligible individuals, HIDE SNPs and coordination-only D-SNPs remain an option.

Comment: Several commenters recommended CMS provide training and technical assistance around exclusively aligned enrollment and its processes to States, plans, benefits counselors, and community partners. A few commenters asked CMS to provide more information and education to States and plans about operationalizing crosswalks to separate FIDE SNP PBPs with aligned enrollment with a companion Medicaid managed care plan from unaligned enrollment, as well as to separate PBPs for partial-benefit dually eligible individuals. A commenter recommended an intentional effort to ensure that dually eligible individuals, including those with limited English proficiency, understand how their enrollment works. The commenter recommended Community Catalyst's publication, "Person-Centered Enrollment Strategies for Integrated Care Toolkit," for additional details on creating person-centered enrollment practices.

Response: We thank the commenters and agree that it is important for CMS to provide education and technical assistance to MA organizations in operationalizing provisions codified in this rule. In particular, we are working closely with California Department of Health Care Services to develop their exclusively aligned enrollment policies and procedures for 2023 and we will offer similar support to other interested States, regardless whether the use of exclusively aligned enrollment or FIDE SNPs is tied to transition out of a FAI demonstration or part of efforts to increase integration for dually eligible individuals.

Comment: Some commenters encouraged CMS to consider extending the requirement for exclusively aligned enrollment to HIDE SNPs, expressing that the rationale for exclusively aligned enrollment for FIDE SNPs is applicable to HIDE SNPs. MedPAC recommended requiring that HIDE SNPs have exclusively aligned enrollment, noting integration would depend on States and plan sponsors, who could either adopt exclusively aligned enrollment so the existing HIDE SNPs could continue to keep that designation or instead let those plans meet the lower coordination-only D-SNP standard for

integration. Further, MedPAC noted the use of exclusively aligned enrollment would also entail some disruption for full-benefit dually eligible beneficiaries who are enrolled in HIDE SNPs but have misaligned enrollment, as well as for any partial-benefit dually eligible individuals who are now enrolled in a HIDE SNP. MedPAC went on to state that requiring HIDE SNPs to use exclusively aligned enrollment could enable CMS to implement a range of policies that promote integration (such as requiring more D-SNPs to have Medicaid contracts to cover Medicare cost-sharing, integrated member materials, and a unified process for handling appeals and grievances) on a wider scale.

Also, a commenter stated opposition to extending exclusively aligned enrollment to HIDE SNPs.

Response: We appreciate the support for requiring exclusively aligned enrollment for both FIDE SNP and HIDE SNP. However, applying this requirement to HIDE SNPs is outside of the scope of this rulemaking. Further, additional factors, such as the potential burden and our goal of adopting requirements to more readily distinguish FIDE SNPs and HIDE SNPs, warrant continued consideration of this policy. We will consider these comments for future rulemaking.

Comment: A commenter requested CMS require matching Medicare and Medicaid effective dates for enrollment and disenrollment into FIDE and HIDE SNPs, leverage CMS mechanisms that can promote alignment, and provide technical assistance and encouragement to States to adjust their processes to ensure matching effective dates.

Response: We appreciate the commenter's perspective and agree that an important component of exclusively aligned enrollment is aligning the Medicare and Medicaid effective dates. There are operational challenges for aligning the timing of Medicaid and Medicare enrollment and disenrollment processes. States may have annual enrollment periods or continuous enrollment and many establish a mid-to-late month cutoff date for processing enrollments into Medicaid managed care plans. Medicare Advantage plans are required to utilize various election periods described at 42 CFR 422.62 and often must accept enrollments through the end of the month. We will work with States to support operationalizing exclusively aligned enrollment to maximize the ability to align enrollment and disenrollment dates. We plan to make available both written resources and technical assistance events promoting best practices that highlight

States that successfully facilitate exclusively aligned enrollment, as well as offer direct State-specific technical assistance through the Integrated Care Resource Center. To maximize flexibility for States that newly implement exclusively aligned enrollment, we decline to codify in regulation the requirement that the effective dates are matching. However, we will monitor where there are misaligned effective dates upon implementation of this rule, and we will strive to provide technical assistance and share promising practices.

Comment: A commenter recommended that CMS, instead of finalizing the proposal, provide guidance and incentives to States to transition to exclusively aligned enrollment, such as adopting a shared savings component for FIDE SNPs, noting shared savings was used as an incentive to encourage States to participate in FAI. The commenter further recommended CMS consider a request for information to identify potential options and guardrails to address benefits, access, and quality.

Response: We appreciate the comment. CMS will continue to provide guidance and support to States that transition to exclusively aligned enrollment for FIDE SNPs, leveraging promising practices from States that already implement it, such as Idaho, Massachusetts, Minnesota, New Jersey, and New York. We decline to accept the commenter's recommendation to collect information in lieu of finalizing our proposal to amend the requirements for FIDE SNPs but instead will finalize as proposed. We intend to concurrently continue to collect promising practices and feedback and share it with States and plans. Finally, we note that payment requirements for MA plans are set by section 1853 of the Act so we have limited ability outside of the context of a demonstration or test of a payment model under section 1115A of the Act to change payment parameters in the MA program.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposed amendment to the definition of FIDE SNP at § 422.2 with a new paragraph (5) to require FIDE SNPs, beginning January 1, 2025, to have exclusively aligned enrollment.

b. Capitation for Medicare Cost-Sharing for FIDE SNPs and Solicitation of Comments for Applying to Other D-SNPs

We proposed to specify in § 422.2 that FIDE SNPs are required to cover

Medicare cost-sharing as defined in section 1905(p)(3)(B), (C), and (D) of the Act, without regard to how section 1905(n) limits that definition to qualified Medicare beneficiaries (QMBs), as part of the FIDE SNP's coverage of primary and acute care; this means that the proposed amendment would require FIDE SNPs to cover Medicare cost-sharing for both QMB and non-QMB full-benefit dually eligible FIDE SNP enrollees. This proposal would cover Medicare cost-sharing in the form of coinsurance, copayments, or deductibles for Medicare Part A and Part B benefits covered by the FIDE SNP. Under this proposal, a FIDE SNP would cover Medicare payment for primary care and acute care covered by Medicare and the Medicaid payment for any Medicare cost-sharing in such cases.

We proposed this change only for FIDE SNPs because FIDE SNPs are the only type of D-SNP that must have capitated Medicaid contracts for coverage of Medicaid acute and primary care benefits and are better equipped, compared to other D-SNPs, to make improvements for coordination of benefits and adjudication of claims. This is especially true when capitation for Medicare cost-sharing is combined with a requirement for exclusively aligned enrollment (as discussed in section II.A.5.a. of this final rule to amend the FIDE SNP definition at § 422.2). Under our proposal, a provider serving a dually eligible individual enrolled in a FIDE SNP with exclusively aligned enrollment would submit a single claim to the FIDE SNP for both Medicare and Medicaid coverage of the service; the FIDE SNP would adjudicate the claim for a covered service for any applicable Medicare payment, Medicaid payment, and Medicaid payment of Medicare cost-sharing. As reflected in paragraph (1) of the definition of FIDE SNPs at § 422.2, the MA organization offering a FIDE SNP is also a Medicaid MCO with a contract under section 1903(m) of the Act, which must be a Medicaid managed care comprehensive risk contract as defined in § 438.2. In order to satisfy the new requirement, we proposed for FIDE SNPs, the Medicaid MCO contract will include capitated coverage of the Medicare cost-sharing for Medicare Part A and Part B benefits. (Like all MA plans, the FIDE SNP will cover Medicare Part A and Part B benefits, subject to limited exclusions for hospice, certain new benefits, and costs of acquisition of kidneys for transplant.) We expect the single legal entity to process and pay claims to the extent there is coverage under its MA contract and its Medicaid managed care

contract without the need for additional claims filing by providers. In this way, the additions we proposed to the definition of FIDE SNPs at § 422.2 would ensure that all FIDE SNPs include elements—capitation for Medicare cost-sharing and exclusively aligned enrollment—that result in improved beneficiary and provider experiences.

As discussed in the proposed rule (87 FR 1863), this policy does not include Medicare Parts A and B premiums in the requirement for FIDE SNPs to cover Medicare cost-sharing. The State Medicaid agency would continue to pay the Medicare Parts A and B premiums on behalf of dually eligible beneficiaries in accordance with §§ 406.26 and 406.32(g) and part 407, subpart C, of the chapter.

We received the following comments on this proposal and respond to them below:

Comment: All commenters supported the requirement of FIDE SNPs to cover Medicare cost-sharing for both QMB and non-QMB full-benefit dually eligible FIDE SNP enrollees as part of the FIDE SNP's coverage of Medicaid-covered primary and acute care services.

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

Comment: A commenter supported the proposal but requested that CMS delay the applicability date of this provision to allow adequate time to implement in Tennessee where the capitated contracts do not currently include Medicare cost-sharing.

Response: In the proposed rule (87 FR 1863), we stated our belief that all FIDE SNPs already receive Medicaid capitation for Medicare cost-sharing consistent with our proposal. Therefore, we assumed no impact on current FIDE SNPs and did not believe there was any reason to delay the implementation of this new requirement. However, comments and our subsequent analysis illustrate that, in contrast to our assertion in the proposed rule, FIDE SNPs in one State (Tennessee) do not currently cover Medicare cost-sharing. As a result, we anticipate that there will be a need for the State and those FIDE SNPs to implement changes to come into compliance with this new requirement. Therefore, we are finalizing a change to make this provision applicable beginning in 2025.

Comment: A commenter encouraged CMS to ensure that capitation rates adequately and appropriately reflect the scope of services covered.

Response: We appreciate the opportunity to clarify that the requirements that apply to Medicaid capitation rates, including actuarial

soundness requirements at 42 CFR 438.4, are applicable to Medicaid capitation rates developed for the affiliated Medicaid MCO for a FIDE SNP. As reflected in paragraph (1) of the definition of FIDE SNPs at § 422.2, the MA organization offering a FIDE SNP is also a Medicaid MCO with a contract under section 1903(m) of the Act, which must be a Medicaid managed care comprehensive risk contract as defined in § 438.2. As required by section 1903(m)(2)(A) of the Act and § 438.4, capitation rates for MCO contracts must be actuarially sound, meaning that the rates are projected to provide for all reasonable, appropriate, and attainable costs for the enrolled population that are required under the terms of the contract. CMS reviews such rates under Medicaid managed care regulations in 42 CFR part 438. We anticipate that capitated coverage of the Medicare cost-sharing for Medicare Part A and Part B benefits that will be required for FIDE SNPs will be included in the MCO contract that the single legal entity offering both the FIDE SNP and the MCO must have with the State. As such, the requirement for actuarially sound capitation rates will apply.

Comment: The commenter requested clarification whether this proposal is limited to covering Medicare cost-sharing for “primary care and acute care” and excluded providers and suppliers of other services (for example, pharmacists providing Part B drugs, DME suppliers, etc.) and, if the exclusion is intentional, why other providers and suppliers should be excluded.

Response: Thank you for the opportunity to clarify our proposal. The reference in paragraph (2)(i) of the FIDE SNP definition encompasses Medicare cost-sharing for all Medicare Part A and B services, including Part B drugs and DME to the extent the Medicaid program covers Medicare cost-sharing for full-benefit dually eligible individuals. We clarify here that in using the definition in section 1905(p)(3)(B) of the Act without regard to the limitation of that definition to QMB dually eligible beneficiaries, we are not requiring that a State expand the categories of full-benefit dually eligible beneficiaries for whom the State covers all Medicare cost-sharing in order to contract with a FIDE SNP.

Comment: A commenter asked if the Medicare cost-sharing for non-QMB dually eligible beneficiaries would be the financial obligation of the FIDE SNP and not included in the calculation of the State's capitated Medicare cost-sharing payment.

Response: Under this proposal, the FIDE SNP would cover Medicare cost-sharing, which includes coinsurance, copayments, or deductibles for Medicare Part A and Part B benefits covered by the FIDE SNP, for all enrollees of the FIDE SNP beginning January 1, 2025. As detailed in section B.5.a of this rule, FIDE SNPs must have exclusively aligned enrollment beginning January 1, 2025, FIDE SNPs will only enroll full-benefit dually eligible individuals, which can include non-QMB full-benefit dually eligible beneficiaries, and cover Medicare cost-sharing for these enrollees beginning January 1, 2025.

For full-benefit QMB dually eligible individuals (that is, QMB+ beneficiaries), “Medicare cost-sharing” includes costs incurred with respect to dually eligible individuals in the QMB program “without regard to whether the costs incurred were for items and services for which medical assistance [Medicaid] is otherwise available under the plan” as described in section 1905(p)(3) of the Act. Therefore, under the new requirement we are finalizing here, the FIDE SNP capitated contract with the State must include State payment of Medicare cost-sharing for full-benefit QMB dually eligible beneficiaries. States may elect to extend coverage of Medicare cost-sharing, including coinsurance, for Medicare beneficiaries eligible for full Medicaid benefits who are not QMBs, (such as SLMB+ beneficiaries), as specified in the Medicaid State plan. For non-QMB full-benefit dually eligible beneficiaries, the FIDE SNP capitated contract with the State must include State payment of all Medicare cost-sharing when the State has elected to extend such coverage for these individuals. Absent such an election, the FIDE SNP's affiliated Medicaid MCO capitated contract must cover Medicare cost-sharing for these non-QMB full benefit dually eligible individuals only for services covered under the State plan. In this last circumstance, the State might adjust the capitation rate paid under the Medicaid MCO contract to reflect coverage of Medicare cost-sharing for non-QMB full-benefit dually eligible individuals only for those services, such as inpatient hospitalization, that are also covered under the Medicaid State plan. In our experience, however, States do not adjust the capitation rate for Medicare cost-sharing for a FIDE SNP's full-benefit dually eligible enrollees to account for those few Medicare-covered services not covered under the Medicaid State plan because the difference in per

member per month costs is not significant.

Comment: A commenter asked how the State coverage of cost-sharing occurs in situations where a FIDE SNP makes alternate payment arrangements with providers (for example, if a FIDE SNP capitates per patient per month payments, quality bonuses, or within a network with salaried providers and facilities directly owned by the plan).

Response: When the State contract with the Medicaid MCO affiliated with a FIDE SNP capitates for Medicaid payment of Medicare cost-sharing, providers no longer bill the State Medicaid agency for Medicare cost-sharing; the FIDE SNP assumes responsibility for making these payments. As proposed and finalized, the requirement for FIDE SNPs to cover the Medicaid payment of Medicare cost-sharing for their enrollees under the capitated contract between the Medicaid MCO affiliated with the FIDE SNP and the State does not dictate the particular payment amounts for covered services. Nor does this final policy address all operational details for identifying Medicare cost-sharing obligations for specific services in the context of specific provider payment arrangements. This new provision only requires that the FIDE SNP's coverage of Medicaid benefits include the Medicare cost-sharing otherwise applicable for Medicare Part A and B benefits for the FIDE SNP's enrollees, which will result in the FIDE SNP's payment to a provider including the FIDE SNP's coverage of the service and any Medicaid-covered Medicare cost-sharing amount.

CMS does not interfere in the negotiations between MA organizations and their contracted providers and does not directly participate in the negotiations between FIDE SNPs and States regarding the capitation amount paid for FIDE SNP's Medicaid coverage (other than to assure that Medicaid managed care requirements for actuarially sound rates in §§ 438.4 through 438.7 are met). CMS will not be in a position, nor have the responsibility, to assess payment methodologies for how the FIDE SNP pays the covered Medicare cost-sharing amounts to their contracted providers or whether those payments are equivalent to comparable payments through Medicare and Medicaid FFS. States can require use of particular payment methodologies for certain providers, such as primary care, mental health, and other high value providers, through contracts with D-SNPs to ensure sufficient access and quality of care meets the needs of D-SNP members. In addition, Medicaid managed care

regulations permit States to direct Medicaid managed care plans to use certain payment arrangements in connection with Medicaid coverage provided certain requirements are met at § 438.6(c). Finally, as previously noted in this rule, we review Medicaid capitation rates to ensure they are actuarially sound.

Comment: A commenter requested CMS consider clarifying elements of the Medicare cost-sharing billing process during a beneficiary's Medicare deeming period to prohibit MA providers from billing Medicare cost-sharing to dually eligible beneficiaries during the Medicare deeming period in order to strengthen balance billing protections for dually eligible beneficiaries.

Response: We share the commenter's concern about the billing of Medicare cost-sharing during the deeming period when a D-SNP enrollee has lost Medicaid eligibility. However, the loss of Medicaid eligibility also means that the prohibition on providers billing the beneficiary for Medicare cost-sharing has also been lost, since the individual is no longer dually eligible for Medicare and Medicaid. We will take this comment into consideration as we work to develop ways to protect individuals from undue expenses and potential access to care barriers during the deeming period. Although these individuals have lost eligibility for Medicaid, they almost always still have very low income, very few resources, and substantial health care needs.

Comment: A commenter requested clarification on how best to apply this requirement in instances where the HIDE SNP or FIDE SNP includes language on capitation for Medicare cost-sharing in the plan's contract with the State, but the State is not paying the plan for the Medicare cost-sharing in accordance with the contract language.

Response: As proposed and finalized, capitated coverage of the Medicare cost-sharing for Medicare Part A and Part B benefits that will be required for FIDE SNPs will be included in the Medicaid MCO contract that the single legal entity offering both the FIDE SNP and the Medicaid MCO must have with the State. Future contract disputes regarding the implementation of State capitated payment for Medicare cost-sharing to a FIDE SNP should be addressed per the Medicaid MCO contract language for dispute resolution. The requirement for capitated coverage of Medicare cost-sharing does not extend to HIDE SNPs; however, States and HIDE SNPs (and other MA plans) are free to negotiate capitated arrangements for facilitating

Medicaid coverage of Medicare cost-sharing for dually eligible individuals.

We appreciate the support for our efforts. We are finalizing our proposed revisions for paragraph (2)(i) of the definition of a FIDE SNP at § 422.2 with a delay in the applicability date until the 2025 plan year for the requirement that FIDE SNPs cover Medicare cost-sharing in their capitated contracts with State Medicaid agencies.

In the proposed rule (87 FR 1862 through 1863) we also solicited feedback on the feasibility, implementation, estimated time to enact, and impact of requiring all D-SNPs to have contracts with State Medicaid agencies for capitated coverage of Medicare cost-sharing to inform future rulemaking. We received many comments in response to our request for information. All comments supported the benefits to requiring capitated Medicare cost-sharing for all D-SNPs, however commenters expressed substantial concerns regarding the implementation of such a policy and how to determine if such a policy achieves the purpose of improving provider access for dually eligible individuals. Commenters provided suggestions regarding implementation timeline, development of resources, and technical assistance.

As we discussed in the proposed rule, we also considered proposing a requirement for State Medicaid data exchanges to provide real-time Medicaid managed care plan enrollment data to D-SNPs to enable better coordination between the D-SNP and the State and/or Medicaid managed care plan. To allow more time for us to consider the operational challenges for States, we did not propose a requirement. We solicited feedback on the pros and cons of requiring State Medicaid data exchanges to provide real-time Medicaid FFS program and Medicaid managed care plan enrollment data with D-SNPs, and the impact of such a requirement on States, Medicaid managed care plans, D-SNPs, providers, and beneficiaries. We received a number of comments in response to our request for information on the pros and cons of requiring State Medicaid data exchanges of Medicaid FFS program and Medicaid managed care plan enrollment data with D-SNPs. All commenters agreed with CMS's assessment of the importance of this data to enable better coordination between D-SNPs and the Medicaid FFS program or Medicaid managed care plan for dually eligible beneficiaries that are not in aligned plans. Many commenters suggested a technical expert panel of States and plans to develop the concept and identify considerations, obstacles,

and implementation timeline for the described data exchange. Finally, we received a couple comments that were concerned with the uniformity of individual State Medicaid data exchanges, and a commenter suggested leveraging the State MMA File Exchange³⁴ as a better alternative for sharing the Medicaid FFS program and Medicaid managed care plan enrollment data.

We appreciate the support for our efforts to raise this issue and will consider comments and suggestions received for future rulemaking, technical assistance, and related work.

c. Scope of Services Covered by FIDE SNPs

(1) Need for Clarification of Medicaid Services Covered by FIDE SNPs

CMS first defined the term “fully integrated dual eligible special needs plan”, or FIDE SNP, at § 422.2 in the “Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes” final rule (76 FR 21432) (hereinafter referred to as the April 2011 final rule) to implement section 3205(b) of the Affordable Care Act (which amended section 1853(a)(1)(B)(vi) of the Act to add a frailty adjustment to the risk adjustment payments for certain FIDE SNPs). That definition provided that a FIDE SNP must have 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.

As discussed in more detail in the proposed rule (87 FR 1864), despite discussion in the April 2011 final rule that FIDE SNPs would provide all primary, acute, and long-term care services and benefits covered by the State Medicaid program, we did not operationalize review of State Medicaid agency contracts in that way. Over the years, CMS has determined D-SNPs to be FIDE SNPs even where the State carved out certain primary care, acute care, and LTSS benefits from the Medicaid coverage required from the D-SNP. In effect, we allowed States flexibility in the coverage provided by FIDE SNPs, not only to accommodate differences in the benefits covered

under various State Medicaid programs but to accommodate differences in State contracting strategies for managed care broadly, and for FIDE SNPs in particular. In the April 2019 final rule (84 FR 15706 through 15707), we revised the FIDE SNP definition at § 422.2 to add Medicaid behavioral health services to the list of services that a FIDE SNP must include in its capitated contract with the State Medicaid agency. But, consistent with how we were operationalizing this definition, we explained that our amendment would allow plans to meet the FIDE SNP definition even where the State excluded Medicaid behavioral health services from the capitated contract.

As discussed in the January 2022 proposed rule (87 FR 1863 through 1864), the way we have applied the definition of FIDE SNPs has not enabled us to ensure FIDE SNPs fully integrate Medicare and Medicaid services for dually eligible individuals. We proposed to revise paragraph (2) of the definition of a FIDE SNP at § 422.2 to clearly specify which services and benefits must be covered under the FIDE SNP capitated contract with the State Medicaid agency, and thus bring fuller integration of Medicaid benefits to individuals enrolled in FIDE SNPs. Our proposal would revise paragraph (2) of the existing definition into paragraphs (2)(i) through (v), with each of the new paragraphs addressing specific coverage requirements. We believe the proposals described in this section strike the appropriate balance between flexibility for variations in State Medicaid policy and our goal of achieving full integration in FIDE SNPs. In addition, as discussed more fully in section II.A.5.e., our proposed revision of the definition, in conjunction with a proposal to add § 422.107(g) and (h), included flexibility for approval of some limited carve-outs of LTSS and behavioral health services.

As described in the proposed rule (87 FR 1864), we proposed that the updates to the FIDE SNP definition at § 422.2 would mean that all Medicaid benefits in these categories would be covered by the MCO that is affiliated with the FIDE SNP, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in the FIDE SNP, and we did not propose any exceptions. Because the same legal entity must have the MA contract with CMS for the D-SNP and the Medicaid MCO contract with the State, and the enrollment in the FIDE SNP must be limited to dually eligible individuals who are also enrolled in the MCO, this entity is functionally all the FIDE SNP.

Comment: Several commenters supported CMS’s proposed clarification of the services that must be covered by a FIDE SNP through a capitated contract with the State Medicaid agency. Other commenters supported CMS’s proposed changes to the FIDE SNP requirements and believed that they would help ensure that FIDE SNPs are fully integrated with Medicaid. Several commenters expressed that the proposed changes would make it easier for beneficiaries to understand how FIDE SNPs differ from other, less integrated D-SNPs. A commenter stated that all full benefit dually eligible individuals should have access to fully integrated care, which should include one benefit package that encompasses all Medicare- and Medicaid-covered services, including primary and acute care benefits, behavioral health, LTSS and dental benefits. A commenter supported CMS’s proposal because they experienced firsthand in the Financial Alignment Initiative how Medicare-Medicaid integration greatly benefits enrollees, providers, and payers. Another commenter believed that providers would experience lower administrative burden when contracting with FIDE SNPs that provide comprehensive coverage of all the services described in our proposal. A commenter supported CMS’s proposal because it accounts for variations in State Medicaid programs, honors beneficiary choice, and promotes quality and value through competition.

Response: We appreciate the widespread support for our proposal to clarify the scope of Medicaid-covered services that must be covered by the affiliated Medicaid MCO for a D-SNP to be a FIDE SNP. We agree that the proposed changes will help ensure fuller integration of benefits for FIDE SNP enrollees. We also agree that the proposal will improve stakeholder understanding of how integrated plan options differ and improve clarity of what those plans cover.

Comment: A commenter believed that the proposed changes to the definition of a FIDE SNP would negatively impact Medicaid programs in a number of States because some plans currently designated as FIDE SNPs would no longer be considered FIDE SNPs. Another commenter opposed CMS’s proposal because they believed that the proposal would discourage States wishing to pursue further integration from doing so as it may not align with the State’s other Medicaid contracting priorities. The commenter noted that Pennsylvania, Virginia, and Arizona have made the decision to permit D-

³⁴ Since 2005, State Medicaid agencies have been submitting files at least monthly to CMS to identify all dually eligible beneficiaries in each State. This includes full-benefit dually eligible individuals and partial-benefit dually eligible individuals. The file is called the “MMA File” (after the Medicare Prescription Drug Improvement and Modernization Act of 2003), or State Phasedown File. See here for more information.

SNPs other than those that have MLTSS contracts to operate in the State.

Response: We acknowledge the comments and recognize the concern that some current FIDE SNPs may no longer meet the requirements to be a FIDE SNP. As we described at 87 FR 1865 through 1866, our analysis found that if our proposed changes went into effect, relatively few FIDE SNPs would lose FIDE SNP distinction. D-SNPs that do not meet the proposed FIDE SNP definition at § 422.2 may still meet the HIDE SNP definition at § 422.2, which we are also updating in this rulemaking. In addition, coordination-only D-SNPs remain permissible, which means that States have flexibility in permitting various types of D-SNPs with different levels of integration and coordination with the States' Medicaid managed care programs. We believe the benefits of our proposed changes outweigh the benefit of continuing to allow FIDE SNP designation for plans that do not have the level of integration achieved by the same legal entity covering Medicare Part A and Part B benefits (subject to limited exclusions required by the Medicare statute) and comprehensive Medicaid benefits as outlined in our proposal. Further, we acknowledge that States may take different pathways toward integrated care, and we believe the proposed change preserves flexibility for States.

Comment: A commenter requested clarification on how States would conform to the changes to the FIDE SNP definition. Another commenter requested clarification on what would happen if a State refused to clarify their State Medicaid agency contract. The commenter also requested clarification on how and whether dental benefits would be considered under this proposal as some State Medicaid programs cover limited dental benefits.

Response: We appreciate the requests for clarification. As proposed and finalized, the amendments to paragraph (2) of the definition of FIDE SNP will require the Medicaid MCO affiliated with the FIDE SNP to cover specified Medicaid benefits under a capitated contract under section 1903(m) of the Act. For contract year 2023 and 2024, the required Medicaid-covered benefits are all primary and acute care benefits and long-term services and supports, including coverage of nursing facility services for a period of at least 180 days during the coverage year, which is consistent with the current regulation and practice (because we currently permit a complete carve-out of Medicaid behavioral health benefits). Beginning with contract year 2025, the required Medicaid-covered benefits are all

primary and acute care benefits (including Medicare cost-sharing for Medicare Part A and Part B benefits), long-term services and supports, including coverage of nursing facility services for a period of at least 180 days during the coverage year, Medicaid home health (as defined in § 440.70), medical supplies, equipment, and appliances (as described in § 440.70(b)(3)), and Medicaid behavioral health services. We expect that States that wish to have FIDE SNPs operate in their State will review and, as necessary, update their MCO Medicaid managed care contracts to include this full scope of services for the necessary time periods.

If the FIDE SNP's MCO contract with the State Medicaid agency does not cover the required scope of Medicaid benefits, the MA organization could still offer a HIDE SNP, as defined at § 422.2, or a coordination-only D-SNP. Under the proposed regulation, CMS is not requiring the FIDE SNP to cover Medicaid dental benefits in order to meet the definition of FIDE SNP, but States may choose to include dental benefits in their Medicaid MCO contract with a FIDE SNP.

Comment: A commenter urged CMS to exercise the appropriate oversight to ensure that D-SNP enrollees have access to the full range of Medicare benefits for which they are eligible, and that D-SNPs adhere to Medicare requirements for access to medically necessary services. The commenter stated that MA plans have limited understanding of Medicare benefit and coverage criteria, leading to inappropriate denials of medically necessary care for vulnerable enrollees. The commenter urged CMS to (1) develop and implement a regulatory mechanism to ensure plan compliance with MA requirements, and (2) allow State Medicaid agencies greater authority over the operations of D-SNPs on the level of care determinations and access to medically necessary services, for example, by including certain reporting requirements in State contracts and using that information in public reporting and when establishing ongoing agreements.

Response: We appreciate the comment. CMS conducts regular program audits of MA plans to assess compliance with Medicare Advantage requirements, which include coverage of almost all Medicare Part A and Part B benefits. As discussed in the proposed rule (87 FR 1869), section 164(c)(4) of MIPPA does not require a State to enter into a contract with an MA organization with respect to a D-SNP (as described in section 1859(b)(6)(B)(ii) of the Act),

which therefore provides States with significant control over the availability of D-SNPs in their markets. The State's discretion to contract with D-SNPs, combined with the State's control over its Medicaid program, creates flexibility to require greater integration of Medicare and Medicaid benefits from the D-SNPs that operate in the State. States have broad authority to include specific requirements for D-SNPs in their State Medicaid agency contracts (and some States currently do so). We believe that State Medicaid agencies have sufficient oversight authority over the operations of D-SNP plans and flexibility to allow States to require that MA organizations provide reports to the States under the State Medicaid agency contracts so long as such reports and information sharing, and/or specific performance standards are consistent with applicable law and do not violate 42 CFR part 422 requirements. In the proposed rule (87 FR 1869 through 1870), we gave examples of States that require specific care coordination or data sharing activities in their contracts with D-SNPs.

(2) Requiring FIDE SNPs To Cover Medicaid Primary and Acute Care Benefits

Primary and acute care benefits for dually eligible beneficiaries are generally covered by Medicare as the primary payer rather than Medicaid. We proposed revisions to the FIDE SNP definition in paragraph (2)(i) of § 422.2 to limit the FIDE SNP designation to D-SNPs that cover primary care and acute care services and Medicare cost-sharing—to the extent such benefits are covered for dually eligible individuals in the State Medicaid program—through their capitated contracts with State Medicaid agencies. As described in the proposed rule (87 FR 1864), we proposed that this requirement would mean that all primary and acute care services, including the Medicare cost-sharing covered by the State Medicaid program (as discussed and finalized for 2025 in section II.A.5.b. of this final rule) must be covered by the FIDE SNP under the MCO contract between the State and the organization that offers the FIDE SNP and the MCO; we did not propose any exceptions or mechanism for carving out coverage of primary and acute care. However, we did clarify that Medicaid non-emergency medical transportation (NEMT) as defined in § 431.53 is not a primary or acute care service included in the scope of this provision. We solicited comment on whether we should allow for specific carve-outs of some of these benefits and services. We welcomed specific

examples of primary and acute care benefits that are either currently carved out of FIDE SNP capitated contracts with State Medicaid agencies or should be carved out and requested that comments include the reason for the existing and proposed future carve-outs.

Comment: Several commenters supported CMS's proposed requirement that all primary and acute care benefits must be covered by FIDE SNPs through a capitated contract with the State Medicaid agency.

Response: We thank the commenters for their support.

Comment: A commenter expressed support and agreement with CMS that Medicaid non-emergency medical transportation, while a critical service, should not be considered a primary or acute care service for the purpose of this definition. Other commenters expressed concern about excluding Medicaid NEMT from the services that must be included in a FIDE SNP's contract with a State. A commenter acknowledged that many States cover NEMT benefit through Statewide contracts with an NEMT provider, but believed that in many States NEMT does not work well for beneficiaries, and coordination with doctors and other service providers has been poor. The commenter believed integrating NEMT, if done well, should be able to help address some of those current deficiencies. Other commenters noted that NEMT is vital to ensure dually eligible individuals with transportation barriers have access to the care they need. These commenters cited a preliminary study on NEMT access in the MA program which shows that the use of an NEMT benefit in MA plans is correlated with an average 1.5 times more primary care physician visits than for those beneficiaries who didn't use the benefit.

Response: We appreciate the comments on the inclusion of NEMT. We acknowledge that NEMT is a critical service for dually eligible individuals. We note that our proposal does not preclude States from including NEMT in their contracts with D-SNPs or their Medicaid managed care plans. However, we continue to believe that it is not a primary or acute care service and therefore, NEMT is not required to be included in the Medicaid capitated contract that is necessary for FIDE SNP designation.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, including those in section II.A.5.b., we are finalizing our proposed revisions for paragraph (2)(i) of the definition of a FIDE SNP at § 422.2 with a delay in applicability date until the

2025 plan year for the requirement that FIDE SNPs cover Medicare cost-sharing in their capitated contracts with State Medicaid agencies.

(3) Requiring FIDE SNPs To Cover Medicaid Behavioral Health Services

We described at 87 FR 1865 the need for and importance of behavioral health services among dually eligible individuals. We explained earlier in this section that, consistent with how we were operationalizing the FIDE SNP definition since first adopting it at § 422.2 as established in the April 2011 final rule, we have allowed plans to meet the FIDE SNP definition even where a State excluded Medicaid behavioral health services from the capitated contract with the State Medicaid agency. In the April 2019 final rule, we added behavioral health services to the list of benefits that a D-SNP must cover, consistent with State policy, to obtain the FIDE SNP designation. We stated that complete carve out of behavioral health by a State from the scope of the Medicaid coverage provided by a FIDE SNP would be permissible (84 FR 15706 through 15707). We believe that a revision to that policy is appropriate and proposed to establish in a new paragraph (2)(iii) in the FIDE SNP definition at § 422.2 requiring that, for 2025 and subsequent years, the capitated contract with the State Medicaid agency must include coverage of Medicaid behavioral health services. This proposal would require the Medicaid MCO that is offered by the same entity offering the FIDE SNP to cover all behavioral health services covered by the State Medicaid program for the enrollees in the FIDE SNP. Our proposal to require FIDE SNPs to cover Medicaid behavioral health services is consistent with sections 1853(a)(1)(B)(iv) and 1859(f)(8)(D)(i)(II) of the Act. We proposed the 2025 date to allow time for MA organizations and States to adapt to our proposal. In addition, we proposed (as discussed in section II.A.5.e. of this final rule) an amendment to § 422.107 to add a new paragraph (h) to adopt a standard for limited exclusions from the scope of Medicaid benefits coverage by FIDE SNPs and HIDE SNPs of certain behavioral health services.

Restricting FIDE SNP designation to D-SNPs that cover Medicaid behavioral health services, as well as other benefits, under a capitated Medicaid MCO contract with the State Medicaid agency has two advantages. First, it better comports with a common understanding of being "fully integrated"—the term used in sections 1853(a)(1)(B)(iv) and 1859(f)(8)(D)(i)(II) of the Act—because

of the importance of behavioral health services for dually eligible individuals. Second, coverage of Medicaid behavioral health services also facilitates integrating behavioral health and physical health services, which can result in improved outcomes for dually eligible beneficiaries.³⁵ In addition, our proposal would more clearly distinguish a FIDE SNP—which would have to cover both LTSS and behavioral health services—from a HIDE SNP—which must cover either LTSS or behavioral health services. This would reduce confusion among stakeholders. As we discussed at 87 FR 1865 through 1866, most FIDE SNPs already have contracts with States to cover Medicaid behavioral health benefits, indicating that the market has already moved in this direction and relatively few FIDE SNPs would be impacted by our proposal. We believe the benefit of restricting FIDE SNP designation to plans that cover Medicaid behavioral health services in the capitated contract with the State Medicaid agency outweighs the benefit of continuing to allow FIDE SNP designation for plans that do not cover these benefits. Increasing the minimum scope of services that FIDE SNPs must cover in an integrated fashion is consistent with how section 1859(f)(8)(D) of the Act identifies Medicaid LTSS and behavioral health services as key areas for the integration of services. While the statute generally describes the increased level of integration that is required by referring to coverage of behavioral health or LTSS or both, we believe that exceeding that minimum standard is an appropriate goal for FIDE SNPs. The most integrated D-SNPs—FIDE SNPs—should cover the broadest array of Medicaid-covered services, including the behavioral health treatment and LTSS that are so important to the dually eligible population.

Further, increasing the minimum scope of services for FIDE SNPs is not inconsistent with section 1853(a)(1)(B)(iv) of the Act, which states that such plans are fully integrated with capitated contracts with States for Medicaid benefits, including LTSS. While section 1853(a)(1)(B)(iv) does not specify coverage of behavioral health services, it does not exclude coverage of behavioral health services either given that the section speaks generally to FIDE SNPs having fully integrated contracts with States for Medicaid benefits. As

³⁵ Medicaid and CHIP Payment and Access Commission. "Integration of Behavioral and Physical Health Services in Medicaid." March 2016. Available at: <https://www.macpac.gov/wp-content/uploads/2016/03/Integration-of-Behavioral-and-Physical-Health-Services-in-Medicaid.pdf>.

discussed at 87 FR 1865, behavioral health services are critical for dually eligible individuals and benefit from coordination with Medicare services and, we believe, coverage of Medicaid behavioral health benefits by a D-SNP is key to achieving fully integrated status.

Comment: Numerous commenters expressed support for CMS's proposal to require FIDE SNPs to cover behavioral health services. Several commenters believed the proposal addresses the intent of the BBA of 2018 to increase Medicare-Medicaid integration. A few commenters stated that behavioral health is a critical component of a fully integrated model of care and that inclusion of behavioral health is essential to providing high-quality, effective care for dually eligible individuals. A commenter stated that issues related to behavioral health and substance use have been exacerbated due to the COVID-19 pandemic, heightening the importance of access to behavioral health and substance use disorder treatment. Several commenters believed that strengthening access to behavioral health services is a growing concern that merits greater attention and that CMS's proposal is an important step in the direction toward improving and protecting access to behavioral health services. A commenter supported the proposal for FIDE SNPs to cover Medicaid behavioral health services along with continued flexibility of allowing some limited carve-outs. A commenter encouraged CMS to require all D-SNPs—not just FIDE SNPs—to cover Medicaid behavioral health services to address misalignment of services for dually eligible individuals with behavioral health diagnoses or addition, but the commenter recognized the proposal as a glide path toward greater integration.

Response: We appreciate the widespread support for our proposal. We agree that requiring FIDE SNPs to cover Medicaid behavioral health services as proposed at paragraph (2)(iii) of the definition of FIDE SNPs in § 422.2 would improve Medicare-Medicaid integration for beneficiaries.

Comment: A few commenters opposed the proposal because States with behavioral health carved out of Medicaid managed care, including California, New York and Pennsylvania, would not be permitted to have FIDE SNPs if the proposal is finalized. A commenter stated that operationalizing this change in Pennsylvania would require legislative action, that a multitude of stakeholder groups would oppose the proposal, and that the current Commonwealth administration

would not support the proposal. The commenter noted that there would be no way for the current Pennsylvania FIDE SNPs to meet the proposed CMS requirements beginning in 2025 to maintain their FIDE SNP status.

Another commenter noted that all D-SNPs in Oregon are required to coordinate with all Medicaid benefits, including dental and behavioral health. However, this commenter emphasized that D-SNPs in Oregon would not be able to easily achieve FIDE SNP status because of statutory carve-outs of LTSS. Several commenters requested clarification from CMS to address situations where benefits such as behavioral health or LTSS are carved out at a State level, including California and Pennsylvania, which prevents D-SNPs from receiving the HIDE SNP and FIDE SNP designation despite meeting other criteria. A commenter explained that some States believe a specialty behavioral health plan with a focused suite of intense services on the highest utilizers to improve outcomes among people with serious mental illness is the most effective way to decrease health care costs and improve quality. The commenter stated that, should D-SNPs in those States lose the ability to receive the HIDE SNP and FIDE SNP designation, it would result in the loss of flexibilities, such as the frailty adjustment, which could limit the D-SNPs' ability to provide complete care and supplemental benefits to their enrollees. To assist with any implementation of this provision, the commenter asked that CMS provide further clarification on the effect of this provision in States where a carve-out exists.

Response: We appreciate the perspective raised by these commenters. We recognize that not all States currently include Medicaid behavioral health and Medicaid LTSS benefits in their capitated Medicaid contracts. We believe the advantages of restricting FIDE SNP designation to plans that cover behavioral health and Medicaid LTSS benefits in the capitated contract with the State Medicaid agency outweigh the advantages of continuing to allow FIDE SNP designation for plans that do not cover these benefits. As stated in the proposed rule, increasing the minimum scope of services that FIDE SNPs must cover in an integrated fashion is consistent with how section 1859(f)(8)(D) of the Act identifies Medicaid LTSS and behavioral health services as key areas for the integration of services. While the statute generally describes the increased level of integration that is required by referring to coverage of behavioral health or LTSS

or both, we believe that exceeding that minimum standard is an appropriate goal for FIDE SNPs. The most integrated D-SNPs—FIDE SNPs—should cover the broadest array of Medicaid-covered services, including the behavioral health treatment and LTSS that are so important to the dually eligible population. As we discussed in the proposed rule (87 FR 1866), based on a New York State Medicaid policy change, we expect FIDE SNPs in New York to cover Medicaid behavioral health services effective January 1, 2023, so we do not anticipate our proposal will negatively impact FIDE SNPs in New York. If other States choose to keep behavioral health carved out of their SNP contracts, the remaining FIDE SNPs in those States would not meet the new requirements for FIDE SNPs that we are finalizing in the definition at § 422.2. Such plans may still meet the HIDE SNP definition at § 422.2, which we are also revising in this rulemaking.

Comment: Some commenters expressed concern about continuity and quality of care with behavioral health being carved into FIDE SNPs. A few commenters supported the provision to require FIDE SNPs cover behavioral health, but cautioned that CMS should require strong steps to avoid disruption in behavioral health care when transitioning individuals in the 24 FIDE SNPs that do not currently have behavioral health in their contracts. A commenter highlighted the importance of consistency, continuity, and ongoing access to trusted providers in behavioral health, and that even small disruptions in provider networks or changes in procedures to access providers can set back progress for affected beneficiaries.

A commenter urged CMS to consider, when approving carve-ins of behavioral health in any D-SNP, the importance of ensuring that the move does not degrade the quality of care. The commenter shared the following example: Some county systems have experience in behavioral health for persons with serious mental illness that is difficult to duplicate. In some jurisdictions, carved-out behavioral service systems, which serve many individuals who are homeless or in danger of homelessness, are closely integrated with housing service providers, working together to bring stability to this high need population. This commenter stated that, in the States where behavioral services were integrated into the FAI demonstrations, the path was often rocky, particularly where plan sponsors had little experience in the area.

Another commenter believed that the agencies with which States contract to provide behavioral health services often

provide inadequate support for individuals needing behavioral health treatment facilities and do not assist with finding community providers.

Response: We appreciate the comments and agree that continuity of care is important for enrollees receiving behavioral health care treatment and the valuable care and supports delivered by behavioral health providers who operating outside of FIDE SNPs. However, our proposal to require FIDE SNPs to cover Medicaid LTSS and Medicaid behavioral health services would not require any enrollees to transition from their current D-SNPs, nor would it require a State to carve-in behavioral health services. If the 24 FIDE SNPs do not meet the proposed FIDE SNP definition at § 422.2 due to a behavioral health carve-out in 2025, they may still meet the HIDE SNP definition at § 422.2 or the definition of a coordination-only D-SNP; therefore, enrollees could remain in these MA plans without disruption. In addition, States have the ability to establish linkages between behavioral health providers and D-SNPs to facilitate coordination of care if the State believes that is preferable to including such behavioral health services in the Medicaid MCO contract held by the FIDE SNP (or a less comprehensive Medicaid managed care contract held by a HIDE SNP). If States decide to carve in behavioral health services into FIDE SNPs or other D-SNPs, they can work with the plans and providers to ensure existing delivery systems for behavioral health are not disrupted.

While we proposed to allow limited carve-outs from the scope of Medicaid LTSS and Medicaid behavioral health services that must be covered by FIDE SNPs and HIDE SNP, as discussed in II.A.5.e., we clarify that we did not propose to establish requirements related to approving a State's decision to include certain services in their Medicaid programs. Our proposal, and the provisions finalized on this point in this rule, are specific to the minimum standards we believe are necessary for an MA plan to be designated as a fully integrated or highly integrated special needs plan for dually eligible individuals.

In addition, if a State newly includes Medicaid LTSS and/or Medicaid behavioral health services into its contract with a D-SNP, the D-SNPs must ensure continuity of care and integration of services, including with community programs and social services, as described at § 422.112(b). This requirement applies to all MA plans, including all types of D-SNPs.

Comment: A commenter expressed appreciation for the delayed effective date of 2025 but also suggested considering a longer timeframe for compliance or additional temporary exclusions from the scope of Medicaid coverage required for FIDE SNPs to allow for transitions. Another commenter urged CMS to consider allowing an extended timeframe beyond 2025 for States that demonstrate commitment to integrating behavioral health services in FIDE SNPs to account for the State's procurement strategy, demonstrate commitment to developing or refining a FIDE SNP model to integrate care for dually eligible individuals, or demonstrate a commitment to designing a State-specific solution to fully coordinate behavioral health services with all Medicare and Medicaid benefits that results in seamless coverage. The commenter requested that CMS offer supports to States that currently carve out behavioral health but wish to pursue more integrated models of care for dually eligible individuals, including technical assistance, additional resources for identifying the most appropriate pathway for carving behavioral health benefits into FIDE SNPs or more generally to Medicaid managed care contracts.

Response: We thank the commenters and appreciate their perspectives. We appreciate that States will have different pathways and considerations for including Medicaid behavioral health services in the MCO contracts held by FIDE SNPs by 2025, but we do not agree with extending the timeline. As we discuss in the proposed rule (87 FR 1865 through 1866), our review of State Medicaid agency contracts for FIDE SNPs in contract year 2021 indicates that States include full coverage of Medicaid behavioral health services for most FIDE SNPs (45 of the 69 FIDE SNPs) and policy changes in New York to be effective in 2023 will increase this number. If the remaining FIDE SNPs in California and Pennsylvania do not meet the additional requirements we proposed and are finalizing as part of the FIDE SNP definition at § 422.2, these plans may still meet the requirements to be a HIDE SNP, consistent with the revised definition that we proposed and are finalizing in this rule at § 422.2. We believe the benefit of restricting FIDE SNP designation to plans that cover Medicaid behavioral health services in the capitated contract with the State Medicaid agency outweigh the benefit of continuing to allow FIDE SNP designation for plans that do not cover these benefits.

We are available to assist States interested in pursuing more integrated models of care for dually eligible individuals, and we are actively planning for upcoming technical assistance opportunities.

Comment: A commenter highlighted the benefits of the behavioral health carve-out model used in Pennsylvania, in which a wide variety of behavioral health services are delivered through a specialized Mental Health and Substance Use Disorder provider network. The commenter stated that the carve-out model implements evidence-based and promising practices in the area of behavioral health, ensures a single point of accountability, better utilization management of services, and overall better management of costs while ensuring improved outcomes for the individuals served.

The commenter did not agree with CMS's logic that FIDE SNPs have an incentive to steer beneficiaries toward behavioral health Medicaid covered services for which they are not financially responsible. The commenter wrote that, since Medicaid is always the payor of last resort, if the service is a covered Medicare service, Medicare would be the primary payor.

The commenter also believes it is possible that changes in the health of enrollees or changes in membership over time could change a FIDE SNP's population mix to the point that it would impact their frailty score and thus make them eligible for the increased revenue from the frailty adjustment. The commenter expects this issue concerning potential future frailty adjustment payments would create pushback from current FIDE SNPs in Pennsylvania if they no longer qualify as FIDE SNPs.

Response: We appreciate that, in Pennsylvania and other States, policymakers may prefer to maintain existing delivery systems for behavioral health rather than to include those services in the MCO contracts held by FIDE SNPs. In those States, current FIDE SNPs would be re-designated as HIDE SNPs in 2025 and thus be ineligible for the frailty adjustment, even if the level of frailty in those D-SNPs would otherwise qualify the plan for frailty adjustment. That is a downside to our proposal but we do not believe it outweighs the other benefits outlined here of limiting FIDE SNP designation to plans that cover Medicaid behavioral health services, subject to minimal exclusions that CMS has approved under proposed § 422.107(h) (which is discussed and finalized in section II.A.5.e. of this final rule).

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed revisions for paragraph (2)(iii) of the definition of a FIDE SNP at § 422.2 without modification.

(4) Requiring FIDE SNPs To Cover Medicaid Home Health and Medical Supplies, Equipment, and Appliances

We proposed to require that, effective beginning in 2025, each FIDE SNP must cover additional Medicaid benefits to the full extent that those benefits are covered by the State Medicaid program. Two categories of Medicaid benefits we proposed to add include home health services, as defined in § 440.70, and medical supplies, equipment, and appliances, as described in § 440.70(b)(3). We believe that FIDE SNPs should be required to cover the Medicaid home health benefits and medical supplies, equipment, and appliances (to the full extent these benefits are covered by Medicaid) because both are critical services for dually eligible individuals, necessitate coordination due to being covered by both the Medicare and Medicaid programs, and are not clearly captured under other parts of the existing definition. Based on our review of State coverage requirements for Medicaid MCOs affiliated with FIDE SNPs, all current FIDE SNPs already cover Medicaid home health services and medical supplies, equipment, and appliances, so we did not expect our proposal to impact any existing FIDE SNPs. However, we proposed that this change in the scope of required coverage by FIDE SNPs would not apply until 2025 in case there were other circumstances of which we were not aware that would necessitate additional time to adapt to our proposal.

As such, we proposed to add new paragraphs (2)(iv) and 2(v) to the FIDE SNP definition at § 422.2 to require that the capitated contract between the State Medicaid agency and the legal entity that offers the FIDE SNP must include Medicaid home health services as defined at § 440.70 and Medicaid DME as defined at § 440.70(b)(3). In this final rule, we are correcting the terminology to use the phrase “medical equipment, supplies, and appliances” to better track the regulation text at § 440.70(b)(3). As described in the proposed rule (87 FR 1864), we proposed that this new requirement would mean that all Medicaid benefits in these categories would be covered by the MCO that is affiliated with the FIDE SNP, to the extent Medicaid coverage of such benefits is available to individuals

eligible to enroll in the FIDE SNP, and we did not propose any exceptions. Because the same legal entity must have the MA contract with CMS for the D-SNP and the Medicaid MCO contract with the State and the enrollment in the FIDE SNP must be limited to dually eligible individuals who are also enrolled in the MCO, this entity is functionally all the FIDE SNP.

Comment: A number of commenters expressed support for CMS’s proposal to require FIDE SNPs to cover Medicaid home health and DME under their Medicaid MCO contracts. Several commenters noted that home health services and DME are critical services for dually eligible individuals. A commenter noted that home health is important because it curtails the need for more expensive health care options such as emergency room visits, hospital readmissions, and skilled nursing facility stays. The commenter also stated that DME benefits are important as they can assist with mobility and independence for beneficiaries and therefore improve quality of life. Several commenters highlighted that beneficiaries have long faced complex barriers to acquiring certain DME. A commenter noted that the proposal addresses the intent of the BBA of 2018 to increase Medicare-Medicaid integration. A commenter expressed their support and noted that D-SNP State Medicaid agency contracts in Arizona already conform to CMS’s proposed definition.

Several commenters agreed with CMS that 2025 implementation is appropriate in case any unforeseen issues arise. A few commenters suggested that the requirement for integration of home health and DME go into effect immediately rather than waiting until 2025.

Response: We appreciate the widespread support of our proposal that FIDE SNPs must cover Medicaid home health and DME under their Medicaid MCO contracts. We agree with commenters who stated that accessing DME (that is, medical equipment, supplies, and appliances) can be a challenge for beneficiaries, and we believe this proposal is a step towards addressing that issue. While a few commenters questioned if it is necessary to wait until 2025 to implement the proposal, we believe waiting until 2025 to require coverage will allow adequate time to adapt to any unforeseen circumstances that may arise and will not cause loss of any integration in current FIDE SNPs that already cover Medicaid home health services and DME.

Comment: A commenter stated that States will need to ensure that D-SNPs understand the details of Medicaid coverage of the required services to ensure that enrollees receive the full extent of benefits they are currently eligible to receive under Medicaid. This will require State oversight and reporting by D-SNPs to the State.

Response: We thank the commenter. As proposed and finalized, this new requirement for FIDE SNPs must be met through the Medicaid MCO contract held by the legal entity that offers both the FIDE SNP and the Medicaid MCO. We anticipate that the Medicaid MCO contract addresses reporting by the entity (as would any Medicaid managed care contract whether associated with a HIDE SNP or coordination-only D-SNP or not) to the State and oversight by the State over Medicaid benefit delivery and administration. Medicaid managed care regulations, such as § 438.66, require States to monitor their Medicaid managed care programs. Further, under current regulation at § 422.107(c)(1), the State Medicaid agency contract must document the D-SNP’s responsibility to coordinate the delivery of Medicaid benefits for its enrollees. States and D-SNPs should already be communicating related to Medicaid benefits. This communication will be important to successful implementation of this final rule.

Comment: A commenter supported the proposal to require that FIDE SNPs cover Medicaid home health services and DME as defined in § 440.70(b)(3) but recommended a modification. The commenter highlighted that the terminology used in § 440.70(b)(3) is “medical supplies, equipment, and appliances suitable for use in any setting in which normal life activities take place.” The commenter recommended that CMS require FIDE SNPs to cover “medical supplies, equipment and appliances” as referenced in that subsection to ensure that the regulation is not interpreted to require coverage of only a subset of that category of services. The commenter believed that allowing nurse practitioners to order and certify Medicare and Medicaid home health services, and Medicaid medical supplies, equipment and appliances for their patients, as authorized in the CARES Act, has been integral to patients receiving medically necessary services in a timely fashion.

Response: We appreciate the commenter’s support and suggestion. We believe that it is important to utilize the prevailing Federal definitions for Medicaid services and therefore will use the terminology in § 440.70(b)(3),

“medical supplies, equipment, and appliances,” along with the reference to § 440.70(b)(3), in the new paragraph (2)(v) of the FIDE SNP definition at § 422.2 to clearly identify the mandatory scope of coverage.

Comment: A commenter stated that the current Puerto Rico D–SNP program offered with the local government, Platino, is fully coordinated but the D–SNPs do not cover certain LTSS and nursing home services because Congress chose not to provide funding to Puerto Rico for these Medicaid services. The commenter urged CMS to allow plans in Puerto Rico to be eligible as FIDE SNPs and receive the frailty adjustment even though those D–SNPs do not cover these benefits.

Response: We appreciate the comment about Puerto Rico’s Medicaid program and understand the lack of Medicaid long term care benefits in Puerto Rico prevents D–SNPs in Puerto Rico from meeting the FIDE SNP requirements. As a result, no D–SNPs in Puerto Rico currently meet the requirements to be a FIDE SNP, and this rulemaking does not change those circumstances.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposed revisions in paragraph (2)(iv) of the definition of FIDE SNP at § 422.2. We are finalizing paragraph (2)(v) of the FIDE SNP definition with a technical change to clarify that for plan year 2025 and subsequent years, the Medicaid capitated contract required for a FIDE SNP must cover medical supplies, equipment, and appliances as described in § 440.70(b)(3).

d. Clarification of Coverage of Certain Medicaid Services by HIDE SNPs

CMS first defined the term “highly integrated dual eligible special needs plan”, or HIDE SNP, at § 422.2 in the April 2019 final rule. As currently defined at § 422.2, a HIDE SNP is 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 Medicaid LTSS, Medicaid behavioral health services, or both, consistent with State policy. As stated in the April 2019 final rule (84 FR 15705), the HIDE SNP designation is consistent with section 1859(f)(8)(D)(i)(II) of the Act that recognizes a level of integration that does not meet the requirements of the

FIDE SNP with respect to the breadth of services provided under a Medicaid capitated contract with the State.

We proposed to revise the HIDE SNP definition at § 422.2 consistent with proposed changes to the FIDE SNP definition described earlier in section II.A.5.c. of this final rule to more clearly outline the services HIDE SNPs must include in their contracts with State Medicaid agencies. Similar to our proposal for the revised FIDE SNP definition, we proposed to move away from the current use of “coverage, consistent with State policy” language in favor of more clearly articulating the minimum scope of Medicaid services that must be covered by a HIDE SNP by using the phrase “to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a highly integrated dual eligible special needs plan (HIDE SNP) in the State.” In section II.A.5.e. of this final rule, we also discuss our proposal to adopt new provisions in § 422.107 to permit limited carve-outs from the required scope of services.

Later in this section, we describe our proposal to require that the capitated Medicaid contract applies in the entire service area for the D–SNP in more detail. Otherwise, our proposal was generally a reorganization and clarification of the scope of Medicaid benefits that must be covered by a HIDE SNP.

Comment: Numerous commenters supported CMS’s proposal for HIDE SNPs to be required to cover the vast majority of Medicaid behavioral health services or the vast majority of Medicaid LTSS. MACPAC expressed support for CMS’s proposed changes to the HIDE SNP definition because the proposed change would further integration and clarify the definitions of these plans. Several other commenters supported the proposal and believed that it would further clarify the distinction between HIDE SNP and FIDE SNP coverage requirements. A commenter expressed support because they believed that there has been a significant lack of clarity and comprehension around HIDE SNP definitions, and, in general, what can be expected of particular types of SNPs. Another commenter expected that the proposal would reduce confusion, provide more transparency of State Medicaid agency contract review, and allow continued flexibility for D–SNPs to provide either LTSS or behavioral health services. Another commenter expressed support because CMS’s proposal maintains flexibility for States to leverage integrated plans even if they cannot meet all the requirements for FIDE SNPs.

Response: We appreciate the numerous comments of support for our proposal to revise the definition of HIDE SNPs at § 422.2. We agree that these changes, as proposed and finalized in this rule, and in conjunction with the proposed changes to § 422.107(g) and (h), will clarify the scope of responsibilities for HIDE SNPs, better distinguish them from FIDE SNPs and coordination-only D–SNPs, and provide flexibility to States in how they use D–SNPs in connection with their Medicaid programs.

Comment: A commenter expressed concern that the proposed revisions may not adequately account for variation in State approaches to Medicaid managed care. The commenter recommended CMS reconsider limiting the HIDE SNP definition to the extent that it would disqualify otherwise integrated agreements. The commenter believed the proposed changes only serve to complicate administration, particularly if States with carve-outs beyond the proposed limits were required to pivot to coordination-only agreements to preserve D–SNPs.

Another commenter recommended that CMS permit a HIDE SNP with a Medicaid MCO contract that covers behavioral health services to operate, without requiring the contract to include LTSS. The commenter also suggested that CMS clarify that a HIDE SNP with a State Medicaid agency contract that includes Medicaid services, including behavioral health, does not need to also have separate Medicaid MCO contract.

Response: While we appreciate the commenters’ perspectives, we believe that the HIDE SNP designation should be consistent with a high level of integration in which the vast majority of Medicaid LTSS or the vast majority of Medicaid behavioral health services are covered by the capitated contract with the State. These proposed changes are consistent with our proposal to amend the FIDE SNP definition described in section II.A.5.c. to more clearly outline the services integrated D–SNPs, meaning both FIDE SNPs and HIDE SNPs, must include in their contracts with State Medicaid agencies. We clarify that if the MA organization offering a D–SNP—or the MA organization’s parent organization, or another entity that is owned and controlled by its parent organization—has a Medicaid managed care contract with the State that includes coverage of Medicaid behavioral health benefits but excludes coverage of Medicaid LTSS, the MA organization may qualify as a HIDE SNP provided other applicable requirements (such as a compliant

Medicaid State agency contract, as required by § 422.107 and, beginning January 1, 2025, minimum service area requirements) are met. We further clarify that the HIDE SNP definition, either currently or as amended in this final rule, does not require the affiliated Medicaid plan to be an MCO contract, it could be a PAHP or PIHP; Medicaid managed care regulations in 42 CFR part 438 establish the requirements for a managed care contract (that is, a capitated contract) for coverage of Medicaid benefits.

Comment: A few commenters requested clarification on whether these provisions limit HIDE SNP enrollments to exclusively aligned enrollment. A commenter noted that while they support greater clarification around alignment for HIDE SNPs, they recognized the challenges of exclusively aligned enrollment and that States may need to contract with D-SNPs in ways that promote integration but also allow States to design programs that meet their specific needs and fit within the parameters of current State benefit offerings. The commenter believed additional clarity may be helpful in defining alignment options for HIDE SNPs.

Response: We welcome the opportunity to clarify our proposal. We clarify that HIDE SNP plans are not required to have exclusively aligned enrollment. Please see the discussion in section II.A.5.f. for more detail about our proposal to require the capitated contract in the entire service area for the D-SNP.

Comment: Some commenters requested that CMS apply the frailty adjustment to all highly integrated products, including HIDE SNPs. A few commenters specifically encouraged CMS to allow HIDE SNPs that provide LTSS to be eligible for the frailty adjustment. Several commenters noted that there are strong similarities between enrollees in HIDE SNPs and FIDE SNPs, and since both plan types serve enrollees that are generally frailer than the typical Medicare population, both should be eligible to receive higher adjustment payments if they have a similar average frailty as the PACE program. A commenter stated that allowing HIDE SNPs to receive the frailty adjustment would more appropriately apply the frailty adjustment to integrated plans serving people dually eligible for both Medicare and Medicaid, while acknowledging State contracting differences. A few commenters stated that allowing HIDE SNPs to receive the frailty adjustment would make the HIDE SNP market more

competitive or incentivize further integration of plans.

Response: We appreciate the comments regarding the frailty adjustment provided by section 1853(a)(1)(B)(iv) of the Act; however, they are beyond the scope of this rulemaking.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed revisions for the definition of a HIDE SNP at § 422.2 without modification.

e. Medicaid Carve-Outs and FIDE SNP and HIDE SNP Status

As discussed earlier, we proposed to require FIDE SNPs and HIDE SNPs to cover the full scope of the Medicaid coverage under the State Medicaid program of the categories of services that are specified as minimum requirements for these plans as outlined in sections II.A.5.c. and II.A.5.d. We also proposed that coverage of the full scope of the specified categories of Medicaid benefits is subject to an exception that may be permitted by CMS under § 422.107(g) or (h). We proposed to codify at § 422.107(g) and (h), respectively, current CMS policy allowing limited carve-outs from the scope of Medicaid LTSS and Medicaid behavioral health services that must be covered by FIDE SNPs and HIDE SNPs. As discussed in section II.A.5.c.1. of this final rule, CMS has historically determined D-SNPs to be FIDE SNPs even where the State carved out certain primary care, acute care, LTSS, and behavioral health services from the Medicaid coverage furnished by the MCO offered by the FIDE SNP. CMS has similarly permitted carve-outs of the scope of Medicaid coverage furnished in connection with HIDE SNPs. We believe that codifying these policies permitting exclusions from the scope of Medicaid behavioral health and Medicaid LTSS would improve transparency for stakeholders and allow us to better enforce our policies to limit benefit carve-outs. We did not propose to permit exclusions from coverage of Medicaid primary care or acute care for FIDE SNPs.

Our proposal is consistent with the policy described in a memorandum CMS issued in January 2020,³⁶ with some revisions to improve clarity and

avoid misinterpretations of our policy that might result from language in the memorandum that differs in the allowed carve-outs for LTSS and behavioral health services. Like the memorandum, our proposal was designed to accommodate differences in State Medicaid policy—for example, the desire to retain delivery through the Medicaid FFS program of specific waiver services applicable to a small, specified population, or to retain coverage in the Medicaid FFS program for specific providers—without significantly undermining the level of Medicaid integration provided by HIDE SNPs and FIDE SNPs. While we generally favor integration and worry that Medicaid benefit carve-outs work against integration, we believe our proposal strikes a balance between the current realities of State Medicaid managed care policy, applicable statutory provisions, and our implementation of those statutory provisions toward the goal of raising the bar on integration.

Currently and under our proposal to revise the definition, a D-SNP may meet the criteria for designation as a HIDE SNP if it covers either Medicaid LTSS or Medicaid behavioral health services under a State Medicaid agency contract. We currently grant HIDE and FIDE SNP status despite Medicaid LTSS carve-outs of limited scope if such carve-outs (1) apply to a minority of the full-benefit dually eligible LTSS users eligible to enroll in a HIDE or FIDE SNP who use long-term services and supports or (2) constitute a small part of the total scope of Medicaid LTSS provided to the majority of full-benefit dually eligible individuals eligible to enroll in a HIDE or FIDE SNP who use Medicaid LTSS. We provided examples of permissible LTSS carve-outs at 87 FR 1867. D-SNPs can currently obtain the HIDE or FIDE SNP designation with limited carve-outs of Medicaid behavioral health services from their capitated contracts. A behavioral health service carve-out would be of limited scope if such a carve-out (that is, exclusion from coverage by the Medicaid managed care plan affiliated with the D-SNP): (1) Applies primarily to a minority of the full-benefit dually eligible users of behavioral health services eligible to enroll in a HIDE or FIDE SNP; or (2) constitutes a small part of the total scope of behavioral health services provided to the majority of beneficiaries eligible to enroll in a HIDE or FIDE SNP. We specified that only a small part of the Medicaid behavioral health services may be carved out in order to ensure that the innovative services that many

³⁶ CMS, “Additional Guidance on CY 2021 Medicare-Medicaid Integration Requirements for Dual Eligible Special Needs Plans”, January 17, 2020. Retrieved from: <https://www.cms.gov/htpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpms-hpms-memos-archive/hpms-memo-5>.

Medicaid programs provide to individuals with severe and moderate mental illness are covered through the D-SNP (through the MA organization's Medicaid managed care capitated contract) or the affiliated Medicaid managed care plan (through the Medicaid managed care capitated contract with the MA organization's parent organization or another entity that is owned or controlled by the parent organization). We believe that level of integrated coverage is a minimum standard for a D-SNP to be considered highly or fully integrated. We provided examples of permissible LTSS carve-outs at 87 FR 1868.

We described our intent to administer this proposed regulation consistent with our current policy and therefore anticipated little disruption to occur because of this proposed change.

Comment: Numerous commenters supported the codification of current CMS policy allowing limited carve-outs from the scope of Medicaid LTSS and Medicaid behavioral health services that must be covered by FIDE SNPs and HIDE SNPs. Several commenters agreed with CMS that limited or narrow carve-outs of LTSS and behavioral health services are essential given the wide variation in how States choose to provide those services. Another commenter suggested the refined definitions of FIDE and HIDE SNPs could encourage States to carve in LTSS for individuals who need the services the most. Another commenter recognized that the proposed revisions to the HIDE SNP and FIDE SNP definitions are intended to enhance the level of integration in such plans.

Response: We appreciate the widespread support we received for our proposal. While we generally favor integration and worry that Medicaid benefit carve-outs work against integration, we believe our proposal strikes a balance between the current realities of State managed care policy, applicable statutory provisions, and our current implementation of those statutory provisions toward the goal of raising the bar on integration. Our proposal is consistent with the policy described in a memorandum CMS issued in January 2020, and we believe that these revisions will improve clarity and avoid misinterpretations of our policy that might result from language in the memorandum that differs in the allowed carve-outs for Medicaid LTSS and behavioral health services. We agree with commenters that monitoring the impact of carve-outs for impacts on enrollees' access to services and care coordination processes is important.

Comment: A commenter recommended that CMS standardize Medicaid benefit carve-out requirements for States implementing a FIDE SNP model. The commenter further suggested that CMS set rules for how many benefit carve-outs States will be allowed, whether the carve-outs include benefits that do not qualify as primary and acute care services (for example, non-emergency transportation), and how the carve-outs would integrate operationally with the FIDE SNPs if the underlying benefit is handled by a delegated vendor.

Response: We thank the commenter for their perspectives. However, we do not believe it is feasible to establish a uniform set of carve-out limits or a numerical limit on carve-outs due to the variation across States. The requirements we are finalizing at § 422.107(g) and (h) permit only limited carve-outs from the Medicaid LTSS and Medicaid behavioral health services coverage that HIDE SNPs and FIDE SNPs must have included in their managed care contract with the State Medicaid agency. We will apply this evaluation looking at coverage of Medicaid LTSS benefits and/or Medicaid behavioral health services as a whole in connection with the scope of coverage in the Medicaid managed care contract affiliated with the FIDE SNP or HIDE SNP. While the limits in the regulations we are adopting do not equate to or specify how many Medicaid LTSS and/or Medicaid behavioral health services carve-outs a State may have, it does act as a substantive limit when we make determinations that a D-SNP qualifies as a FIDE SNP or HIDE SNP.

The finalized paragraph (2)(i) of the FIDE SNP definition at § 422.2 (discussed earlier in sections II.A.5.c. of this final rule) requires each FIDE SNP to cover primary and acute care services, including Medicare cost-sharing covered by the State Medicaid program as of 2025, under the MCO contract between the State and the organization that offers the FIDE SNP. We did not propose and are not adopting any exceptions or permissible carve-outs for this required coverage. We solicited comment on whether we should allow for specific carve-outs of some primary and acute care benefits and welcomed examples of such benefits that are either currently carved out of FIDE SNP capitated contracts with State Medicaid agencies or should be carved out. We did not receive any comments in response to this solicitation and are finalizing our proposal without modification. We stated in section II.A.5.c. that Medicaid

NEMT as defined in § 431.53 is not a primary or acute care service included in the scope of this provision, but that goes to identifying the scope of acute and primary care services, not establishing permissible carve outs for categories of acute and primary care services.

Comment: Another commenter believed carve-outs interfere with true integration but indicated that some Medicaid services may have, historically, not been provided appropriately by managed care plans. The commenter suggested that a State carve-out may be necessary to ensure that enrollees have access to the care they need and recommended that CMS work closely with States to determine why certain carve-outs exist and what the impact may be on access to care if the carve-outs are eliminated. Another commenter stated that the application of a carve-out to a minority of enrollees has less of an impact on individuals needing Medicaid LTSS services and behavioral health services, and several commenters advocated that States should monitor the impact of any service carve-out on enrollees and their quality of care and life.

Response: We thank the commenters and appreciate their perspectives. We agree that monitoring and oversight of carve-outs is important and will work with States to ensure quality of care is not compromised and enrollees are educated about changes to the scope of benefits available through a HIDE SNP or FIDE SNP, particularly in the case of Medicaid LTSS and behavioral health services. We clarify that our proposal would not require that States carve in benefits if they prefer not to do so because MA program regulations permit a D-SNP to be offered without the MA organization (or its parent organization or an entity also owned by its parent organization) having a capitated contract for coverage of Medicaid behavioral health or LTSS benefits. As proposed and finalized, § 422.107(g) and (h) are specific to the required scope of coverage of Medicaid benefits by FIDE SNPs and HIDE SNPs with regard to behavioral health and LTSS benefits.

Comment: A commenter provided an example whereby beneficiaries who may consider enrolling in plans with carve-outs are notified that the integrated services do not include Medicaid LTSS and/or behavioral health services to the extent they are carved-out.

Response: We appreciate this comment and example. Per § 422.2267(e)(5)(ii)(D), all D-SNPs must clearly state which services are included in their plan benefit packages, including

Medicaid benefits, by either including the description in the required summary of benefits or putting the description in a separate document that is provided to enrollees with the summary of benefits. In addition, § 422.111 requires annual disclosures by all MA plans, including D-SNPs, of the scope of and rules for coverage under the plan.

Comment: Another commenter supported full integration and described experience with State carve-outs of Medicaid behavioral health and LTSS services, which the commenter indicated prevents D-SNPs from receiving the HIDE SNP and FIDE SNP designation. The commenter suggested addressing the needs of the dually eligible population which may require specialized programs and tailored methods to support recovery-oriented systems of care.

Response: We thank the commenter and agree that addressing the needs of the dually eligible population is vital for improving health outcomes and is greatly facilitated when the broadest scope of Medicaid behavioral health and LTSS services are integrated into HIDE SNP and FIDE SNP benefit packages.

Comment: Several commenters requested guidance and technical assistance in various areas. A commenter suggested guidance to States to promote interoperability and data sharing between plans specifically when a benefit is carved out. Another commenter suggested CMS provide guidance to States on how to implement a model of care that allows for complete integration.

Response: We thank the commenters and appreciate these suggestions. We anticipate offering technical assistance and providing sub-regulatory guidance based on this final rule.

Comment: Several commenters requested clarification on what is meant by “a minority of beneficiaries eligible to enroll” and “small part of the total scope of services” as those phrases are used in proposed § 422.107(g) and (h). These commenters suggested that CMS provide additional examples or further description of the review process that would be utilized to make these determinations.

Response: We appreciate the commenters’ desire for additional clarification. We believe the examples we provided in the proposed rule at 87 FR 1867 through 1868 are instructive of the type of Medicaid LTSS and behavioral health carve-outs we would permit under § 422.107(g) and (h). We prefer to not inadvertently limit the terms “minority of beneficiaries eligible to enroll” or “small part of the total scope of services” by providing

additional examples, given the potential variation across States. We determine the integration status for MA organizations offering D-SNPs through our annual review of State Medicaid agency contracts (that is, the contracts between States and D-SNPs required by § 422.107) in July. As part of that review, we will assess the scope of existing or proposed carve-outs against the §§ 422.2 and 422.107(g) and (h) requirements and determine whether a D-SNP meets the FIDE SNP or HIDE SNP designation. Where the State Medicaid agency contract is a separate contract from the Medicaid MCO contract, we may review the Medicaid MCO contract available on the State Medicaid agency’s website when that is necessary to our evaluation. We strongly encourage States and MA organizations to seek technical assistance from CMS as necessary. As the scope of coverage of Medicaid benefits must be set in the Medicaid capitated contract with the Medicaid managed care plan, we anticipate that States may seek technical assistance outside of the timeline for MA organizations to submit their State Medicaid agency contracts that are required by § 422.107(a) through (c).

Comment: In addition, a commenter suggested CMS clarify what happens in certain States that impose caps on Medicaid LTSS eligibility resulting in enrollment limits and how this carve-out provision would be applied or affected in those cases. This commenter also urged CMS take into consideration that, when determining criteria for carve-outs in applicable integrated plans, even minor Medicaid carve-outs can greatly complicate the unified grievances and appeals process to which they are subject, causing more confusion for beneficiaries and providers as well. The commenter suggested that CMS educate States about these impacts as part of the process.

Response: We thank the commenter. FIDE SNPs and HIDE SNPs are required by this rule to provide the minimum required Medicaid benefits to the extent that Medicaid coverage is available to beneficiaries who are eligible to enroll in the FIDE SNP or HIDE SNP. So, if the Medicaid State plan excludes coverage altogether of certain benefits for certain beneficiaries (that is, there is no Medicaid coverage at all, as opposed to Medicaid coverage being carved out of a managed care program or contract), our regulatory provision will not withhold designation of the D-SNP as a FIDE SNP or HIDE SNP solely based on that. Thus, FIDE SNPs are required to provide Medicaid LTSS to all who meet the State eligibility criteria for LTSS (for example, nursing home level of care)

but not to all FIDE SNP enrollees, some of whom might not be eligible for the Medicaid benefit at all. HIDE SNPs are required to provide Medicaid LTSS, and/or Medicaid behavioral health services. To the extent Medicaid LTSS is not available to an enrollee because there is an enrollment cap or waiting list (for example, such as those related to Medicaid home and community-based services waivers), then the enrollee has not met the State eligibility criteria and the D-SNP could still meet the requirements at proposed § 422.107(g) and (h) to be a HIDE or FIDE SNP. Regarding applicable integrated plans, only the services covered by the applicable integrated plans are subject to the unified appeals and grievances processes. However, all D-SNPs that receive an appeal for a carved-out Medicaid services have a responsibility to assist the enrollee in the appeals process for that service, per § 422.562(a)(5).

Comment: Several commenters expressed concern that carve-outs may lead to disjointed and uncoordinated care and that carve-outs do not enhance care coordination. Another commenter indicated that they believe the proposal at § 422.107(g) and (h) impinges on State autonomy and flexibility.

Response: We appreciate the commenters’ concerns and we acknowledge the commenters’ perspective on this issue. However, we believe that the requirements proposed at § 422.107(g) and (h) strike an appropriate balance between the current realities of State managed care policy, applicable statutory provisions, and our implementation of those statutory provisions toward the goal of raising the bar on integration, while permitting State flexibility.

Comment: A commenter expressed concerns regarding the carve-out examples provided by CMS. Specifically, the commenter questioned use of substance abuse treatment, rural health clinic (RHC) and FQHC services as examples of permissible carve-outs, and requested feedback on whether the examples provided were appropriate. The commenter opined that these services are not limited in scope and should not be included as permissible carve-outs. The commenter noted that, according to the Substance Abuse and Mental Health Administration, dually eligible beneficiaries have a significantly higher rate of behavioral health and substance use disorder conditions than the non-dually eligible population. The commenter noted that, for many dually eligible individuals, RHCs and FQHCs are their primary source of behavioral health and

substance use disorder treatment. Therefore, the commenter requested that CMS not include these services as permissible carve-outs.

Response: We appreciate the comment and agree that the services identified are important to dually eligible individuals and care coordination would be facilitated if these services were not carved out from FIDE SNP or HIDE SNP Medicaid benefits. However, to our knowledge, only one State carves out FQHC and RHCs from Medicaid benefits covered under the FIDE SNP's or HIDE SNP's MCO contract with the State Medicaid agency. That State, Minnesota, has carved out Medicaid FQHC and RHC services from the benefits delivered by FIDE SNPs and HIDE SNPs because of the complexity in adjudicating Medicaid payments for these provider types and services. The State has implemented a data exchange process between these providers and the State's FIDE SNPs and HIDE SNPs to facilitate care coordination. At least six States carve substance use disorder services out from the services delivered by HIDE SNPs and FIDE SNPs. We believe the frequency of such carve-outs may be indicative of the difficulty in subsuming these services under Medicaid managed care. We do not have any information indicating that Medicaid behavioral health services or LTSS delivered by FQHCs and RHCs or substance use disorder services do not constitute a small part of the total scope of such services provided to the majority of beneficiaries eligible to enroll in these D-SNPs. Thus, we are finalizing language at § 422.107(g) and (h) that will continue to allow such limited carve-outs of Medicaid LTSS and Medicaid behavioral health services from the services covered by FIDE SNPs and HIDE SNPs. We will continue to assess whether these specific carve-outs meet our criteria in light of the specific facts in a given situation. In addition, we may consider future rulemaking to revise the standard in § 422.107(g) and (h) if necessary.

Comment: A commenter agreed with CMS that personal care services should not be carved out but also suggested that there could be instances where FIDE SNPs and HIDE SNPs do carve out services, such as behavioral health and Medicaid LTSS, and integration could still be achieved. This commenter provided an example where county personnel from the In-Home Supportive Services Program, California's carved-out personal care program, participated in care planning meetings with the MMP.

Response: We appreciate the comment and an example of engagement between personal care services staff and the MMP under circumstances where personal care services are carved out. While we recognize there may be other similar examples, as we discussed at 87 FR 1867 through 1868, our current policy, which we proposed and are finalizing in the definitions of FIDE SNP and HIDE SNP in § 422.2 and in § 422.107(g) and (h), is that FIDE SNP or HIDE SNP designation is not available for D-SNPs where the Medicaid coverage has extensive carve-outs of Medicaid behavioral health and/or Medicaid LTSS benefits. While we encourage the use of additional means of coordinating services, we do not believe that to be the appropriate standard to use.

Comment: A commenter requested additional clarification on how CMS views Medicaid carve-outs, including how CMS would address circumstances where a State's configuration of services and coverage differs from CMS's proposed requirements at §§ 422.2 and 422.107(g) and (h) for FIDE SNP and HIDE SNP coverage of Medicaid LTSS and Medicaid behavioral health services, as is the case in California. This commenter sought clarification of CMS's expectation that the FIDE SNP and/or HIDE SNP cover community-based LTSS. Similarly, the commenter requests information on CMS's view of behavioral health carve-outs in California, where behavioral health services for individuals with serious mental illness are the responsibility of the county mental health plan.

Response: Our proposal at § 422.107(g) through (h) does not change States' abilities to make decisions about its Medicaid managed care program or how services are delivered in Medicaid. Instead, our regulations at § 422.107(g) and (h) as well as the revisions to the definitions of FIDE SNP and HIDE SNP in § 422.2 limit the HIDE SNP and FIDE SNP designation based on the extent of carve-outs or exclusions from Medicaid coverage furnished under the Medicaid capitated contract required with the D-SNP or an affiliated Medicaid managed care plan. The current combination of LTSS and behavioral health carve-outs in California precludes most D-SNPs operating in California from qualifying for HIDE SNP or FIDE SNP designation.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed provisions at § 422.107(g) through (h) without modification.

f. Service Area Overlap Between FIDE SNPs and HIDE SNPs and Companion Medicaid Plans

MA organizations can achieve greater integration when they maximally align their FIDE SNP and HIDE SNP service areas with the service areas of the affiliated Medicaid managed care plan (meaning the entities that offer capitated Medicaid benefits for the same enrollees under a capitated contract with the State). Service area alignment also better comports with the minimum Medicare-Medicaid integration standards established by section 50311(b) of the BBA of 2018, which amended section 1859 of the Act. We codified the required level of integration for D-SNPs in paragraph (4) of the definition of D-SNP at § 422.2 in the April 2019 final rule.

Currently, under § 422.2, a D-SNP can meet the requirements to be designated as a FIDE SNP or HIDE SNP even if the service area within a particular State does not fully align with the service area of the companion Medicaid plan (or plans) affiliated with their organization.³⁷ For FIDE SNP or HIDE SNP enrollees outside the companion Medicaid plan's service area, this lack of alignment does little to integrate Medicare and Medicaid benefits as the D-SNP enrollee does not have the option to join the companion Medicaid plan. We believe requiring service area alignment in the definitions of FIDE SNP and HIDE SNP would encourage MA organizations and States to create better experiences for beneficiaries and move toward greater integration, which would be consistent with the amendments to section 1859(f) of the Act made by section 50311(b) of the BBA of 2018.

Under our authority at section 1859(f)(8)(D) of the Act to require that all D-SNPs meet certain criteria for Medicare and Medicaid integration, we proposed to amend the FIDE SNP definition at § 422.2 by adding new paragraph (6) and the HIDE SNP definition at § 422.2 by adding new paragraph (3) to require that the capitated contracts with the State Medicaid agency cover the entire service area for the D-SNP for plan year 2025 and subsequent years. Requiring the service area of the D-SNP contract to completely overlap with the service area of the Medicaid capitated (that is, managed care) contract will facilitate all

³⁷ CMS has acknowledged this and encouraged MA organizations to align these service areas in guidance issued on January 17, 2020, regarding D-SNPs. See <https://www.cms.gov/files/document/cy2021dsnpsmedicaremedicaidintegrationrequirements.pdf>.

FIDE SNP and HIDE SNP enrollees having access to both Medicare and Medicaid benefits from a single parent organization.

Our proposal addressed an unintended loophole to the minimum D-SNP integration criteria we adopted as part of the definitions of FIDE SNP and HIDE SNP: Where a D-SNP can qualify as either a FIDE SNP or HIDE SNP by only having a small portion of its service area (and therefore, enrollment) in the same service area as the companion Medicaid plan. We do not believe that the existing definitions are consistent with the goals and purposes of increasing Medicare-Medicaid integration for D-SNPs as a whole or particularly for FIDE SNPs and HIDE SNPs, which are supposed to have more than a bare minimum level of integration.

We did not intend for the proposal to limit State options for how they contract with managed care plans for their Medicaid programs, but to require the FIDE and HIDE SNPs to limit their MA service areas to areas within the service areas for the companion Medicaid plan. We did not propose to limit the service area of the companion Medicaid plan to that of the D-SNP service area. Therefore, the companion Medicaid plan may have a larger service area than the D-SNP. States, in their contracting arrangements for Medicaid managed care programs, may wish to limit the service areas of the affiliated Medicaid managed care plans, but we recognize that States may have other policy objectives better met with larger service areas in their Medicaid managed care programs.

In plan year 2022, all FIDE SNPs met the service area requirement being proposed. Most, but not all, HIDE SNPs also met the proposed requirement. Of the 219 HIDE SNP plan benefit packages across 18 States,³⁸ only 15 HIDE SNPs in four States had service area gaps with their affiliated Medicaid managed care plans, leaving 106,075 enrollees in 194 counties with no corresponding Medicaid plan.³⁹ As noted in our

proposed rule, an MA organization impacted by our proposal would have several pathways to comply with the change to the definition of HIDE SNP at § 422.2. The options include using the crosswalk exception currently at § 422.530(c)(4) (which we are redesignating as § 422.530(c)(4)(i) in section II.A.6.a. of this final rule) in conjunction with dividing an existing FIDE or HIDE SNP into two (or more) separate D-SNPs, with the service area of the FIDE or HIDE SNP being within the service area of the affiliated Medicaid managed care plan. We solicited comment on whether this proposal would likely result in additional, unintended disruption for current FIDE SNP and HIDE SNP enrollment. We direct readers to the proposed rule, at 87 FR 1869, for a more detailed description of our projected impacts on HIDE SNPs and options available for MA organizations impacted by this change.

We explained in the proposed rule how we were considering an alternative of establishing a minimum percentage of enrollment or service area overlap between the D-SNP affiliated Medicaid plan and having FIDE SNPs and HIDE SNPs attest to meeting the minimum overlap requirement. We were also considering an amendment to explicitly codify how the current requirements permit D-SNPs to be designated as a FIDE SNP or HIDE SNP even if their service area within a particular State does not fully align with the service area of the companion Medicaid plan (or plans). We did not propose either of these alternative approaches because we believed these alternatives would create greater operational complexity (in the case of establishing a minimum percentage overlap) and would fail to help us achieve our objectives of clarifying options for beneficiaries and creating better coordination of Medicare and Medicaid benefits for all enrollees of the FIDE SNP or HIDE SNP compared to current practice.

Comment: A number of commenters supported of the proposal to require FIDE SNPs and HIDE SNPs have capitated contracts with the State Medicaid agency covering the entire service area for the D-SNP. A commenter noted that existing unaligned service areas for HIDE SNPs resulted in confusion among enrollees, providers, and plan staff and limited opportunities for integrated notices and appeals. Some commenters believed

that CMS's proposal would increase Medicare-Medicaid integration. Several commenters noted CMS's proposal would facilitate the ability to offer exclusively aligned enrollment for D-SNP and the affiliated Medicaid plan. A commenter believed most, if not all, beneficiaries enrolled in HIDE SNPs and FIDE SNPs should have access to companion Medicaid plans. Another commenter noted that dually eligible individuals should be in Medicare and Medicaid plans under one parent company. Some commenters stated that CMS's proposal would clarify the definitions of FIDE SNPs and HIDE SNPs, and prevent less integrated plans from claiming these designations.

Response: We thank commenters for their support of our proposal. We agree that this change to the FIDE SNP and HIDE SNP definitions at § 422.2, and therefore in the requirements for these types of D-SNPs, will improve Medicare-Medicaid integration for dually eligible beneficiaries.

Comment: A commenter supported this proposal at the plan benefit package (PBP) level, rather than the contract level, in States where Medicare Advantage contracts include non-FIDE and non-HIDE PBPs that are D-SNPs. Another commenter supported the proposal and encouraged CMS to extend this requirement to all D-SNPs that operate in the same area as a Medicaid managed care plan, unless the State requests an exception. The commenter believed that when a State has risk contracts with managed care plans to provide Medicaid coverage to the dually eligible population, D-SNPs should only be permitted to operate if they have one of these Medicaid managed care contracts. This commenter believed that allowing integrated D-SNPs to compete with non-integrated D-SNPs confuses beneficiaries and degrades the definition of a D-SNP.

Response: We appreciate the support from these commenters. We confirm that the service area requirement we proposed and are finalizing here applies to FIDE SNPs and HIDE SNPs at the PBP level. While we did not accept the recommendation to deny D-SNP MA contracts to plans that do not (themselves or through an affiliated entity) have a capitated contract for Medicaid benefits with the State Medicaid agency in States where such contracts exist, we do note that States can choose to execute State Medicaid agency contract only with those D-SNPs that also cover Medicaid benefits under Medicaid managed care contracts, through a direct contract with the State or through an affiliated Medicaid managed care plan. Our final policy

³⁸ CMS, SNP Comprehensive report, January 2022. Retrieved at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartIDEnrolData/Special-Needs-Plan-SNP-Data>.

³⁹ Internal analysis based on data from: CMS, Monthly Enrollment by Contract, January 2022. Retrieved from: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartIDEnrolData/Monthly-Enrollment-by-Contract>; CMS, Monthly Enrollment by Contract/Plan/State/County, January 2022. Retrieved from: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartIDEnrolData/Monthly-Enrollment-by-Contract-Plan-State-County>; CMS, D-SNP Integration Levels for CY 2022. Retrieved

from: <https://www.cms.gov/files/document/smactsnpintegrationstatusdata2022.xlsx>; and service area information from State Medicaid agency websites.

provides flexibility for States to permit coordination-only D-SNPs.

Comment: Some commenters opposed the requirement to align the FIDE SNP or HIDE SNP service area with the affiliated Medicaid plan service area. A few commenters expressed concern that the requirement will create significant, unnecessary disruption to existing D-SNP enrollees. A commenter believed requiring a Medicaid contract to cover the entire HIDE SNPs service area would limit the ability of small or new plans to offer a HIDE SNP and this would not be in beneficiaries' best interests.

Response: We appreciate the commenters' concern about the disruption to enrollees of FIDE SNPs and HIDE SNPs. We clarify that an impacted MA organization can keep operating in the existing service area for both the D-SNP and Medicaid plan; the difference would be that beginning with plan year 2025, the D-SNP would not qualify for FIDE SNP or HIDE SNP designation. Therefore, there is no need for a D-SNP to terminate and disrupt the coverage provided to current enrollees. The impacted MA organization that is not changing its service area or PBP offerings as a result of this rule would be required to update the contract with the State Medicaid agency required by § 422.107 to include the notification requirement specified at § 422.107(d). We note that, based on our review of D-SNP contracts for 2022, no FIDE SNPs are impacted by this requirement, and the States with impacted HIDE SNPs also offer non-HIDE D-SNPs; therefore, these States have established and are experienced with the notification requirement at § 422.107(d).

Comment: Several commenters also noted their concern about how the new service area requirement would negatively impact the State Medicaid agencies' contracting priorities and their ability to contract with D-SNPs. A few commenters requested CMS engage with impacted States to prevent any potential impacts and beneficiary disruption. A commenter requested further analysis and explanation of how the proposal would work with current State laws, and requested CMS research why there may be regions where a capitated contract does not extend to the entire D-SNP service area. Another commenter noted States may need some flexibility to come into compliance with the requirement and design programs and benefit offerings to meet their needs.

Response: We thank the commenters. However, we do not believe that this change will impact the flexibility that States have to use their contracts with

D-SNPs to design programs that meet the needs of dually eligible beneficiaries. States can continue to contract with D-SNPs that have an affiliated Medicaid managed care plan in only a portion of the service area. While we agree with MACPAC's recommendation that States use the State Medicaid agency contracts that are required for D-SNPs by § 422.107(b) to completely align service areas between a D-SNP and a Medicaid managed care plan to better integrate coverage and care,⁴⁰ our proposal only mandates such alignment for HIDE SNP and FIDE SNPs with their affiliated Medicaid managed care plans. Coordination-only D-SNPs can continue to operate without alignment of the service area of the D-SNP with an affiliated Medicaid managed care plan. We continue to conduct outreach and technical assistance to States to better understand their use of capitated contracts (that is, Medicaid managed care contracts under 42 CFR part 438) and their Medicare-Medicaid integration goals.

Comment: A commenter noted that the proposed changes have already been implemented in Arizona. Another commenter expressed concern that the requirement would impact the landscape of D-SNPs in Oregon.

Response: We thank the commenters for offering their perspective. In our analysis of FIDE SNP and HIDE SNP service areas,⁴¹ we identified some service areas in which HIDE SNPs in Arizona do not offer an affiliated Medicaid plan; however, we believe the impacted plans and the State have sufficient time to choose an approach to come into compliance (or default to coordination-only D-SNP status) that is in line with the State's integration goals. Our analysis also showed that HIDE SNPs in Oregon would not be impacted by this proposal because each of Oregon's HIDE SNPs' service areas

⁴⁰ MACPAC, Report to Congress on Medicaid and CHIP, "Chapter 6: Improving Integration for Dually Eligible Beneficiaries: Strategies for State Contracts with Dual Eligible Special Needs Plan," June 2021. Retrieved at <https://www.macpac.gov/wp-content/uploads/2021/06/June-2021-Report-to-Congress-on-Medicaid-and-CHIP.pdf>.

⁴¹ Internal analysis based on data from: CMS, Monthly Enrollment by Contract, March 2021. Retrieved from: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDENrolData/Monthly-Enrollment-by-Contract>; CMS, Monthly Enrollment by Contract/Plan/State/County, March 2021. Retrieved from: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDENrolData/Monthly-Enrollment-by-Contract-Plan-State-County>; CMS, D-SNP Integration Levels for CY 2021. Retrieved from: <https://www.cms.gov/files/document/smacdsnintegrationstatusdata.xlsx>; and service area information from State Medicaid agency websites.

completely overlap with an affiliated Medicaid plan. We will reach out to States impacted by this change to provide technical assistance in advance of the contract year 2025 MA bidding cycle.

Comment: A few commenters requested that CMS clarify the scope of the proposed requirement. A commenter requested clarification on whether this provision, or others in the rule, would limit HIDE SNP enrollments to exclusively aligned enrollment or otherwise limit HIDE SNPs with unaligned enrollment. Another commenter requested confirmation that an MA organization that has a Medicaid MCO contract that covers the applicable geography and that includes behavioral health benefits for dually eligible beneficiaries would be allowed to operate HIDE SNPs, even if the MA organization does not have a managed long-term services and supports (MLTSS) contract. The commenter also requested CMS confirm that an MA organization that offers a HIDE SNP that includes Medicaid services (including behavioral health) in the State Medicaid agency contract should not need to also have separate Medicaid MCO contract. Lastly, the commenter requested CMS clarify that an MA organization is not required to also have a general Medicaid MCO contract or MLTSS contract to offer a HIDE SNP if the State has separate selection process for integrated plans.

Response: We thank the commenters for their request for clarity on the scope of the proposals. We confirm that this provision and others being finalized in this rule do not require HIDE SNPs to have exclusively aligned enrollment. (The definitional change to require exclusively aligned enrollment beginning in 2025 is limited to FIDE SNPs.) We also note that in addition to requiring that the capitated contract with the State Medicaid agency cover the entire service area for the HIDE SNP starting in plan year 2025, the HIDE SNP definition as finalized in this rule requires: (1) The capitated contract be between the State Medicaid agency and the MA organization, its parent organization, or another entity that is owned and controlled by its parent organization; (2) coverage of LTSS or behavioral health services. HIDE SNPs are not required to have a capitated contract with the State for both behavioral health and LTSS. These capitated contracts with the State Medicaid agency are Medicaid managed care risk contracts between the State and MA organization offering the HIDE SNP, its parent organization, or another entity owned and controlled by the

parent organization and the Medicaid managed care risk contracts must comply with 42 CFR part 438 provisions for Medicaid managed care contracts. Therefore, the Medicaid managed care plan that is affiliated with a HIDE SNP may be an MCO, a PIHP, or a PAHP, so long as coverage of at least Medicaid LTSS or Medicaid behavioral health services is included. Under this additional amendment, the D-SNP's service area must be completely overlapped by the service area of this affiliated Medicaid managed care plan beginning in 2025 in order for the D-SNP to be a HIDE SNP; actual enrollment in the HIDE SNP and the affiliated Medicaid managed care plan is not required to be aligned. We note that some States directly contract with D-SNPs under a single contract that meets both the managed care contract requirements under 42 CFR part 438 and the D-SNP contract requirements under § 422.107, but this is not required and a State may use a Medicaid managed care contract under part 438 and a separate contract for § 422.107 purposes.

Comment: A few commenters supported CMS giving impacted MA organizations the opportunity to crosswalk enrollees from the existing D-SNP that includes the service area outside of the companion Medicaid plan service area into a new D-SNP PBP. However, several commenters noted creating two different PBPs creates additional burdens for MA organizations. A commenter also noted there is additional burden for the States to operate and oversee additional D-SNP PBPs.

Response: We thank the commenters for this feedback and recognize that creating a new PBP (that is, a new MA plan) creates additional burden for MA organizations. We reiterate that MA organizations do not need to change how they operate an impacted HIDE SNP. The HIDE SNP would lose its HIDE SNP designation and become a coordination-only D-SNP, which requires compliance with § 422.107(d). However, the D-SNP's contract with the State Medicaid agency under § 422.107(a) through (c) would likely need to be amended to include the notification requirement at § 422.107(d). We believe any burden to the State from an additional D-SNP PBP due to the notification requirement at § 422.107(d) or other State oversight of D-SNPs would be minimal. As noted previously in this section, all States with D-SNPs impacted by this provision already have coordination-only D-SNPs in their markets.

Comment: Some commenters suggested that CMS delay the proposed 2025 effective date of the requirement for service area overlap. While these commenters did not suggest an alternative effective date for this provision, they stated that it may take States and current HIDE SNPs longer to comply given State legislative and budgetary cycles.

Response: We recognize the commenters' concerns and acknowledge the difficulty with aligning State Medicaid agency and Medicare Advantage contracting timelines. However, we decline to make this change. For the HIDE SNPs that are not able to align their MA service area with the affiliated Medicaid plan's service area for contract year 2025, they may be able to continue operating as a non-HIDE D-SNP and regain HIDE status once the service areas align. We note, however, that this final rule is effective in 2022, more than two years before the beginning of 2025 when this new service area requirement will apply.

Comment: Several commenters requested CMS provide guidance to impacted States and MA organizations. A few commenters requested CMS educate States on how service area alignment impacts integrated care, and provide resources to help States address challenges such as different Medicaid procurement and D-SNP contract timelines. A commenter noted SHIP and MA brokers would also benefit from educational resources. Another commenter suggested that CMS educate beneficiaries ahead of this change.

Response: We thank the commenters for their input. We will continue to engage with States to understand challenges and priorities in establishing Medicare-Medicaid integration to improve beneficiary experience and integration options. We will provide education and outreach to States about changes in this final rule through the Integrated Care Resource Center (see <https://www.integratedcareresourcecenter.com/>). We are also exploring ways to improve awareness of available integrated care options for dually eligible beneficiaries.

Comment: A few commenters did not support the alternatives CMS considered to establish a minimum percentage of enrollment or service area overlap between the D-SNP and affiliated Medicaid plan. A commenter noted that these alternatives would cause confusion and limit opportunities for integration. A commenter supported the alternative of establishing a minimum percentage of enrollment at 75 percent or higher. This commenter noted that this percent would limit the

number of FIDE SNP or HIDE SNP enrollees who find themselves without access to both Medicare and Medicaid benefits from a single parent organization but allow FIDE SNPs and HIDE SNPs in areas of the State where the companion Medicaid managed care plan may not be able to attract enough providers to meet network adequacy standards required by the State.

Response: We thank these commenters for their input. We acknowledge the difficulty for health plans to meet both Medicare and Medicaid network adequacy standards in rural areas. We are not finalizing the alternative considered of setting a minimum percentage of enrollment as we believe requiring FIDE SNPs and HIDE SNPs to have, beginning with the 2025 plan year, MA service areas that are entirely covered by the service area of the Medicaid capitated contract will create sufficiently better coordination of Medicare and Medicaid benefits compared to current practice.

Comment: Some commenters suggested that CMS allow existing HIDE SNPs to continue operating as HIDE SNPs and allow beneficiaries to choose to remain in unaligned plans. A commenter requested that CMS clarify network requirements to ensure alignment between a FIDE SNP's Medicare and Medicaid provider network. Another commenter suggested an attestation process which would require increasing levels of network alignment to maintain HIDE SNP status, similar to an initiative in Washington State.

Response: We thank commenters for their recommendations. We decline to accept the recommendation to allow existing HIDE SNPs to operate as HIDE SNPs despite not meeting this new requirement because this alternative may create greater operational complexity for overseeing HIDE SNPs and would fail to meet the objectives that underpinned our proposal.

Regarding network requirements to align the D-SNP's and companion Medicaid plan's provider networks, we will consider issuing future guidance and rulemaking on this topic. While we recognize the potential for improved continuity of care for dually eligible enrollees from State initiatives to increase the proportion of Medicaid plan providers in the D-SNP network alignment like the example from Washington State, this alternative is outside of the scope of this rulemaking.

After consideration of the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed amendments at § 422.2 to the

FIDE SNP definition by adding new paragraph (6) and the HIDE SNP definition by adding new paragraph (3) to require that the capitated contracts with the State Medicaid agency cover the entire service area for the D-SNP for plan year 2025 and subsequent years.

6. Additional Opportunities for Integration Through State Medicaid Agency Contracts (§ 422.107)

Section 164 of MIPPA amended section 1859(f) of the Act to require that each D-SNP contract with the State Medicaid agency to provide benefits, or arrange for the provision of Medicaid benefits, to which an enrollee is entitled. Implementing regulations are codified at § 422.107. Notwithstanding this State contracting requirement for D-SNPs, section 164(c)(4) of MIPPA does not obligate a State to contract with a D-SNP, which therefore provides States with significant control over the availability of D-SNPs in their markets. The State's discretion to contract with D-SNPs, combined with the State's control over its Medicaid program, creates flexibility for the State to require greater integration of Medicare and Medicaid benefits from the D-SNPs that operate in the State.

Even among States that have used the State Medicaid agency contract at § 422.107 to promote integration, we believe additional opportunities exist to improve beneficiary experiences and health plan oversight.

We proposed a new paragraph (e) at § 422.107 to describe conditions under which CMS would facilitate compliance with certain contract terms that States require of D-SNPs that operate in the State. As discussed in the proposed rule at 87 FR 1870, CMS would take certain steps when a State Medicaid agency's contracts with D-SNPs require exclusively aligned enrollment and require the D-SNPs to request (from CMS) MA contracts that only include one or more State-specific D-SNPs and that such D-SNPs use integrated member materials. As discussed below and in the proposed rule beginning at 87 FR 1870, the requirements described in proposed paragraph (e)(1) require work on the part of CMS to facilitate compliance by D-SNPs with the State's requirements. Therefore, proposed paragraphs (e)(2) and (3) described steps CMS would take when the conditions of proposed paragraph (e)(1) were met.

a. Limiting Certain MA Contracts to D-SNPs

Special needs plans, including D-SNPs, are currently included as separate MA plans, also known as "plan benefit packages (PBPs)," under the same

contract number along with any other MA plans of the same product type (for example, health maintenance organization (HMO), preferred provider organization (PPO), etc.) offered by the legal entity that is the MA organization. As described in the proposed rule at 87 FR 1870, PBPs under a single contract may offer different benefit packages and serve multiple populations but still report medical loss ratios and certain quality measures at the contract level. While some quality measures are collected at the PBP level, unless a D-SNP is the only PBP in a contract, it is not possible to ascertain a full and complete picture of the quality performance of the D-SNP distinguished from other PBPs in the contract. In addition, there is currently no formal pathway for States to coordinate with CMS to require D-SNP PBPs to utilize model materials that integrate information regarding Medicare and Medicaid coverage.

It has been a long-standing CMS policy that CMS only award a legal entity one contract for each product type (for example, HMO, PPO, regional preferred provider organization (RPPO), etc.) it seeks to offer for all PBPs for the totality of the States, with limited exceptions.⁴² Given the important distinctions of D-SNPs in comparison to other MA plans, States and other stakeholders have expressed an interest in better understanding performance of these plans without data being combined with non-D-SNPs and tailoring the information provided in member materials to more aptly suit the dually eligible population.

Therefore, we proposed to codify a pathway where if a State requires an MA organization to establish a MA contract that only includes one or more D-SNPs with exclusively aligned enrollment within a State and for that D-SNP to then utilize integrated materials, the MA organization may apply for such a contract using the existing MA application process. The proposed language at § 422.107(e)(1)(i) would give States the flexibility to require an MA organization to apply and seek CMS approval for one or more D-SNP-only contracts, which would provide more transparency in D-SNP plan performance within States. We direct readers to the proposed rule 87

FR 1870 for a more detailed explanation of the benefits and challenges of this proposal.

We described at proposed § 422.107(e)(2) how the CMS administrative steps to permit a new D-SNP-only contract would be initiated by receipt of a letter from the State Medicaid agency indicating its intention to include the contract requirements under § 422.107(e)(1) in its contract with specific MA organizations offering, or intending to offer, D-SNPs with exclusively aligned enrollment in the State. While we would provide States with additional information on timelines and procedures in sub-regulatory guidance, we would follow the steps consistent with existing timeframes and procedures for the submission of applications, bids, and other required materials to CMS. Examples of those activities are summarized in the proposed rule at 87 FR 1871. Our proposal did not include exemptions or changes in the current regulations and process for contract applications.

To avoid any significant beneficiary disruption while implementing the proposed change, we proposed a new crosswalk exception (to be codified at § 422.503(c)(4)(ii)) to allow MA organizations to seamlessly move existing D-SNP enrollees into a D-SNP-only contract created under this proposal. Our proposed crosswalk exception would apply only for movement between plans of the same product type (HMO, PPO, etc.) under the same parent organization for the following contract year when the new D-SNP is created under a new D-SNP-only contract based on a State requirement as described in proposed § 422.107(e). To add this new crosswalk exception, we proposed redesignating the existing paragraph (c)(4) as new paragraph (c)(4)(i) and creating a new paragraph (c)(4)(ii) in § 422.530. Under this proposal, the processes used for other crosswalk exceptions (for example, the notice to CMS and CMS's review and approval of the crosswalk exception) would apply to this new crosswalk exception.

We solicited comment on limiting certain MA contracts to D-SNPs and whether any additional beneficiary protections should apply.

Comment: Many commenters support this proposal as a step to improve quality, transparency, plan performance, and oversight of D-SNPs. Several commenters indicated having D-SNP-only contracts established under § 422.107(e) would enable a clearer understanding of the dually eligible population outcomes and needs in each

⁴² The following memo outlines the policy for CY 2020, which has been in effect for several years: CMS HPMS Memo, "Release of Notice of Intent to Apply for Contract Year 2021 Medicare Advantage (MA), Medicare-Medicaid Plans (MMP), and Prescription Drug Benefit (Part D) and Related CY 2021 Application Deadlines", October 17, 2019. Retrieved from <https://www.cms.gov/files/document/2021-noia-partpartd-mmp.pdf>.

State. MACPAC commented that the proposal aligned with prior work highlighting how States can use authority under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, Pub. L. 110-275) to promote integration in their contracts with D-SNPs.

Response: We thank commenters for their support. We agree that having D-SNPs with exclusively aligned enrollment separated into distinct contracts will provide greater transparency into plan performance and ultimately improve quality for dually eligible enrollees.

Comment: Several commenters expressed support for efforts to encourage greater integration; however, they also expressed concerns with permitting States to request to CMS that D-SNPs with exclusively aligned enrollment be in separate MA contracts. Some commenters were concerned that the ability to have D-SNP-only contracts established under § 422.107(e) complicates State contracting requirements and could create barriers to new market entrants, thereby limiting enrollee choice and decreasing competition. A commenter encouraged CMS to ask States to implement the provisions of D-SNP-only contracts established under § 422.107(e) in a manner that does not discriminate between existing and new plans. Another commenter indicated that the proposal would create more heterogeneity among States in terms of State requirements for integrated plans and for quality assessments that will not improve evaluating or comparing plan quality for dually eligible individuals, indicating that D-SNPs already provide extensive quality information to States and CMS.

Response: We appreciate the commenters' perspectives on the potential impacts of having D-SNP-only contracts established under § 422.107(e); however, we do not believe that this proposal would cause States to discriminate between new and existing plans. Some States already limit market entry by only executing State Medicaid agency contracts with organizations with Medicaid MCO contracts or by utilizing competitive bidding and procurements to select organizations to participate as Medicaid MCOs. Our proposal does not change this existing State flexibility. As noted in the proposed rule at 87 FR 1869, section 164(c)(4) of MIPPA does not obligate a State to contract with a D-SNP, and therefore provides States with significant control over the availability of D-SNPs in their markets. States have flexibility in pursuing D-SNP-only

contracts through § 422.107(e), but that flexibility is not unlimited. As we proposed and are finalizing, this pathway will only be available for D-SNPs that have exclusively aligned enrollment (which means that all the D-SNPs' enrollees are also enrolled in an affiliated Medicaid MCO) and where both a D-SNP-only contract and a minimum set of integrated materials are used. We believe in most circumstances it will be most beneficial if use of D-SNP-only MA contracts is implemented consistently for all D-SNPs with exclusively aligned enrollment within a State so that all these D-SNPs are on the same footing and these plan enrollees benefit from the use of integrated materials and greater transparency of quality ratings.

We disagree with the commenter that D-SNP-only contracts established under § 422.107(e) would not provide States with insight on D-SNP quality and performance. Unless a D-SNP is the only PBP in a contract, it is not possible to ascertain a complete picture of performance on HEDIS, CAHPS, HOS, and Star Ratings. As discussed below, the Star Ratings methodology includes both measure-level adjustments (where specified by measure stewards) and the CAI to adjust disparities in performance caused by social risk factors beyond the MA organizations' control.

Comment: A few commenters requested that CMS revisit the number of MA contracts a legal entity can hold or this proposal would limit the viability of some D-SNPs. Some commenters expressed concern that creating new legal entities is an expensive endeavor, including meeting State licensure and capital requirements. These commenters sought clarification if separate entities would be needed to enter into the D-SNP-only contracts established under § 422.107(e).

Response: We appreciate commenters' concerns regarding the number of MA contracts a legal entity can hold and agree that establishing new legal entities may be a burden to MA organizations. In the limited instance set forth in § 422.107(e), MA organizations with existing contracts that are required by the State to separate out the D-SNP with exclusively aligned enrollment would not be required to create a new legal entity and would be permitted the additional MA contract. CMS has authority, at § 422.503(e), to sever specific MA plans from a MA contract that covers multiple MA plans. While we have established an operational policy of requiring an MA contract to cover all MA plans of the same type for the same MA organization, we would

create exceptions to that policy when § 422.107(e) applies.

Comment: Some commenters, as further discussed in section II.A.6.d., indicated that the proposal sets a framework that provides a clearer assessment of financial performance of D-SNPs.

Response: We thank the commenters for their input related to assessment of D-SNPs' financial performance. We agree that having D-SNP-only contracts established under § 422.107(e) will enhance States' and other stakeholder's ability to examine the financial performance of D-SNPs.

Comment: Some commenters noted D-SNP-only contracts established under § 422.107(e) would allow for better oversight of network adequacy for the dually eligible population.

Response: We thank commenters for their perspective related to oversight of network adequacy for the dually eligible population. We agree that having network submissions from D-SNP-only contracts established under § 422.107(e) will provide better oversight of network adequacy and insight on patterns of care unique to the dually eligible population in the covered service areas.

Comment: Some commenters supported the State flexibility in the proposal. A commenter indicated that the flexibility is necessary since States are at different points on the D-SNP integration pathway and noted that the requirements in the proposal would add duties for both State and D-SNP staff. A few commenters from one State indicated support for the proposal because current State policy would align with the ability to limit D-SNPs to D-SNP-only contracts specific to that State. A commenter acknowledged that they are actively considering implementing the option for D-SNP contracts established under § 422.107(e) should the proposal be finalized.

Response: We thank commenters for their support towards State flexibility. We anticipate that different States will implement this flexibility at different times as they progress along the pathway towards more integration of Medicaid and Medicare through their D-SNP contracts and engage with their contracted D-SNPs and CMS on this issue.

Comment: A commenter indicated that while the proposal could advance the goal for better alignment, care management, provider service and quality monitoring, many States will benefit from additional guidance and support to operationalize the proposal. Another commenter urged CMS to aid States in making these changes and proposed that CMS provide that support

through grants or enhanced Federal medical assistance percentage (FMAP) to address capacity issues. The commenter indicated that one-on-one intensive technical assistance and template materials would also be needed.

Response: We thank the commenters for their input. In addition to our own direct outreach to States, we will provide education and resources to States to support implementation of this rule through the Integrated Care Resource Center.⁴³ As discussed in the section that follows, we will develop template materials (see Integrated Member Materials).

We appreciate the commenter's request that CMS provide support through grants or enhanced FMAP to help States develop capacity to implement D-SNP-only contracts established under § 422.107(e). We will consider ways that CMS can provide support to States to further integration but note that there are limits on CMS's ability to issue grants or change FMAP levels.

Comment: A commenter expressed concern that timing of State decisions regarding D-SNP-only contracts established under § 422.107(e) will be unclear and inconsistent across markets, resulting in administrative challenges for plans.

Response: We agree with the commenter that the timing of State decisions regarding D-SNP-only contracts may not be consistent. To address this potential issue, we established at § 422.107(e)(2) that—because the timing of applications, bids, and other contracting procedures under §§ 422.250 through 422.530 remain applicable—CMS will work in good faith following receipt of a letter from a State Medicaid agency indicating their intent to pursue D-SNP-only contracts and the use of integrated materials to implement these provisions for a future contract year. We further direct the commenter's attention to the proposed timeline discussed in the proposed rule at 87 FR 1871. When we issue the additional information on timelines and procedures in sub-regulatory guidance, we will consider current MA timeframes and procedures for submission of applications, bids and other required materials to CMS, in addition to the need for MA organizations to make business decisions in a timely manner. We anticipate that efforts to achieve D-SNP-only MA contracts in a State may take two years or more, depending on current MA and Medicaid managed care

contract arrangements, such as whether a current D-SNP has exclusively aligned enrollment, and the level of effort needed to develop integrated enrollee materials.

Comment: A commenter indicated support for the proposal only where the State and the plans agree to have D-SNP-only contracts established under § 422.107(e). Another commenter suggested limiting the option for D-SNP-only contracts established under § 422.107(e)(1) to those States where separate contracts are needed for additional State quality programs.

Response: We appreciate the commenter's support for establishing D-SNP-only contracts under § 422.107(e) where the State and the plans agree to take such steps. We recommend that the State consult with CMS, MA organizations, and other stakeholders on whether and how to pursue this step toward integration, but we recognize that section 164(c)(4) of MIPPA does not obligate a State to contract with a D-SNP, and therefore provides the States with significant control over which MA organizations offer D-SNPs in their markets. We disagree that the State requirements to establish D-SNP-only contracts under § 422.107(e) should be limited to circumstances where it is needed for additional State quality programs. While State quality programs may be facilitated by D-SNP-only contracts under § 422.107(e), there are other reasons, including transparency of MLRs and improved State oversight, that are also valid reasons for States to require such contracts.

Comment: A few commenters opposed the proposal indicating it may create additional administrative burden. A commenter cited burdens for the industry including transitioning enrollees to the new contract, providing separate Star Ratings measure support and reporting, managing additional HEDIS hybrid sample reviews and supplemental data work streams, and administering separate HOS and CAHPS surveys. In addition, the commenter noted that providers could be adversely impacted by additional HEDIS medical record reviews for hybrid measures and supplemental data collection efforts.

Response: We acknowledge the concerns raised by commenters that there may be additional administrative burden for MA organizations and providers. We anticipate that there will be impacts shared by CMS, States, and MA organizations as discussed in the proposed rule at 87 FR 1846 and in section V.C.3.b of this final rule; however, we believe the benefits from having separate D-SNP-only contracts established under § 422.107(e) outweigh

these concerns. Further, we do not expect a large volume of new contracts would be created in the foreseeable future because most States do not meet the prerequisite of requiring exclusively aligned enrollment, and among those States that do, some D-SNPs are already in D-SNP-only contracts.

Comment: Many commenters expressed concerns regarding quality measurement for D-SNP-only contracts established under § 422.107(e). Citing anticipated smaller enrollment in D-SNP-only contracts established under § 422.107(e), many commenters believed CMS's proposal could create pervasive issues with small sample sizes, which may diminish reportability and reliability of various quality measures, thereby producing less visibility into D-SNP performance than with the current system. Some commenters were concerned that the variability in measure reporting would also affect the reliability of Star Ratings. Additionally, many commenters conveyed consternation based on their expectation that Star Ratings would be lower for D-SNP-only contracts established under § 422.107(e) because they would be scored against MA contracts with few or no dually eligible enrollees. A commenter noted that CMS research has shown a link between the length of time a contract has been in place and its Star Ratings performance. A few commenters noted that lower Star Ratings could reduce bonus payments and therefore rebates and supplemental benefits offered to beneficiaries. A commenter noted that lower bonus and rebate dollars may make it harder to address disparities. Finally, several commenters indicated that the impact to specific components of Star Ratings would need to be assessed further, including the Categorical Adjustment Index (CAI). A commenter noted that the CAI is insufficient to address concerns regarding lower Star Ratings for plans that disproportionately serve the most vulnerable populations. Additionally, a commenter expressed concern that moving to a separate contract would impact the Members Choosing to Leave the Plan measure, and asked CMS to exclude D-SNP enrollees switching between unaligned and aligned D-SNPs that are under the same parent organization.

Response: It is not clear to us that measure data from D-SNP-only contracts established under § 422.107(e) would be unreliable. Under the FAI demonstrations, MMPs have not experienced pervasive sample size issues, even with lower enrollment relative to broader MA contracts, and therefore we do not anticipate

⁴³ See <https://www.integratedcareresourcecenter.com/>.

widespread measurement issues for D–SNP-only contracts established under § 422.107(e). We also note that we would work with States interested in this opportunity to be sure they understand whether there is high risk of sample size problems and possible strategies for mitigation. That said, there are methodologies that prevent unreliable data from impacting Star Ratings. Star Ratings measures have minimum sample size and/or denominator requirements to ensure measure data are reliable. Further, to improve stability of cut points and prevent cut points from being influenced by outliers, Tukey outlier deletion will be implemented beginning with the 2024 Star Ratings. Through the use of Tukey outlier deletion, extreme outliers will be removed from measure scores prior to clustering to prevent outliers from impacting cut points for all contracts.

We do not believe that a new D–SNP-only contract created under § 422.107(e) would likely have lower Star Ratings by virtue solely of being a new contract. The lower Star Ratings associated with new contracts is likely due to the time MA organizations need to implement quality improvement initiatives that impact Star Ratings. Such quality improvement initiatives should already be in place for MA contracts from which the new D–SNP-only contracts are carved out using the process under § 422.107(e). We anticipate that an MA organization would continue administrative and operational initiatives that are currently in place across multiple plans even if the D–SNP(s) in a particular State are placed into a D–SNP-only contract.

While we understand the concern that D–SNP-only contracts established under § 422.107(e) would be scored against MA contracts that may have few or no dually eligible enrollees, the Star Ratings methodology includes both measure-level adjustments where specified by measure stewards and the CAI to adjust for within-contract disparities in performance on social risk factors. There are currently 84 D–SNP-only contracts, and the CAI methodology works as intended in the presence of these contracts.⁴⁴ CAI values are assigned to contracts based on the contracts' percentage of LIS or dual eligible (DE) (LIS/DE) beneficiaries and the percentage of beneficiaries with disabilities. The percentage of LIS/DE

beneficiaries is set to 100 percent for D–SNP-only contracts.

We are aware of the commenters' concern that the CAI does not fully address the challenge of achieving high Star Ratings for D–SNP-only contracts whose ratings are based on comparisons to MA contracts with few dually eligible enrollees. We continue to monitor the impact of the CAI, particularly to evaluate whether an increase in D–SNP-only contracts limits the statistical basis for the within-contract performance differences on which it is based, and whether any methodological enhancements are necessary. In addition, we refer commenters to the CY 2023 Advance Notice (<https://www.cms.gov/files/document/2023-advance-notice.pdf>) and CY 2023 Rate Announcement (<https://www.cms.gov/files/document/2023-announcement.pdf>) for information regarding a health equity index to potentially replace the current reward factor. The addition of a health equity index to the Star Ratings would need to be proposed through rulemaking.

Regarding the commenter's concern about the Members Choosing to Leave the Plan measure, we note that this measure currently excludes enrollees that are affected by a PBP termination. Therefore, we do not anticipate a negative impact to this measure when enrollees are crosswalked from the non-renewing D–SNP PBP into the new D–SNP-only contract established as described in § 422.107(e).

Comment: In lieu of creating D–SNP-only contracts established under § 422.107(e), many commenters suggested that the goals of this proposal could be met via other strategies. Many commenters recommended that CMS work with plans and States to either create D–SNP reporting and quality measures or expand the number of SNP-only measures reported at the PBP level. A commenter suggested that CMS require more detailed, stratified reporting of Star Ratings measures for D–SNPs. A commenter suggested that CMS consider additional reporting requirements in State Medicaid contracts, while a few commenters noted that States already have the option to require supplemental reporting for their Medicaid enrollees. A commenter noted the importance of ensuring that any State-specific quality measures are collected in a way that does not impose additional burden on D–SNPs.

Response: While we acknowledge that there are other strategies to collect quality data regarding D–SNPs other

than permitting (or requiring) use of D–SNP-only contracts as described in § 422.107(e), the commenters' suggestions would not fully meet the goal of providing States and the public with greater transparency on MA quality ratings for D–SNPs. This can only be accomplished through separate Star Ratings specific to the performance of D–SNPs within a State. Although States may separately collect quality data for D–SNP enrollees, those data would not feed into Star Ratings. States also would not be able to collect CAHPS or HOS data specific to a D–SNP PBP, because the surveys are administered at the contract level. Furthermore, separate reporting reinforces unaligned measurement systems that exacerbate burden for plans and States, and may cause confusion for consumers as they attempt to consider quality information from different sources.

We note that in the CY 2023 Advance Notice and CY 2023 Rate Announcement, we discuss confidential stratified reporting of certain quality measures by dual eligible status, which will aid MA organizations in focusing quality improvement on dually eligible enrollees. Such reporting would not, however, feed into Star Ratings at this time.

Comment: A few commenters requested that CMS delay finalizing the proposal until a further evaluation can be done to determine all the consequences, while another commenter requested that CMS apply this provision prospectively for new D–SNP contracts awarded after the implementation date rather than requiring existing D–SNP PBPs to transition to separate D–SNP-only contracts. A commenter suggested that CMS not finalize the proposal at this time and instead monitor impacts of the changes occurring in California between 2023 and 2025.

Response: We acknowledge the commenters' interest in seeking a delay to implement this provision. Because of the timing of MA applications, bids, and contract execution, the earliest time that a separate D–SNP-only contract could be established using the process created by § 422.107(e) would be for the 2024 plan year, and then only if CMS receives a timely request from a State that is willing to meet the criteria set forth in § 422.107(e), the MA organization submits a timely notice of intent to apply and subsequent application for a D–SNP-only contract for a service area in the State, and the State and the MA organization successfully negotiate and execute the State Medicaid agency contract required by § 422.107(a) through (c). Therefore, we do not

⁴⁴ See 2022 SNP Landscape Source Files (v 10_26_21) retrieved at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn>.

believe a delay in the implementation of these provisions is necessary. Further, we believe that only implementing these provisions for new D-SNPs would constrain States that desire consistency in their contracting and oversight strategies and would preclude CMS, States, MA organizations, and other stakeholders from gaining a full understanding of plan performance to improve the quality of care and level of integration for the dually eligible population within a State.

Comment: Many commenters indicated that having D-SNP-only contracts established under § 422.107(e) would provide a complete picture of plan performance in areas like HEDIS, HOS, CAHPS, and Star Ratings. Several commenters encouraged transparency on the quality ratings for D-SNPs to better reflect experiences unique to the population. They noted that separate reporting will enable CMS, States, and plans to more fully analyze the data, thereby improving oversight and accountability. A commenter indicated that the proposal would provide more accurate benchmarks for plans serving dually eligible individuals. Another commenter noted that it may also provide insight into whether D-SNPs are measured on the right outcomes, and whether different or additional measures should be considered. Another commenter noted that this change could enable CMS to modify Star Rating criteria in the future to specifically account for the unique challenges of providing care for D-SNP beneficiaries.

Response: We thank commenters for their acknowledgement that our proposal would provide greater transparency on quality measurement for D-SNPs. We believe that separate reporting for D-SNP-only contracts has the potential to deliver many benefits, including enhancing oversight efforts and creating clearer performance expectations. We agree that separate reporting for D-SNP-only contracts will enable CMS to consider possible adjustments to the D-SNP measurement strategy in the future.

Comment: A commenter noted that this proposal would allow potential enrollees to compare Star Ratings more accurately across D-SNPs, since it would remove the impact of healthier MA membership on the Star Ratings for D-SNPs that are operated by plans with significant non-SNP MA membership. Another commenter noted that this proposal would allow agents and brokers to provide beneficiaries with more accurate plan metrics and enable better consumer decision-making.

Response: We agree with the commenters that separate Star Ratings for D-SNP-only contracts will provide valuable insights for consumers and the professionals who advise them. We believe that Star Ratings that are specific to local D-SNP(s) would be an important tool for comparison shopping and enhancing consumer choice.

Comment: Some commenters expressed concern for unintended consequences of assessing D-SNP-only contracts established under § 422.107(e) separately under the current Star Ratings methodology, and urged CMS to undergo a thorough evaluation and analysis on the impact of this proposal on Star Ratings. A few commenters asked CMS to consider developing modifications that account for differences with MA plans, while another commenter asked CMS to account for differences in population rather than quality of care provided by plans. A commenter wondered if further consideration should be given to comparing D-SNP performance exclusively to other D-SNPs when assessing Star Ratings, while another commenter contended that separate baselines and cut points may need to be created for the D-SNP-only contracts established under § 422.107(e). A few commenters referenced discussion in the CY 2023 Advance Notice about potential improvements to quality measurement to address social risk factors, and encouraged CMS to complete that effort before trying to measure D-SNP-only contracts established under § 422.107(e). A commenter urged CMS to work with plans to identify a long-term and more comprehensive solution to the impact of beneficiary demographics and social risk factors on Star Ratings. Another commenter suggested that CMS convene a technical expert panel to look at options for adjusting Star Ratings for D-SNPs. Finally, a commenter suggested that CMS evaluate D-SNPs with a different quality payment structure entirely, similar to the strategy used for MMPs.

Response: We are aware that for certain Star Ratings measures, it is challenging for most plans to achieve the same outcomes for groups with higher rates of disability, functional impairment, or social risk factors. This may be due to transportation issues, lower health literacy, communication challenges, residential instability, and other factors. As noted previously, the Star Ratings methodology includes both measure-level adjustments where specified by measure stewards and the CAI to adjust for within-contract disparities in performance on social risk

factors. The CAI is a data-driven approach designed to improve the accuracy of performance measurement, while not masking true differences in performance between contracts. Many D-SNP contracts do well in the Star Ratings with 44 percent of D-SNP-only contracts earning 4 or more stars for the 2021 Star Ratings.

CMS continually seeks to refine the Star Ratings approach, and we encourage commenters to review the CY 2023 Advance Notice and CY 2023 Rate Announcement for information regarding potential new methodological enhancements related to expanding stratified reporting and developing a health equity index, both of which may help support efforts to address disparities in care and advance health equity. Substantive changes to the Star Ratings are adopted through the rulemaking process, which provides an opportunity for public notice and comment before CMS finalizes policy changes for the Star Ratings program.

Regarding the suggestion to create a different quality payment structure entirely for D-SNP-only contracts, MA payment requirements are set under statute, specifically section 1853 of the Act. We believe that Star Ratings are an effective motivator for performance that incentivize MA and Part D plans to provide quality care for all enrollees, including those that are socially at-risk. Furthermore, using the same ratings approach for all contracts helps consumers understand and compare quality across plan offerings.

Comment: A commenter expressed support that D-SNP-only contracts established under § 422.107(e) provide a pathway to D-SNP specific measurement. However, the commenter noted that combining D-SNP-only contracts established under § 422.107(e) with the transition of MMPs to D-SNPs would shift which populations are combined in a single Medicare contract with aggregated Star Ratings. The commenter recommended maintaining the ability to manage and see reporting at the product level for each of these distinct offerings to allow States to effectively measure and manage both programs.

Response: We appreciate the commenter's support that D-SNP-only contracts established under § 422.107(e) provide a pathway to D-SNP specific measurement. Our proposal does not preclude a State from requiring separate D-SNP-only contracts under § 422.107(e) for separate D-SNP programs serving distinct populations (for example, separate integrated care programs for dually eligible enrollees over and under age 65). In discussions

with States considering requiring such separate contracts, we would raise the issue with the applicable State(s) whether those contracts had sufficient enrollment for the calculation of Star Ratings.

Comment: Some commenters indicated that if CMS moves forward with this proposal, it should remove past performance as a factor in issuing the D–SNP-only contracts established under § 422.107(e). A commenter noted that low Star Ratings could prevent an organization from getting a D–SNP-only contract established under § 422.107(e) if CMS finalizes the proposal to include Star Ratings in past performance.

Response: We agree with commenters that MA organizations entering into a D–SNP-only contract based on the provisions set forth at § 422.107(e) should not be included in the past performance analysis as described in §§ 422.502 and 422.504. MA organizations that currently offer D–SNPs with exclusively aligned enrollment would not otherwise be seeking to enter into a D–SNP-only contract. We note that since the existing regulations at § 422.502(b)(1) provide CMS the flexibility of when to deny an application related to past performance that no changes are needed.

Comment: Several commenters, including MACPAC, suggested that CMS expand the ability of States to request that CMS allow D–SNP-only contracts established under § 422.107(e) beyond those D–SNPs with exclusively aligned enrollment. MACPAC and other commenters noted that a State's ability to assess quality in D–SNPs is important regardless of whether the D–SNP operates with exclusively aligned enrollment. A few commenters indicated that in order to ensure disparities between dual eligible enrollees are assessed on a level playing field, all D–SNPs should be in separate contracts from non-D–SNP MA plans. A commenter requested that CMS use the process as a template for a wider required, not optional, separation of D–SNP contracts in the future.

Response: We thank commenters for sharing their concerns on the parameters of this proposal to only apply to D–SNPs with exclusively aligned enrollment; however, we believe starting at this point is an incremental step on the integration platform. We will consider future rulemaking on whether to expand the ability for States to request to CMS separate D–SNP contracts for D–SNPs that do not have exclusively aligned enrollment.

Comment: A few commenters urged CMS to do more to allow for precise understanding of the policies, qualities,

and obligations of specific D–SNPs by requiring separate contracts and public posting of model State Medicaid agency contracts. The commenters believe that this would improve oversight and allow data to more clearly reflect the outcomes, needs, satisfaction, and quality of care for people in D–SNPs.

Response: We appreciate the commenters' request that CMS require separate D–SNP-only contracts and public posting of model State Medicaid agency contracts in order to increase transparency about D–SNP obligations. We point the commenters to the Integrated Care Resource Center for sample language that State Medicaid agencies can use in their contracts.⁴⁵ As noted in response to other comments, we may also consider opportunities to expand or modify the approach for D–SNP-only contracts through future rulemaking.

Comment: A few commenters provided feedback regarding the ability of the MA organization offering a D–SNP under this proposal to crosswalk enrollees to the new D–SNP-only contract established under § 422.107(e). Some commenters expressed support for the new crosswalk proposed at § 422.530(c)(4)(ii) as it provides a smooth process for organizations to retain their enrollees. Some commenters expressed concern that moving the impacted enrollees to the new D–SNP-only contract would require a new enrollee identification card and could change bill routing by providers. Another commenter indicated that it would be important for plans to demonstrate how they will communicate the shift to beneficiaries in plain language and where to go for options counseling.

Response: We agree that these enrollees will need to receive a new identification card with the correct information. Our goal is to minimize enrollee disruption as we work towards more integrated care for the dually eligible population. We will work with States and the D–SNPs with exclusively aligned enrollment to appropriately communicate to the impacted enrollees why they are receiving new identification cards.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed provisions at § 422.107(e) regarding the creation of D–SNP-only contracts without modification, and we

are finalizing our provisions at § 422.530(c)(4) with minor edits for clarification.

b. Integrated Member Materials

Communicating information to enrollees and potential enrollees is an important function of MA plans, Part D plans, and Medicaid managed care plans—and D–SNPs with exclusively aligned enrollment must comply with all of those rules.⁴⁶ There are advantages for enrollees in D–SNPs with exclusively aligned enrollment in receiving one set of communications that integrates all of the required content, as discussed later in this section. We proposed a mechanism and some parameters to facilitate a State's election to have D–SNPs with exclusively aligned enrollment use certain communications materials that integrate content about Medicare and Medicaid. As proposed and finalized, a State is only able to elect this if the State has also required the D–SNP with exclusively aligned enrollment to also apply for and seek CMS approval for a D–SNP-only MA contract. Under this rule, the applicable Medicaid managed care and MA requirements and standards continue to apply to the integrated materials.

CMS requires MA plans and Part D plans to furnish specific information to enrollees and potential enrollees, with some specific requirements outlined in §§ 422.111 and 423.128 and additional requirements at §§ 422.2261, 422.2267, 423.2261, and 423.2267. For information that CMS deems vital to Medicare beneficiaries, including information related to enrollment, benefits, health, and rights, CMS may develop and provide materials or content for MA organizations and Part D sponsors in either standardized or model form. These materials are subject to requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) and the Office of Management and Budget (OMB) collection of information approval process no less than every three years.⁴⁷ CMS creates *standardized* materials and content that MA organizations and Part D sponsors must use in the form and manner CMS provides under a separate OMB collection of information approval process. CMS *model* materials and

⁴⁶ Because D–SNPs must offer Part D benefits, they are subject to both MA requirements in part 422 and Part D requirements in part 423. See §§ 422.2 (definition of specialized MA plans for special needs individuals) and 422.500.

⁴⁷ Refer to www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995 and www.govinfo.gov/content/pkg/FR-1995-08-29/pdf/95-21235.pdf.

⁴⁵ See <https://www.integratedcareresourcecenter.com/resource/sample-language-state-medicaid-agency-contracts-dual-eligible-special-needs-plans>.

content are examples of how to convey information to beneficiaries. MA organizations and Part D sponsors may use CMS's *model* materials or craft their own materials or content, provided the MA organization or Part D sponsor accurately conveys the vital and required information in the required material or content to the beneficiary and follows CMS's order of content, when specified. In §§ 422.2267 and 423.2267, we refer to such materials and content collectively as *required* materials.

CMS also includes similar, minimum Federal requirements in § 438.10 for Medicaid managed care plans (including MCOs) to furnish certain materials and information to enrollees and potential enrollees in a manner that is easily understood and readily accessible (OMB control number 0938-0920). Among the materials that Medicaid managed care plans must distribute are Enrollee Handbooks, Provider Directories, and Formularies.

As summarized in our proposed rule at 87 FR 1872 through 1873, the required materials that MA organizations and Part D sponsors must provide to current and prospective members and post to their websites by October 15 prior to the beginning of the plan year include the Evidence of Coverage (EOC) and the Annual Notice of Changes (ANOC), which are standardized communication materials. The required model communications materials include the Summary of Benefits (SB), Formulary, and Provider and Pharmacy Directories.

CMS encourages D-SNPs to add related Medicaid information in the EOC, ANOC, SB, and Provider Directory. Further integrating Medicare and Medicaid information in these required materials, as well as in the Formulary and Pharmacy Directory, would improve beneficiary experiences by providing a more seamless description of health care coverage and enhancing the understanding of, and satisfaction with, the coverage both programs provide.

In the proposed rule at 87 FR 1873, we described previous studies that assessed the effectiveness of integrated required materials for beneficiaries in the MMPs in the FAI and the Minnesota Senior Health Options (MSHO) plans in the Demonstration to Align Administrative Functions for Improvements in Beneficiary Experience. Beneficiaries provided positive feedback on the combined materials, as compared to separate Medicare and Medicaid materials. In addition, since 2019 CMS has worked with States and FIDE SNPs that are not

demonstration participants to develop and annually update certain integrated materials that the States require and issue to plans.

For the States and FIDE SNPs we have worked with, we typically begin development of integrated national templates and State-specific models with the SB; a Formulary that contains Medicare Part D, Medicaid, and over the counter (OTC) drugs as well as non-drug OTC products; and one combined Medicare and Medicaid Provider and Pharmacy Directory. As described in our proposed rule, starting with these materials has several advantages, including that these materials integrate key Medicare and Medicaid information, they are required materials but are not standardized and, therefore, are not subject to the PRA clearance process, and the models are not lengthy or overly complex. They also offer opportunities for D-SNPs in different States with different Medicaid requirements to provide prospective and current dually eligible enrollees a more seamless presentation of essential information about their Medicare and Medicaid coverage. This would contribute to increased understanding of and satisfaction with the coverage both programs provide.

To provide a more coordinated beneficiary experience, we proposed at § 422.107(e) to codify a pathway by which, following receipt of a letter from a State Medicaid agency indicating their intent to pursue D-SNP-only contracts and the use of integrated model materials, CMS would coordinate with a State that chooses to require, through its State Medicaid agency contract, that a D-SNP with exclusively aligned enrollment use an integrated SB, Formulary, and combined Provider and Pharmacy Directory. CMS will work with States to ensure these integrated materials comply with §§ 422.111, 422.2267(e)(11), 423.128, 423.2267(e), and 438.10(h). Proposed § 422.107(e)(1) established factual circumstances that would commit CMS to certain actions under proposed paragraphs (e)(2) and (3). We anticipate that there would be operational and administrative steps at the CMS and State level that would be necessary before a D-SNP could implement use of integrated communications materials, such as collaboration and coordination by CMS and the State on potential template materials, identification of potential conflicts between regulatory requirements at 42 CFR parts 422 and 423 for D-SNPs generally and 42 CFR part 438 and State law for the D-SNP's affiliated Medicaid MCO, and setting up a process for joint or coordinated review

and oversight of the integrated materials. CMS annually reviews the contracts between States and D-SNPs that are required by § 422.107(b) each July for the following plan year. There would generally be insufficient time for the necessary operational and administrative steps to implement integrated communications materials between the review of the contract and the dates by which communications materials must be provided to current enrollees and made available for prospective enrollees during the annual coordinated election period that begins October 15 each year. Additionally, an MA organization would need to apply for a D-SNP-only contract consistent with existing timeframes for submission of applications, bids, and other required materials to CMS, and in accordance with forthcoming sub-regulatory guidance on timelines and procedures. Therefore, paragraph (e)(2) would require that CMS work in good faith with States upon receipt of a letter of intent regarding the State's inclusion of a requirement for a D-SNP with exclusively aligned enrollment to use integrated materials and apply for a D-SNP-only contract. We intended that these efforts include the work to develop model integrated materials before the State Medicaid agency contract submissions are due for the contract year for which the D-SNP would use the integrated materials, and before D-SNP-only contracts are finalized.

We did not intend through this rule to significantly change timelines for plans to prepare materials nor did we intend to require any State to mandate that D-SNPs use integrated materials. We intended for this rule to assure interested States that CMS would do its part to make it possible for D-SNPs to comply with State Medicaid agency contract terms to use materials that integrate Medicare and Medicaid content, including at a minimum the Summary of Benefits, Formulary, and combined Provider and Pharmacy Directory if a State Medicaid agency seeks to require D-SNPs with exclusively aligned enrollment to perform as described at § 422.107(e)(1).

We considered including the EOC and ANOC as part of the minimum scope of integrated materials identified in § 422.107(e)(1)(ii). We explained in the proposed rule at 87 FR 1874 why we did not propose to include these alternative materials but solicited comment on whether these alternative materials should be included as part of the minimum scope of integration for D-SNPs. This rule would not preclude CMS and States from collaborating on

other integrated materials, including an integrated EOC or ANOC. As proposed, § 422.107(e) would apply only when a State required D-SNPs with exclusively aligned enrollment to use the minimum scope of integrated materials specified in paragraph (e)(1)(ii) and to seek CMS approval of D-SNP-only contracts. While we proposed minimum parameters, a State that wishes to require D-SNPs with exclusively aligned enrollment to do more (for example, use additional integrated materials) may do so using, or in conjunction with, the process in § 422.107(e). Further, we did not intend to prohibit or foreclose the possibility that CMS would work with States on other potential integration efforts that are not within the scope of § 422.107(e)(1).

Comment: Many commenters expressed support for the proposal to codify a pathway by which CMS would coordinate with a State that chooses to require, through its State Medicaid agency contract, that certain D-SNPs use an integrated Summary of Benefits (SB), Formulary, and combined Provider and Pharmacy Directory.

Numerous commenters stated that the proposed regulation would lead to reduced enrollee confusion because integrated materials would simplify and more clearly articulate the full scope of benefits across Medicare and Medicaid that are available through a given plan. A commenter noted that this proposed regulation would also simplify information for caregivers and advocates. Other commenters also stated that the proposed regulation would improve enrollee quality of and access to care and help enrollees understand how plan benefits can work together.

A commenter stated that integrated materials would create consistency for beneficiaries when evaluating plan choices. Another commenter noted that integrated materials would improve beneficiary awareness of integrated care options. A commenter also stated that integrated materials would help States and D-SNPs to provide clearer explanations of the advantages of integrated care, improve navigation of the health care system, and reduce health system fragmentation and administrative misalignment. Another commenter stated that the benefit of having Medicare and Medicaid plan information integrated into the same document is the reduction in mailings, a common request among enrollees.

Other commenters noted that States have successfully partnered with CMS to implement integrated materials. A commenter stated that the proposed

regulation would create a pathway for States to continue to integrate materials.

Response: We appreciate the widespread support we received for our proposal to create a pathway for States to require certain D-SNPs with exclusively aligned enrollment and D-SNP-only contracts to use integrated materials. We concur that the integration of materials will increase understanding of available benefits, improve the enrollee experience, and decrease confusion by providing a simplified set of beneficiary materials.

Comment: A few commenters recommended that States be required to use their authority to standardize materials and ensure consistent messaging wherever possible. Other commenters noted their support of the flexibility in requiring the use of integrated materials, noting that States are at different points of integration, and that CMS's proposal would result in additional responsibilities for State and D-SNP staff.

Response: We acknowledge the interest in increasing the prevalence of integrated materials. However, we decline to require that States integrate materials, recognizing that States are at different phases of integration, and may have limited resources to devote to integrating materials. We concur that States should work to integrate materials when feasible and CMS will coordinate with them when possible.

Comment: A few commenters stated that CMS should provide States with clear direction and authority to ensure State-specific policies and requirements are included in integrated materials. A commenter continued to note that without such State-specific policy and requirements, integrated materials may not accurately reflect programmatic realities including important beneficiary-facing information such as cost-sharing responsibilities and eligibility rules.

Response: We acknowledge the commenters' concerns and, as we currently do with D-SNPs and Medicare-Medicaid Plans with integrated materials, we will work with States to ensure that, when a State requires a D-SNP to have integrated materials under § 422.107(e), the integrated materials accurately reflect applicable requirements for both Medicare Advantage and Medicaid managed care plans.

Comment: A few commenters recommended that States and CMS review materials in partnership, which is critical to develop comprehensive, accurate, and clear materials. Another commenter noted that States will need to provide information to D-SNPs and

receive information from D-SNPs to ensure that information is kept up-to-date for materials such as integrated Provider Directories and information repositories for Medicaid.

Response: We thank the commenters for raising the importance of close collaboration and communication. We agree that coordination between CMS, States, and D-SNPs is necessary to ensure effective integration of model materials.

Comment: A commenter noted the operational challenges of integrating materials such as the different types of materials CMS and the State Medicaid agency require to be provided and differences in naming.

Response: We appreciate the comment and note that this rule focuses on materials which are required by both Medicare Advantage and Medicaid managed care regulations. We believe that integrating these materials will eliminate differences in naming and material formats and simplify the information for enrollees.

Comment: A few commenters noted that unaligned enrollment dates complicate efficient and timely distribution of integrated materials and suggested that CMS should work with States to implement necessary State and Federal changes that support alignment of enrollment dates. Another commenter urged CMS to limit its proposal to States where effective dates for Medicare and Medicaid plan years are aligned on the first day of the month. A commenter noted unaligned enrollment dates could cause members to receive duplicative information. The commenter also stated that there is no coordination between CMS and the State sending enrollment data to plans. They also noted that integrated materials can be operationally complex, as many plans automate the generation of enrollee materials on different platforms for Medicare and Medicaid plans.

Response: We appreciate the commenters' perspectives on this issue. We understand the potential for differences in enrollment dates between Medicare Advantage and Medicaid managed care plans and will continue to work with States to minimize enrollee disruption. In advance of implementation of integrated materials, CMS will discuss with participating States any differences in enrollment dates between Medicare Advantage and Medicaid managed care plans that may result from annual Medicare Advantage enrollment periods or State-specific enrollment timelines. Where differences in enrollment dates occur, CMS and the State will jointly decide on a strategy to implement integrated materials while

minimizing beneficiary confusion. Per § 422.107(e)(2), CMS will continue to work with a State so long as the State chooses to work with CMS on integrated materials. We believe that requiring integrated materials for enrollees with exclusively aligned enrollment in applicable States will help to reduce beneficiary confusion by providing one set of materials that combines Medicare and Medicaid information instead of two.

Comment: A commenter requested that CMS consider the challenges associated with Medicaid benefit and service carve-outs before implementing a requirement for D-SNPs to use integrated materials.

Response: We acknowledge the commenter's concern. We intend to work with States to ensure that the model materials include sufficient flexibility in order to adapt the description of benefits when needed.

Comment: A commenter stated that CMS should require States to indicate in their letters of intent that they have support from D-SNP partners to require integrated materials. The commenter believes CMS should require involvement and cooperation with participating D-SNPs in this process. The commenter suggested that CMS outline and require a standardized coordinated process across States for including or consulting with all plans in a given State with the goal of reaching consensus with all participating plans on basic models and changes.

Response: We thank the commenter for their input and suggestion. We intend to raise with States the importance of early and consistent collaboration with D-SNPs in advance of implementing any requirement for integrated materials. However, we believe the decision of whether to include this requirement in the State Medicaid agency contract should be left to the State.

Comment: A commenter stated that model documents for creating integrated materials have been invaluable, and especially helpful when models are developed for a particular State. These materials have State-specific references and data, which allows States to ensure enrollees across plans receive the same accurate State-specific information. Other commenters urged CMS to establish a consistent, standardized format for integrated materials that have been globally approved by States, instead of allowing each State to determine for itself.

Response: We appreciate the commenters perspectives on this issue. CMS will be creating models based off our experience on the FAI and a related

demonstration in Minnesota for State use and will also collaborate with States to ensure that they appropriately integrate Medicare and Medicaid information for beneficiaries.

Comment: A commenter recommended that CMS should collaborate with States to develop a regulatory or other framework that aligns Medicaid managed care and D-SNP requirements into one clear set of governing rules for integrated materials.

Response: We thank the commenter for their suggestion and modified the regulation text at § 422.107(e)(1)(ii) to require that the integrated member materials meet Medicare and Medicaid managed care requirements consistent with applicable regulations in parts 422, 423, and 438 of the chapter. As we work with States that take advantage of the new pathway created by § 422.107(e) and we gain additional experience in developing integrated materials with States, we may consider future rulemaking to establish integrated disclosure and communication materials where the applicable statutory authority permits sufficient flexibility.

Comment: Some commenters expressed concerns or were unsure of the timeframe for developing and implementing integrated materials. A commenter expressed concern that if a State is working on the State Medicaid agency contract during the same timeframe as it is developing integrated materials, the State may not have the ability to complete both tasks in a competent and thorough manner. A few commenters noted that CMS should take into consideration the timeframe of when States release their model materials, since State timeframes may differ from CMS timeframes. Another commenter recommended that the production schedule for integrated notices provide adequate time for use of focus groups to ensure that information is communicated effectively and meets the real needs of beneficiaries; the focus groups should consist of a diverse group of beneficiaries that is representative of each plan's demographic mix. A few commenters noted that they have experienced State backlogs in reviewing materials. A commenter requested that CMS work with the States to ensure State review is timely. Another commenter recommended that CMS require States to review plan materials within the existing HPMS platform and minimize template versions used at the State level. Other commenters believe States do not need to review all materials, noting that this can lead to backlogs in materials and place additional administrative burden on plans. MACPAC stated that States

should have the opportunity to review all D-SNP integrated materials to ensure accuracy and improve beneficiary understanding of integration.

Response: We thank the commenters for sharing concerns about the timeline needed to implement integrated materials. We will work in good faith with participating States, following receipt of a letter from a State Medicaid agency indicating their intent to pursue D-SNP-only contracts and the use of integrated materials, to ensure that integrated models are provided to D-SNPs in a timely manner and intend to set clear timelines for review with the States. We note that that this proposal pertains only to those States that choose to require, through their State Medicaid agency contracts, that D-SNPs with exclusively aligned enrollment use integrated materials (and that these D-SNPs also apply for a D-SNP-only MA contract with CMS). We anticipate that there would be operational and administrative steps at CMS and each State that would be necessary before a D-SNP could implement integrated materials, such as collaboration and coordination by CMS and the State to identify potential conflicts between Federal regulatory requirements for D-SNPs and Medicaid managed care plans and State law and setting up a process for coordinated review and oversight of the integrated materials. Additionally, we modified the regulation text at § 422.107(e)(1)(ii) to require that the integrated member materials meet Medicare and Medicaid managed care requirements consistent with applicable regulations in parts 422, 423, and 438 of the chapter; this change makes it clearer that § 422.107(e) does not create exceptions to other laws that govern the content and timing of materials provided to enrollees. Rather, our intent is to create a pathway for integrated materials to present all of the required information to enrollees in a more understandable and streamlined way.

CMS will work with the State to create model integrated materials before the State Medicaid agency contract submissions are due for the contract year for which the D-SNP would use the integrated materials upon a receipt of a letter of intent regarding the State's inclusion of a requirement to use integrated materials and apply for a D-SNP-only contract. While these materials will be created based on models that have been tested as part of the FAI, we will ensure that the timeline accounts for any additional beneficiary testing, as necessary.

In order to allow sufficient time for the D-SNPs to populate required materials with plan-specific

information, submit applicable materials through HPMS, translate into any non-English language of at least five percent of the individuals in the service area, and make them available to beneficiaries by the required dates, we will aim to work with States to issue to the affected D-SNPs the required materials and instructions annually by the end of May for the following plan year. While we acknowledge that State review of only a subset of materials would save time and reduce administrative burden, we disagree with the suggestion to limit State review, because we believe that States should determine which integrated materials they want to review and then clarify this information with applicable D-SNPs.

Comment: A commenter recommended that CMS pilot this proposal with a small subset of plans and States before formalizing this proposal as an option for all States. They asked that CMS make this requirement effective no earlier than 2024.

Response: We thank the commenter for their suggestion and note that we have been piloting this approach with several States. Since 2019, we have worked with Massachusetts and New Jersey to develop and update certain integrated materials for FIDE SNPs in each State. For contract years 2020 and 2021, we provided high-level assistance to New York as the State developed select integrated materials that its exclusively aligned D-SNPs and Medicaid managed care plans, called Medicaid Advantage Plus plans, could use. We are also working with California to develop integrated materials for contract year 2023 for D-SNPs with exclusively aligned enrollment. We note that, based on the timeframes involved, the regulatory authority adopted in § 422.107(e) will apply to integrated materials that D-SNPs create for enrollment dates beginning with contract year 2024 if CMS receives a timely request from a State that is willing to meet the criteria set forth in § 422.107(e).

Comment: A few commenters requested more granular details and implementation guidance on this proposal.

Response: We appreciate the comments and anticipate that there will be operational and administrative steps at the CMS and State level before a D-SNP could implement integrated materials. D-SNPs required to use these integrated materials will receive additional information through State Medicaid agency contracts and model materials.

Comment: A number of commenters requested that CMS pay particular attention to linguistic and cultural competence and accessibility for people with disabilities. A commenter stated that greater effort is needed to ensure the information itself is more understandable to those at all levels of health literacy. They suggested that States test different messaging with dually eligible individuals, including individuals from diverse backgrounds and/or those with limited English proficiency, to create understandable materials with consistent messaging. They also noted that, to design messaging that resonates with dually eligible individuals, States should collaborate with community-based organizations and enrollment assisters. Some commenters stated that CMS should include a provision that accessibility, cultural competency, and translation requirements for integrated model materials should follow the standard (either State or Federal) which is more favorable to the beneficiary. A commenter recommended that CMS consider incorporating infographics, which may be easier for some enrollees to understand, into specific model documents. Another commenter noted that Provider Directories should be updated at least monthly and be available in multiple formats and languages, including American Sign Language. The commenter stated that beneficiaries should be able to access Provider Directories without submitting an account or policy number and should be able to distinguish between providers who are in network accepting new patients and providers who are not accepting new patients. They also noted that beneficiaries should be able to easily search Provider Directories by tier, product, languages spoken by provider in addition to languages available by interpreter, disability accessibility (accessible examination equipment, dressing room, parking etc.) and information about specialty and subspecialty providers.

Response: We appreciate the commenters' perspective on this issue and believe these are important goals. We did not propose and are not finalizing any waiver or exclusion from other, generally applicable, MA or Part D regulations concerning these mandatory disclosure documents from D-SNPs. In addition, as discussed in the proposed rule, the regulation at § 438.10 also addresses disclosure requirements for Medicaid managed care plans; we did not propose and are not finalizing exceptions to that regulation or other generally applicable rules for Medicaid

managed care plans that apply to these mandatory disclosures either. In order to make that clear, we are finalizing a modification to the regulation text at § 422.107(e)(1)(ii) to require that the integrated model materials meet Medicare and Medicaid managed care requirements consistent with applicable regulations in parts 422, 423, and 423 of the chapter. Because D-SNPs must cover Part D benefits, they are subject to both the MA and Part D requirements when furnishing Provider and Pharmacy Directories. We note that §§ 422.2267(a)(2) and 423.2267(a)(2) require translation of required materials and content into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area. Similarly, § 438.10(d)(3) requires that Medicaid managed care contracts make available written materials that are critical to obtaining services, including, at a minimum, provider directories, enrollee handbooks, appeal and grievance notices, and denial and termination notices, in the prevalent non-English languages in a Medicaid managed care plan's particular service area. These requirements will continue to apply to a D-SNP with exclusively aligned enrollment and its affiliated Medicaid MCO when integrated materials are used as provided in § 422.107(e).

In § 422.112(a)(8), we require that MA organizations that offer MA coordinated care plans ensure that services are provided in a culturally competent manner to all enrollees, including to beneficiaries with limited English proficiency or reading skills, and diverse ethnic and cultural backgrounds. In addition, § 422.2267(e)(11)(iv) requires that MA organizations update Provider Directories any time the MA organization becomes aware of changes. Integrated materials must also meet requirements at § 438.10(h)(3), which requires Medicaid managed care plans to update an electronic provider directory no later than 30 calendar days after receiving updated provider information. We note that States can choose to include more stringent requirements for models in their State Medicaid agency contracts. We will take the additional recommendations regarding the Provider Directory into consideration when creating a model.

Comment: A commenter requested that CMS amend § 422.629 or § 422.630 or both to require D-SNPs to have specific publicly published procedures for making reasonable accommodation requests under the Americans with Disabilities Act, for D-SNP

consideration of such requests, and procedures for disputing denials of reasonable accommodation requests.

Response: While this comment is not strictly within the scope of this final rule, we note that MA plans, including D-SNPs, must comply with the applicable Federal civil rights authorities. Section 504 of the Rehabilitation Act of 1973 prohibits disability discrimination and includes requirements for effective communication for individuals with disabilities (45 CFR 84.52), accessibility standards for buildings and facilities (45 CFR 84.22 and 84.23), and the filing of grievances and complaints (45 CFR 84.61 and 84.7).

Comment: Some commenters requested that CMS extend this proposal beyond only those D-SNPs with exclusively aligned enrollment to those without D-SNP-only contracts or to all FIDE and HIDE SNPs. Other commenters suggested it apply to all D-SNPs. A commenter noted that having to implement separate material development and review processes can present operational challenges. A commenter requested that CMS define the “certain D-SNPs” in the proposal. A few commenters also requested that CMS clarify which materials require integration as well as which materials, or sections of materials, would require State feedback.

Response: We acknowledge that increased integration of materials for D-SNP enrollees and potential enrollees can help to reduce confusion and increase satisfaction. However, we proposed and are finalizing § 422.107(e) to adopt a pathway for States to require, through their State Medicaid agency contract, the use of integrated materials (at a minimum, an integrated SB, Formulary, and combined Provider and Pharmacy Directory) by D-SNPs with exclusively aligned enrollment, where the State is also requiring the D-SNP to apply for and request from CMS a D-SNP-only MA contract. By “certain D-SNPs” in the preamble of the proposed rule, we meant the D-SNPs that meet these specific requirements and are in this specific situation. Our proposal and final policy are limited to this group of D-SNPs because we believe exclusively aligned enrollment and a motivated State partner are both critical to effectively integrate materials. We will clarify through models and communication with States the sections of materials that require State feedback. We continue to work to improve current MA models for all D-SNPs, such as the ANOC and EOC, which allow D-SNPs to adjust the material to accurately

reflect information such as Medicaid benefits and cost-sharing.

Comment: A number of commenters support the inclusion of the ANOC and the EOC as part of the minimum scope of integrated materials. Several commenters noted that they appreciate the ability to use the Member Handbook as the integrated model, noting that the Member Handbook is more enrollee-friendly than the EOC. A commenter stated that the ANOC provides critical information about the changes that beneficiaries need to consider during the Open Enrollment Period. They noted that the ANOC is relatively short and most likely to be read by the beneficiary. In addition, they stated that it helps to prevent surprises and disruptions because of unanticipated changes in coverage or providers. Another commenter noted that, since CMS cannot change timelines for preparation of materials, CMS should start with the SB, Formulary, and combined Provider and Pharmacy Directory and reassess integration of ANOCs and EOCs once these first documents are in place, except in cases where collaboration on those additional documents already exists. They request that as part of the reassessment of the ANOC and EOC documents in the PRA process, CMS should facilitate allowing D-SNPs to use the Member Handbook format and approach upon request and agreement with the State. If this is not possible, they request that CMS clarify what additional authorities are needed in order to do so.

Response: We appreciate the commenters’ support for integrated ANOCs and EOCs. We have determined that we will take an incremental approach and finalize § 422.107(e)(1)(ii) as identifying the SB, Formulary, and combined Provider and Pharmacy Directory as the minimum set of documents to be integrated; these integrated materials must also meet Medicare and Medicaid managed care requirements in 42 CFR parts 422, 423, and 438. However, as stated in the proposed rule (87 FR 1874), we do not intend to preclude CMS and States from collaborating on other integrated materials, including an integrated ANOC or EOC.

We intend to develop an integrated Member Handbook (also known as the EOC) and ANOC for contract year 2024 through the PRA process, which will include making the documents available to the public for review and comment during the publication of 60- and 30-day **Federal Register** notices. These models will be based off of models that we created for the FAI and a related demonstration in Minnesota. We intend

to make the integrated versions of these models available for States that want to collaborate with CMS in furthering the use of integrated materials by D-SNPs with exclusively aligned enrollment.

Comment: A commenter suggested that CMS consider establishing a CMS-centralized repository of State information that includes accurate State agency addresses, phone numbers, and State Pharmaceutical Assistance Program information that MA organizations can access and utilize for beneficiary communications such as ANOC and EOC. The commenter noted that this State information could be displayed in the same way CMS already provides Quality Improvement Organization information for each State.

Response: We thank the commenter for this suggestion and may re-examine it in the future. However, this comment is not within the scope of this rulemaking, as the proposed rule did not discuss a regulatory requirement for centralized State information.

Comment: The commenter suggested that an integrated ID card include information on the beneficiary’s dual eligibility status, D-SNP type, the party that should receive and pay provider claims, and the party that is responsible for paying the beneficiary’s cost-sharing obligations. The commenter stated that this will reduce administrative burden and reduce risk that a beneficiary is improperly billed.

Response: We thank the commenter for this suggestion. While setting new standards for the content of an integrated ID card is outside the scope of the regulation, we will consider including this information on ID cards in the future.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the provision at § 422.107(e)(ii) with a modification to require that the integrated member materials meet Medicare and Medicaid managed care requirements consistent with applicable regulations in 42 CFR parts 422, 423, and 438.

c. Joint State/CMS Oversight

MA organizations receiving capitated payments through MA and from the State Medicaid agency must comply with different sets of Medicare and Medicaid requirements. This includes requirements imposed at the State level that are not identical to Federal minimum standards for Medicaid managed care plans in 42 CFR part 438. We explained in the proposed rule, at 87 FR 1874, three drawbacks to CMS and States’ separate infrastructures to

monitor compliance: (1) State regulators and CMS may be unaware of important compliance or performance problems related to the delivery of Medicare and Medicaid services; (2) State and CMS officials may pursue different performance improvement priorities; and (3) uncoordinated oversight by CMS and the States can create inefficiencies for health plans. We proposed to address these drawbacks by giving States the opportunity to collaborate with CMS on oversight activities for the specific D-SNPs that operate under the conditions described at proposed paragraph (e)(1). We received several comments supporting our overall approach to provide States an opportunity to collaborate with CMS on oversight activities.

Comment: Many commenters expressed support for State and CMS collaboration for joint oversight activities. Several commenters believed that improved data exchange and transparency would better align the State and CMS's improvement activities for D-SNPs. These commenters also noted that joint oversight would help the State and CMS establish awareness and appropriate accountability for plan performance. A few commenters noted that joint oversight is needed for quality of care and providing enrollees with a better integrated care experience. Several commenters indicated that increased collaboration would help the D-SNPs better manage staff resources in areas where there might be duplicative oversight activities. One commenter generally supports the opportunities for joint oversight and suggested guardrails to ensure that coordinated oversight activities are limited to D-SNPs to avoid overreach and promote improved outcomes and efficiencies.

Response: We thank the commenters for their support on our proposed rule. We agree that State and CMS collaboration for oversight activities of D-SNPs can increase transparency and improve efficiency of integrated care for Medicare and Medicaid services.

(1) State Access to the Health Plan Management System

The CMS Health Plan Management System (HPMS) is web-enabled information system where health and drug plans, plan consultants, third party vendors, and pharmaceutical manufacturers work with CMS to fulfill the plan enrollment, operational, and compliance requirements of the MA and Prescription Drug programs. We proposed in paragraph (e)(3)(i) that CMS would grant State access to HPMS to facilitate monitoring and oversight for D-SNPs operating under the specific

contract terms required by the State that are described in proposed paragraph (e)(1).

The proposal would permit approved State Medicaid officials to use HPMS for a number of information sharing and oversight activities for these D-SNPs. This access would allow State users the ability to directly view D-SNP information without requiring the D-SNP to send the information separately.

We proposed that State access would be limited to approved users and subject to compliance with HHS and CMS policies and standards and with applicable laws in the use of HPMS data and the system's functionality. This proposal would not limit CMS's discretion to make HPMS accessible in other circumstances not described in our proposal. State access authorization would include access to information about the MA organization and the applicable D-SNP(s) and D-SNP-only contract, and information submitted by the MA organization through HPMS, under the specific circumstances described in the proposed regulation. We solicited feedback on our proposal, including feedback from MA organizations about CMS providing approved State officials with access to HPMS as a means to share information as it relates to the provisions of this final rule.

Comment: Many commenters expressed support for our proposal to grant State access to HPMS to facilitate monitoring and oversight of for D-SNPs operating under the specific contract terms required by the State that are described in § 422.107(e)(1). Some commenters noted that HPMS access is important for better information and oversight of D-SNPs. Other commenters noted that providing States with access to HPMS will give the State officials important insight into areas such as marketing materials, models of care, enrollee complaints, plan benefits, formulary, network, and other basic contract information without having to ask the D-SNP and as a result will streamline the oversight process. A commenter noted that granting certain State Medicaid agency officials access to HPMS, which CMS has identified as a useful practice, aligns with their recommendation that CMS apply best practices from the FAI to FIDE SNPs.

Response: We appreciate the commenters' support for providing State Medicaid officials with HPMS access. We agree that providing States with access to these areas of HPMS will improve the coordination and oversight of D-SNPs by States and CMS.

Comment: A commenter supported our proposal to grant States access to

HPMS and suggested that CMS encourage States to update their State Medicaid agency contracts to reflect State access to this information. Specifically, the commenter encouraged States to eliminate the requirement that plans provide notices of audits since States will now be able to get the information through HPMS and will be able to have access to audit findings from CMS.

Response: We appreciate the commenter's perspective on this issue. We are not proposing to limit what States can include in their State Medicaid agency contracts, which are required by § 422.107(b) for all D-SNPs, but we hope that this new pathway for sharing information with States that require certain D-SNPs to use certain integrated materials and request a D-SNP-only MA contract with CMS will result in less burden for sharing information among the States that use this pathway, the affected D-SNPs, and CMS.

Comment: MACPAC and another commenter noted that limiting HPMS access to D-SNPs meeting the criteria of § 422.107(e) would mean that States would only be able to view information for a small number of D-SNPs with exclusively aligned enrollment and requested that CMS consider allowing States to view information for all D-SNPs. A commenter stated they understood there could be systems complexities with allowing States to access information for only a subset of enrollees when MA contracts include both D-SNP and non-D-SNP plan benefit packages. They suggest that CMS ensure that any language in the final rule is flexible enough to allow broader State access to HPMS without additional rulemaking. They believe that this was CMS's intent based on the language in the proposed rule stating: "This proposal would not limit CMS's discretion to make HPMS accessible in other circumstances . . ."

Response: CMS appreciates the commenters' support for providing State Medicaid officials with HPMS access. We will consider other options for permitting expanded HPMS access for State Medicaid officials over time. Under § 422.107(e), the regulation we proposed and are adopting here, access to States is tied to the D-SNP-only contracts for D-SNPs with exclusively aligned enrollment that are required to use specified integrated enrollee materials.

Comment: A commenter reiterated the importance of de-identifying information that could reveal the identity of the enrollee that has made a complaint, to ensure that their privacy

is upheld and to prevent any actions that could lead to or be perceived as enrollee retaliation. Another commenter requested CMS and State assurance of appropriate safeguards in place so that State employees accessing HPMS assure protection of proprietary information.

Response: CMS understands the commenters' concerns regarding enrollee privacy and the protection of proprietary information. Our experience granting States access to HPMS through the FAI and a related demonstration in Minnesota suggests that State access is without known problematic unintended consequences. In addition, we refer readers to our discussion in the proposed rule (87 FR 1874) that State users would be subject to compliance with HHS and CMS policies and standards and with applicable laws in the use of HPMS data and the system's functionality.

Comment: A commenter proposed that enrollee complaint information be aggregated and stratified and that the information be utilized by health plans for quality improvement and performance purposes.

Response: We appreciate the comment. MA organizations have access to all of their enrollee complaints in HPMS and we encourage them to utilize the data for quality improvement purposes.

Comment: A commenter strongly recommend interoperability between State monitoring systems and HPMS.

Response: We appreciate the comment; however, it is outside the scope of this rulemaking.

After consideration of the comments received and for the reasons provided in the proposed rule and our responses to comments, we are finalizing § 422.107(e)(3)(i) as proposed to provide State Medicaid officials with access to HPMS for purposes of oversight of D-SNP contracts described in § 422.107(e)(1). We are also finalizing § 422.107(e)(1) and (2) as discussed elsewhere in this final rule.

(2) State-CMS Coordination on Program Audits

We proposed in paragraph (e)(3)(ii) that CMS would coordinate with State Medicaid officials on program audits. This coordination would include sharing major audit findings for State awareness related to the D-SNPs subject to proposed paragraph (e)(1).

As summarized in the proposed rule at 87 FR 1874 through 1875, we believe that there are benefits for CMS, States, and MA organizations to increasing coordination in connection with such audits. As proposed, CMS would also offer to work with States to attempt to

avoid scheduling simultaneous State and Federal audits. This process would reduce the likelihood of concurrent Medicare and Medicaid program audits, thereby reducing the risk that an MA organization is insufficiently responsive to auditors or its performance slips because it is managing concurrent audits. While we described examples of how we may coordinate activities under the proposal, we did not intend to limit our discretion to coordinate with States in the audit process outside of the parameters in proposed § 422.107(e)(3)(ii); we would evaluate the extent of coordination in each circumstance relevant to the D-SNP-only contract established as a result of the State's contract requirements described in paragraph (e)(1).

Comment: Many commenters expressed support for the proposal for CMS-State coordination on program audits. Some commenters noted that greater State involvement provides States with valuable information and provides a stronger vantage point to determine plan performance. A few commenters indicated that program audits are resource intensive and plans face administrative burdens and challenges when State and Federal audits are concurrent. A commenter noted that when audits are concurrent this may decrease the plan's ability to respond appropriately and timely to audit inquiries.

Response: CMS appreciates the commenters' support and agrees that there are benefits in increasing CMS, State, and MA organization coordination.

Comment: A few commenters recommended additional steps to coordinate audits across Medicare and Medicaid. A commenter suggested that CMS provide States with additional guidance on current Federal audits and NCQA model of care review requirements. The commenter believed that this type of coordination would allow regulators to consider if one audit could satisfy the requirements for both a Federal and State audit. The commenter also urged CMS to consider collaborating with States to develop a crosswalk for auditors and plans to reference to ensure all audit parameters are clear and not in conflict. Another commenter encouraged States to consider what audits have been performed by CMS and whenever possible the audits should be linked, deeming the D-SNPs that have clean audits as meeting standards. A commenter suggested that CMS improve coordination with States for other audit types and between audit divisions in CMS. This commenter indicated that it

would be advantageous to have an increased level of scheduling coordination between Federal audit types; for example, between program audits and other routine reviews such as the one-third financial audit.

Response: CMS appreciates the perspectives and recommendations of the commenters for additional ways to coordinate audits and will take these into consideration for future audit-related work.

After consideration of the comments received and for the reasons provided in the proposed rule and our responses to comments, we are finalizing § 422.107(e)(3)(ii) as proposed address how CMS will coordinate with States on program audits for the D-SNP contracts described in § 422.107(e)(1).

(3) State Input on Provider Network Exceptions

As described in the proposed rule at 87 FR 1875, CMS expects to use existing authority and flexibility as it pertains to the review of MA plan provider networks, particularly in CMS's review of network exceptions, to solicit and receive input from State Medicaid agencies. CMS requires all MA organizations to maintain a network of appropriate providers that is sufficient to provide adequate access to covered services. Currently, MA organizations submit their provider networks to CMS for review at the overall contract level on a triennial basis or when there is a triggering event such as an application or a significant provider/facility termination.⁴⁸ As discussed in the proposed rule at 87 FR 1875, if an MA organization that offers one or more D-SNPs seeks an exception to our network adequacy standards in § 422.116, State Medicaid officials may be uniquely positioned to provide relevant information to CMS. We did not propose to adopt specific regulation text in § 422.107(e)(3) regarding potential collaboration with State Medicaid agencies in connection with adjudicating requests for an exception to network adequacy requirements for D-SNPs that operate under the conditions described at proposed paragraph (e)(1) because a regulatory amendment is not necessary to support this process; however, the proposed rule outlined how we expect this type of engagement between CMS and States to work.

When an MA plan fails to meet the network adequacy criteria in § 422.116(b) through (e), the MA plan

⁴⁸ Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance (Last updated: June 17, 2020). Retrieved at Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance ([cms.gov](https://www.cms.gov)).

may request an exception. Exceptions are limited to specific situations and conditions identified in § 422.116(f)(1) and, in considering whether to grant an exception, CMS considers whether current access to providers and facilities is different from what appears to be indicated by the data CMS uses to evaluate and set minimum standards for network adequacy for MA plans.

In the proposed rule, CMS proposed to amend § 422.116(a)(1)(ii) to require compliance with network adequacy standards as part of an application for a new or expanding MA service area (see section II.C. of this final rule). In addition, we described our intent to reach out to States to learn if there is any information that would meet the requirement at § 422.116(f)(2)(ii) when a MA organization with a D-SNP contract described in § 422.107(e) submits an exception request. CMS may consult with the respective State to identify if there are other factors, as described at § 422.112(a)(10), that may be relevant before making a determination on the exception request. We solicited comment on this approach.

Comment: We received a number of comments expressing support for our efforts to consult with States when an MA organization with a D-SNP contract described in § 422.107(e)(1) submits an exception request that does not meet the requirements at § 422.116(f)(1). A few commenters indicated that the States have information that would be pertinent to CMS's determinations. Some commenters noted that States have a deep knowledge of their local markets and can help CMS determine the validity of plans' exception requests. A commenter also suggested that States' involvement in the network exception process can highlight provider shortages.

Response: CMS appreciates the commenters' support for our efforts to consult with and solicit input from States in these circumstances.

Comment: A few commenters recommended that we add a provision that CMS notify the D-SNP of the consultation with the State so that the D-SNP is fully informed of additional factors being considered in the exception request.

Response: We appreciate the commenters' interest in having CMS notify a D-SNP when CMS consults with or solicits input from a State on a specific exception request. We decline to adopt a requirement that CMS notify the D-SNP whenever we consult with a State on an exception request because it would be too burdensome given the short timeframe we take to review all exception requests, in general. The D-

SNP will ultimately be informed of the basis for CMS's approval or denial of the exception request, and we do not believe there is any added benefit to the D-SNP knowing about the State outreach during the exception review process.

Comment: A commenter requested that we consider the timeliness in receiving responses from the State(s).

Response: We thank the commenter for their request and note that we expect States to respond timely to our requests to engage with CMS and to provide us with information that will be relevant to our determinations on exception requests submitted by MA organizations with D-SNP contracts described in § 422.107(e). To the extent States are not willing or able to provide information in a timely fashion, we will proceed with the network adequacy determination with the information available to us.

Comment: We received a few comments that did not support the proposal for State input of Medicare network exception requests on the grounds that States already have network standards in place and may not have specific insights into the Medicare requirements.

Response: We believe the commenters misinterpreted the discussion of CMS's authority under § 422.116(f) and our intent to solicit and receive input from State Medicaid agencies. Our consultations with States in the context of our proposal are limited to exception requests to the MA network adequacy standards and do not involve State Medicaid network standards. The purpose of the consultation with the State is to help CMS gain access to information that may be relevant to our determinations on exception requests from MA organizations with D-SNP contracts described in § 422.107(e).

The discussion in the proposed rule on this topic was not a proposal, and we are not finalizing any rules or regulations about CMS's ability to solicit comment from and consult with a State regarding a request from certain MA organizations (specifically, MA organizations with a D-SNP-only MA contract described in § 422.107(e)) for an exception from the MA network adequacy requirements in § 422.116. As described in the proposed rule and our responses to comments, we intend to solicit comment from and engage with States as appropriate and necessary when evaluating requests for exceptions from the network adequacy requirements in § 422.116.

d. Comment Solicitation on Financing Issues

Based on our experience in the FAI, we solicited comments on two opportunities to advance financial integration for integrated plans: (1) Medicare medical loss ratios (MLRs) that include only D-SNP experience and other options to evaluate the financial performance of integrated plans; and (2) consideration of the expected impact of benefits provided by MA organizations on Medicaid cost and utilization in the evaluation of Medicaid actuarial soundness.

We did not propose new Medicare or Medicaid policies in this discussion. Instead, we requested public comments on possible future initiatives. In this section of this rule, we summarize our requests for comments, comments received, and provide our responses.

At 86 FR 1870, we proposed at § 422.107(e) to make an option available through which States could require D-SNPs with exclusively aligned enrollment to operate under MA contracts that only include one or more D-SNPs that operate in that State. Such D-SNPs would still have to calculate and report separate Medicare and Medicaid MLRs, and having a separate contract for certain D-SNPs would better allow evaluation of MLRs and financial performance specific to that D-SNP product. We solicited feedback on the extent to which the proposal at § 422.107(e) would better allow States to evaluate the performance of integrated plans.

In the discussion at 87 FR 1877, we noted that we believe that Medicaid managed care capitation rates can be actuarially sound as required by § 438.4 when those rates consider the impact of MA supplemental benefits and any State-specific requirements for dually eligible individuals on the projected costs and utilization of the Medicaid benefits covered by the Medicaid managed care capitation rates. We solicited feedback on the extent to which this consideration of the impact of Medicare-covered benefits on costs and utilization of Medicaid services advances integration goals and is consistent with actuarial standards of practice. We also requested input on what information States, actuaries, and others would need to evaluate actuarial soundness under this approach.

Finally, we solicited feedback on other options related to financing for integrated plans CMS should evaluate and consider for future rulemaking or sub-regulatory clarification.

Comment: Several commenters expressed support for approaches to

MLR reporting that meaningfully improve stakeholders' visibility into the financial performance of integrated plans. Some commenters agreed that the proposal at § 422.107(e) would provide for MLR results exclusive to D-SNPs with exclusively aligned enrollment, thus enhancing transparency and relevancy of the MLR data used to assess and oversee financial performance for these plans in a way not currently possible. A commenter noted stakeholders already collect and analyze Medicare and Medicaid financial data and the benefits of the proposal would depend on the extent to which CMS facilitated or standardized analysis of MLR data in ways not possible today. Finally, a commenter recommended CMS explore how MLR calculations can improve services and outcomes for dually eligible individuals, especially those enrolled in HIDE and FIDE SNPs.

Response: We thank the commenters for their input and suggestions and will take them under advisement for future rulemaking and in developing technical assistance for States in analyzing MLR data.

Comment: Some commenters stated separate Medicaid and Medicare MLR requirements create challenges to meeting integration goals, such as inhibiting flexibility and not incentivizing integrated care, while another commenter stated the inconsistent availability of encounter data and lack of framework for allocating cost to Medicare versus Medicaid pose significant challenges.

A commenter objected to CMS ending the FAI capitated financial alignment model and expressed that this represents an undesirable move away from an integrated MLR, a change they believed would erode transparency in medical spending and increase the risk that plans will pad allowable administrative costs.

Response: We thank the commenters for their input and suggestions and will take them under advisement for future rulemaking. We address other comments on the FAI later in this final rulemaking.

Comment: Many commenters supported maintaining separate Medicare and Medicaid MLR requirements and several commenters expressed opposition to any changes. A few commenters expressed uncertainty that the benefits of an integrated MLR would outweigh the burden of reporting integrated MLR data. A commenter opposed any requirement for D-SNPs to report an integrated MLR or any other changes to current D-SNP financing and infrastructure. Many commenters also

noted barriers to or concerns with integrated MLR reporting that they believe CMS should take into consideration, including misalignments between Medicare and Medicaid funding, cost reporting definitions, and program requirements; the lack of a standardized methodology for calculating an integrated MLR; and the fact that current Medicaid rate development guidance does not provide for an integrated MLR to be used in Medicaid rate development for an integrated D-SNP. Some commenters indicated plans' operational and financial workflows are not currently structured to support or yield encounter or financial data of sufficient quality to support integrated MLR reporting.

A few commenters expressed support for integrated MLR reporting. A few commenters responded that they do not believe the current MLR approach provides sufficient data for State decision making and policy development; they instead supported an integrated MLR approach, including CMS requiring an integrated MLR for integrated products, as a better way to track and oversee plan spending, set actuarially sound rates, and establish plan performance targets. Several commenters supported States having the flexibility to determine MLR requirements. A commenter stated the integrated MLR reports that MMPs submit under FAI offer a more complete picture of plan financial performance than would otherwise be available. Another commenter acknowledged what while there are significant technical and legal hurdles to achieving integrated MLR reporting, overcoming these would support data-driven decision making and policy. A commenter noted the potential benefit to States of CMS's proposed requirement to reinstate the detailed MLR reporting requirements under §§ 422.2460 and 423.2460 (87 FR 1902 through 1906) as it may better support States to compare Medicare and Medicaid MLR reporting under a D-SNP contract.

Response: We would like to clarify that we did not propose to require an integrated MLR for integrated products; as we stated at 87 FR 1876, we do not believe we have the statutory authority to include Medicaid experience as part of the Medicare MLR requirement. We thank the commenters for providing thoughtful input on these issues. We will take these comments and concerns into consideration for any future guidance on this topic.

Comment: Several commenters agreed with CMS's interpretation that Medicaid managed care capitation rates can be actuarially sound, as required by

§ 438.4, when those rates consider the impact of MA supplemental benefits and State-specific requirements for dually eligible individuals, as included in the State Medicaid agency contract, D-SNP MOC, or MMP contract, on Medicaid costs and utilization. A few other commenters did not reference Medicaid actuarial soundness requirements but stated that MA supplemental benefits and State-specific requirements should be considered in setting Medicaid managed care capitation rates or supported States having the flexibility to consider the impact of such benefits and requirements when setting Medicaid managed care capitation rates. Several commenters indicated they expect MA supplemental benefits or other State-specific requirements to have minimal impact on the cost and utilization of Medicaid benefits. A commenter recommended that Medicaid actuaries be required to consider the impact of Medicare costs and utilization in Medicaid rate setting.

A few commenters expressed concern with States considering the impact of MA supplemental benefits and other State-specific requirements for dually eligible individuals when establishing Medicaid managed care capitation rates, citing potential negative impacts including: Reductions in Medicaid managed care capitation rates without sufficient transparency; Medicaid rates not meeting actuarial soundness requirements; and States offering less robust Medicaid benefits by substituting these benefits with MA supplemental benefits. A few commenters expressed concern about the impact of these Medicaid-rate setting considerations on MA market dynamics or beneficiaries' access to certain benefits, including: the potential for D-SNPs to be less competitive; or for such benefits to only be made available in MA plans, resulting in less beneficiary choice. For example, a commenter stated that significant expansion of MA supplemental benefits could give States less incentive to expand their Medicaid benefit package if coverage, such as for dental care, were widely provided in MA plans that are available to dually eligible individuals; in such scenario, beneficiary choice could be limited if needed dental coverage were only available in MA plans. A commenter also expressed concern that for integrated products, Medicare financial information alone might suggest funds are available to support funding Medicaid benefits, but that combined Medicare and Medicaid funding could indicate otherwise, limiting an

integrated plan's ability to fund investments in Medicaid services with savings from reduced Medicare acute care utilization. A few commenters stated that CMS should also consider the impact of Medicaid benefits in lowering Medicare costs and utilization.

Response: We thank the commenters for providing thoughtful input on this issue. We appreciate the support for CMS's interpretation that Medicaid managed care capitation rates can be actuarially sound when those rates consider the impact of MA supplemental benefits and any State-specific requirements on the projected costs and utilization of the Medicaid benefits. We thank the commenters for providing input on the potential unanticipated impacts of such an approach. We will take these comments and concerns into consideration for any future guidance on this topic.

Comment: A number of commenters provided input on the types of information States, actuaries, and others would need to evaluate actuarial soundness under this approach. A commenter noted that Medicaid rate development for programs with enrollment aligned across Medicare and Medicaid may currently use a wide variety of information that generally meets actuarial soundness needs. However, this commenter and a number of others provided feedback on potential implementation challenges CMS should consider that could impact States' and actuaries' ability to estimate the impact of such supplemental benefits on Medicaid costs and utilization.

Commenters noted barriers including: Timing differences between the MA bidding cycle and Medicaid rate-setting periods; the lack of uniformity and sameness in supplemental benefits across MA plans or within MA plans as a result of MA uniformity flexibility or provision of SSBCI; States not having sufficient MA bid data that describes supplemental benefits, and the lack of a consistent framework for allocating Medicare versus Medicaid costs or claims.

Some commenters encouraged CMS to provide additional guidance to ensure consistency in how States and actuaries consider of the impact on MA supplemental benefits or State-specific requirements in Medicaid managed care rate setting, in areas including: CMS's expectations for plan-specific Medicaid rates to account for plan differences in MA supplemental benefits; using a historical MA benefits package to establish Medicaid rates; and what quantitative support would be necessary to support CMS' review of Medicaid rates in these scenarios.

Response: We appreciate the feedback on the additional information States, actuaries and others would need to evaluate actuarial soundness under this approach, as well as other potential implementation challenges. We also thank the commenters for their input concerning what guidance would be useful for States and Medicaid actuaries. We will take this input into account as we consider updates to CMS's Medicaid Managed Care Rate Development Guide, as well as other avenues to provide guidance and technical assistance on this topic.

Comment: We received many comments on other options related to financing for integrated plans. For any future rulemaking, a commenter requested CMS collaborate with stakeholders in advance, while another commenter requested CMS take into consideration plans' need for flexible deadlines and written guidance.

Many commenters recommended that CMS work with States, managed care organizations, and actuaries on opportunities to improve financial alignment between Medicare and Medicaid. Other commenters expressed interest in CMS sharing best practices, such as how experience from the FAI could be applied in the context of a D-SNP or a FIDE SNP, or continuing to explore topics related to financial alignment, such as curbing incentives for cost shifting, methodologies to value supplemental benefits, and investments that target social determinants of health. A commenter that believes CMS should increase the level of coordination between CMS and States regarding community supports and in-lieu-of services that impact Medicare costs and utilization requested a new requirement for advance notification of changes in community support services.

A few commenters emphasized their support for CMS examining experienced-based rate setting approaches for adoption in integrated products outside of FAI, where cost neutrality was required. A commenter noted States participating in other aligned approaches may want to consider requesting more explicit cost offsets from CMS, such as sharing in the Medicare MLR remittances. A few commenters encouraged CMS to continue to offer States financial incentives for integration, with a commenter suggesting CMS offer States alternative value-adds such as access to implementation resources; ongoing increased FFP for administrative and IT changes; and improved coordination, quality, access, and simplification for beneficiaries.

Finally, a few commenters disagreed with the degree of emphasis they believe is placed on financial savings derived from integrated products, arguing CMS should pursue integration because it is an alternative to the current fragmented, inefficient system. A commenter disagreed with designing integrated approaches under a standard of budget neutrality, noting this is a standard to which MA organizations and Medicaid capitation payments for D-SNPs are not likewise held. Another commenter expressed support for replacing Titles 18 and 19 of the SSA to fund integrated services through a single source of financing used to fund benefits; this commenter stated this alternative model should feature State contracting with administering entities, financing mechanisms to ensure accountability and eliminate incentives for cost shifting, and required reinvestments of savings into efforts to support the population.

Response: We appreciate the commenters' input and suggestions on how to improve financial alignment across the Medicare and Medicaid programs and will take them under advisement for future rulemaking.

7. Definition of Applicable Integrated Plan Subject to Unified Appeals and Grievances Procedures (§ 422.561)

In § 422.561, we proposed to expand the universe of D-SNPs that are required to have unified grievance and appeals processes by revising the definition of an applicable integrated plan. The April 2019 final rule introduced the concept of applicable integrated plans, which we defined as FIDE SNPs and HIDE SNPs in which Medicare and Medicaid enrollment is exclusively aligned (meaning State policy limits a D-SNP's enrollment to those whose Medicare and Medicaid enrollment is aligned as defined in § 422.2) and the companion Medicaid MCOs for those D-SNPs, thereby making it feasible for these plans to implement unified grievance and appeals processes. We limited the universe of potential applicable integrated plans 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 grievances 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.

Because the landscape of integrated plans has evolved in the past several

years, we believe there are integrated D-SNPs other than FIDE SNPs and HIDE SNPs for which a unified grievance and appeals process is feasible. Expanding the process to these plans would simplify the grievance and appeals steps for beneficiaries enrolled in these plans for their Medicare and Medicaid benefits and extend the protection of continuation of benefits pending appeal as described in § 422.632 to additional beneficiaries. Accordingly, we proposed, effective January 1, 2023, to expand the definition of the term applicable integrated plan to include an additional type of D-SNP and the affiliated Medicaid managed care plan subject to the rule.

We proposed to include as applicable integrated plans certain combinations of Medicaid managed care plans and D-SNPs that are not FIDE SNPs or HIDE SNPs but meet three other conditions. First, State policy must limit the D-SNP's enrollment to beneficiaries enrolled in an affiliated Medicaid managed care plan that provides the beneficiary's Medicaid managed care benefits. Second, each enrollee's Medicaid managed care benefits must be covered under a capitated contract between (1) the MA organization, the MA organization's parent organization, or another entity that is owned and controlled by its parent organization, and (2) a Medicaid MCO or the State Medicaid agency. Third, the Medicaid coverage under the capitated contract must include 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 must include at least one of the following: Medicaid home health services (as defined in § 440.70), Medicaid medical supplies, equipment and appliances (as described in § 440.70(b)(3)), or Medicaid nursing facility services. The affiliated Medicaid MCO in which all of the D-SNP's enrollees are also enrolled in this scenario would also be included in our proposed expansion of applicable integrated plans. As a result, the following arrangements would be applicable integrated plans under our proposal, where both plans include membership that is fully aligned between the D-SNP and an affiliated MCO: (1) A D-SNP and affiliated Medicaid MCO where the D-SNP holds a contract with a separate Medicaid MCO to cover all capitated managed care benefits in the State and the separate Medicaid MCO holds the contract with the State for those benefits (2) a D-SNP and affiliated Medicaid

MCO where the affiliated Medicaid MCO holds a contract with the State for the capitated Medicaid benefits.

Where each of these conditions is met, enrollees receive all of their Medicare and Medicaid benefits that are available through managed care in the State through a D-SNP and affiliated Medicaid managed care plan.

We proposed to reorganize the definition of applicable integrated plan in § 422.561 by adding new subsections to the definition in § 422.561 to show separate definitions before and after January 1, 2023. The proposed definition after January 1, 2023, expands the universe of applicable integrated plans to include a D-SNP and affiliated Medicaid managed care plan that meets these three criteria. Under the proposed revisions to § 422.561, current paragraphs (1) and (2) would become paragraphs (2)(i)(A) and (B) and apply before January 1, 2023. Proposed new paragraph (2) of the definition would apply beginning January 1, 2023, and would include the current definition and the proposed new category of D-SNPs and affiliated Medicaid managed care plans that would qualify as an applicable integrated plan.

Comment: We received numerous comments in support of our proposal to expand the unified plan-level appeals and grievance processes to cover additional D-SNPs and enrollees where the State Medicaid managed care program may have carve-outs of LTSS and behavioral health services that prevent the plans from qualifying as FIDE or HIDE SNPs. In support of our proposal and covering more enrollees with the unified procedures, several commenters noted that the unified processes are simpler and easier to navigate for enrollees and will expand access to Medicare services while an appeal is pending. A commenter also noted that our proposed benefit coverage criteria for affected plans are largely areas where overlap is most common, including specifically durable medical equipment and home health. Some commenters, while supportive of our proposal, encouraged CMS to extend the unified processes to additional D-SNPs to cover more enrollees, including D-SNPs that do not have exclusively aligned enrollment.

Response: We appreciate the broad support for our proposal to expand the definition of applicable integrated plans to encompass more plans and cover more enrollees. We agree with those commenters who stated that the unified processes are clearer and easier to navigate for enrollees and provide additional benefits such as continuing Medicare services while an appeal is

pending. As we noted in the April 2019 final rule (CMS-4185-F), we do not think it is feasible to align appeals and grievance processes where the D-SNP is not affiliated with the Medicaid MCO covering the enrollee's Medicaid benefits. This includes a plan where some enrollees are aligned but not all. We will continue to monitor for additional opportunities for streamlining and clarifying the process for enrollees. We also remind D-SNPs that they have obligations under § 422.562(a)(5) to assist enrollees with obtaining and appealing Medicaid benefits covered by Medicaid, including when those Medicaid benefits are covered by unaffiliated Medicaid managed care plans or Medicaid FFS programs, as discussed in the April 2019 final rule (84 FR 15723), and that States may include additional integration requirements in their State Medicaid agency contracts with D-SNPs.

Comment: Some commenters, while supportive of our proposal, requested that CMS delay the implementation date. A commenter also asked how CMS would work with States that resist modifying appeals and grievance procedures to comply with the rule.

Response: We acknowledge that plans newly covered by the definition of applicable integrated plan will have less than a year to ensure that they have appropriate processes in place. However, most of the plans that we anticipate will be covered by the revised definition in 2023 currently operate as MMPs in California, and thus have several years' experience operating very similar unified appeals and grievance processes. With the transition of Cal MediConnect, we would like for enrollees who transition to D-SNPs and MCOs operated by the same parent organization to continue to benefit from the unified appeals and grievance processes that they have come to know in Cal MediConnect. We also note that materials and guidance already exist for applicable integrated plans⁴⁹ and the Medicare-Medicaid Coordination Office provides technical assistance to States on integration issues. We will continue to engage States, plans, and other stakeholders as we implement the unified appeals and grievance processes for additional plans, particularly in

⁴⁹ The Addendum to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, Coverage Decision Letter (Form CMS-10716), Letter about Your Right to Make a Fast Complaint, and Appeal Decision Letter can be found at [https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination-Office/D-SNPs](https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/D-SNPs).

California. We are also committed to continuing our work with States to gather and disseminate best practice information and to engage stakeholders to ensure a successful implementation.

Comment: Some commenters requested clarification, or through their comments suggested a need for clarification, with respect to whether the applicable integrated plans must have exclusively aligned enrollment to be covered under our proposed expansion of the definition of applicable integrated plans. A few commenters specifically suggested that we apply the applicable plan definition to HIDE SNPs, in addition to FIDE SNPs.

Response: We clarify that only D-SNPs with exclusively aligned enrollment, as defined in § 422.2 as those D-SNPs where State policy limits enrollment to full-benefit dual eligible individuals also covered by the affiliated Medicaid managed care organization, will be newly covered by the expanded definition of applicable integrated plans. Exclusively aligned enrollment, as a practical matter, generally refers to HIDE SNPs and FIDE SNPs. In this rule we are including in the definition of applicable integrated plans a subset of D-SNPs that are not HIDE SNPs or FIDE SNPs but still share membership with the Medicaid MCO. Plans covered under the existing definition of applicable integrated plans at § 422.561, meaning FIDE and HIDE SNPs that have exclusively aligned enrollment, will continue to be applicable integrated plans.

Comment: Several commenters opposed finalizing our proposal based on the misunderstanding that the unified procedures would apply to benefits beyond those covered by the D-SNP and Medicaid capitated contracts, potentially making the unified processes unworkable for plans. A few commenters requested clarification on how Medicaid benefits that are carved out of managed care in a State would be covered by the unified appeals and grievance process, and suggested that CMS facilitate data sharing between States and plans so that plans know what Medicaid benefits are covered and what the State requirements are for processing Medicaid appeals. A commenter also questioned the value of unified appeals and grievance processes that do not cover all of an enrollee's benefits due to benefits being carved out of managed care in the State.

Response: The Medicaid benefits covered by the applicable integrated plan will be delineated as covered benefits in the Medicaid managed care contract that the D-SNP has with the State Medicaid agency or other

Medicaid MCO. These will be the only Medicaid benefits subject to the unified appeals and grievance process. To the extent that the Medicaid MCO covering the Medicaid managed care benefits is not the same legal entity as the D-SNP, both the Medicaid MCO and the D-SNP must collaborate to implement a unified appeals and grievance process to cover the enrollees' full capitated Medicaid and Medicare benefits, and ensure they are complying with the regulations at §§ 422.629 through 422.634. The appeals and grievances processes for Medicaid benefits that are not capitated to the applicable integrated plan (that is, the plan is not responsible for covering) remain unchanged. For example, if an enrollee appeals the denial of a Medicaid service that is carved out, that appeal would continue to be processed and decided through the State's appeal process as it is today. Similarly, Medicare benefits that are not covered by the D-SNP, specifically hospice benefits, acquisition costs of kidneys for transplant, and certain new benefits that are the subject of an NCD or legislative change in benefits, will not be subject to the unified appeal and grievance process. Benefits that are not covered by the D-SNP or MCO contract will not be covered by the unified grievance and appeals procedures. However, we believe that bringing as many benefits as the plans cover, under the MA contract and under the capitated contract for Medicaid managed care benefits, into the unified procedures still benefits the enrollee by providing the enrollee a single pathway for appeals and grievances for those overlapping benefits, as opposed to separate paths for appeals and grievances based on Medicare or Medicaid coverage. We note that, with respect to the workability of unified appeals and grievance procedures generally, 95 applicable integrated plans in eleven states are currently operating, and we have heard very few questions or concerns. We also reiterate the requirement for all D-SNPs to assist enrollees with obtaining, including appealing, access to all Medicaid benefits, including those that the plan does not cover, per § 422.562(a)(5).

Comment: We received a comment requesting that applicable integrated plans be permitted to use the MA Integrated Denial Notice for ease of plan process and for less enrollee confusion. Another commenter raised questions about the impact of the unified processes on Part C reporting.

Response: We decline to allow applicable integrated plans to use the Integrated Denial Notice (Form CMS-10003-NDMCP) and note that we have

issued a specific denial notice for applicable integrated plans, the Coverage Decision Letter (Form CMS-10716). The Coverage Decision Letter⁵⁰ is tailored to the unified process and appeal rights and covers the requirements at § 422.631. It is currently in use by existing applicable integrated plans. We have not heard concerns about difficulties in using this notice or confusion on the part of enrollees. As far as Part C reporting requirements, we can confirm that we previously reviewed these requirements and made minor adjustments prior to the implementation of the unified appeals and grievance processes in 2021.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the amendment to the definition of applicable integrated plans in § 422.561 with slight modifications to increase clarity. We are revising the definition to be clearer where there are references to other paragraphs within the definition and to clarify in paragraph (2)(ii)(C) that, in addition to primary care and acute care (including Medicare cost-sharing), the capitated contracts for Medicaid coverage must cover at a minimum, one of the following categories of Medicaid benefits: Home health services as defined in § 440.70 of the chapter, medical supplies, equipment, and appliances as described in § 440.70(b)(3) of the chapter, or nursing facility services as defined in § 440.155 of the chapter.

8. Permitting MA Organizations With Section 1876 Cost Contract Plans To Offer Dual Eligible Special Needs Plans (D-SNPs) in the Same Service Area (§ 422.503(b)(5))

Section 1876(h) of the Act established reasonable cost reimbursement contracts or "cost contracts," as defined at § 417.401, as Medicare contracts under which CMS pays an HMO or competitive medical plan on a reasonable cost basis. By contrast, MA plans bear the risk of coverage of Medicare and supplemental benefits for their enrollees and are paid risk adjusted capitation by CMS. Cost contracts arrange for Medicare services and provide enrollees several flexibilities not offered to MA plan enrollees, such as the ability to enroll in a plan that offers only Part B benefits and to receive health care services outside of the cost contract plan's

⁵⁰ The Coverage Decision Letter (Form CMS-10716) can be found at <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/D-SNPs>.

network of providers through original Medicare. As of March 2022, approximately 184,000 beneficiaries were enrolled in six cost contracts offered in nine States.⁵¹

We direct readers to the proposed rule, 87 FR 1878, for discussion of how Federal statute and regulation restrict cost contracts in several ways. We proposed to modify the prohibition at § 422.503(b)(5) on an entity accepting new enrollees in a cost contract plan while offering an MA plan in the same service area applicable to: (1) A parent organization owning a controlling interest in a separate legal entity accepting new enrollees under a cost contract plan, and (2) another separate legal entity owned by the same parent organization as the legal entity accepting new enrollees under a cost contract plan.

As described in our proposed rule, since CMS finalized the policy at § 422.503(b)(5), we have gained more experience relevant to this D-SNP policy decision through the Demonstration to Align Administrative Functions for Improvements in Beneficiary Experience conducted in partnership with the State of Minnesota.⁵² Three of the seven MA organizations offering Minnesota D-SNPs participating in the demonstration—comprising almost 60 percent of the demonstration enrollment—also sponsored cost contract plans in overlapping counties. To prevent potential disruption to the demonstration, we waived § 422.503(b)(5) for these entities, using our authority under section 1115A of the Act. This waiver avoided the risk that these entities would, instead of closing the cost contract plans to new enrollment where the service areas overlapped with D-SNPs, non-renew their D-SNPs during the demonstration, which would undermine our ability to carry out successfully the model test. In addition, non-renewal of these D-SNPs could potentially have led to large-scale disenrollment from Minnesota Senior Health Options, a D-SNP and Medicaid MCO program with evidence of strongly favorable outcomes for dually eligible older adults.⁵³

⁵¹ Retrieved from: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartIDEnrollData/Monthly-Enrollment-by-Contract>.

⁵² See <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Minnesota.html>.

⁵³ Anderson, W.L., Feng, Z., & Long, S.K. *Minnesota Managed Care Longitudinal Data Analysis*, prepared for the U.S. Department of Health and Human Services Assistant Secretary for

Although the waiver and model were not designed to test this specific issue, the waiver of § 422.503(b)(5) provided an opportunity to test whether creating an exception for D-SNPs would result in substantial shifts of D-SNP enrollees to cost contract plans offered under the same parent organization. We direct readers to the proposed rule, 87 FR 1878 through 1879, for a more detailed description of the data reported by D-SNPs with cost contract plans in Minnesota. The data from the Minnesota demonstration showed allowing both a D-SNP and a cost contract plan under the same parent organization did not result in a substantial number of enrollees moving from the D-SNP to the cost contract plan.

Based on this evidence, we believe that allowing a parent organization to accept new enrollees in a cost contract plan it offers in the same service area as the entity offers a D-SNP or seeks to offer a new D-SNP would not undermine the policy goals that underlie § 422.503(b)(5)—that is, prohibiting entities from steering high-cost enrollees to their cost contract plans and lower cost enrollees to their risk-bearing MA plans. In addition, creating an exception to § 422.503(b)(5) for D-SNPs would allow the entities in Minnesota that currently offer both D-SNPs (through the demonstration) and cost contract plans in the same market to continue enrollment in both plans after the end of the demonstration, thus avoiding potentially significant disruption to Medicare beneficiaries that would result from each MA organization's non-renewal of one of the two types of products. More broadly, the exception removes a regulatory barrier that, in Minnesota and several other States, can impede D-SNPs from entering a market where cost contract plans remain. Therefore, we proposed to revise paragraph § 422.503(b)(5)(i) and (ii) to allow an MA organization to offer a D-SNP and also—

- Offer an 1876 reasonable cost plan that accepts new enrollees;
- Share a parent organization with a cost contract plan that accepts new enrollees;
- Be a subsidiary of a parent organization offering a cost contract plan that accepts new enrollees; or
- Be a parent organization of a cost contract plan that accepts new enrollees.

In our proposed rule, we solicited comment on the proposed exception for

Planning and Evaluation (ASPE) (March 31, 2016). Retrieved from <https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis>.

D-SNPs and our process for monitoring for unintended consequences. We also explained how we were considering more limited exceptions to the requirements at § 422.503(b)(5) that may more closely fit our policy goal of removing regulatory obstacles to the availability of D-SNPs that further Medicare-Medicaid integration. Specifically, we were considering limiting the exception to:

- D-SNPs designated as HIDE SNPs, as defined at § 422.2, and FIDE SNPs, as defined at § 422.2;
- D-SNPs that only enroll full-benefit dually eligible individuals;
- D-SNPs that charge no beneficiary premium for individuals eligible for the full Part D low income subsidy;
- D-SNPs that are affiliated with cost contract plans that charge premiums for enrollees eligible for the full Part D low income premium subsidy; or
- Combinations of these types of D-SNPs.

We did not propose these alternatives, citing our belief that they would add complexity to the regulation that we did not believe would be necessary to achieve our primary aim of removing regulatory obstacles to the availability of D-SNPs that integrate Medicare and Medicaid services and improve care for dually eligible individuals. However, we solicited comment on whether inclusion of some or all of these additional alternative criteria in the revisions to § 422.503(b)(5) would strengthen the overall policy.

Comment: A few commenters supported our proposal to allow a parent organization to accept new enrollees in a cost contract plan it offers in the same service area as the entity offers a D-SNP or seeks to offer a new D-SNP. No commenters opposed the proposal. A few commenters noted that the proposal would ensure continuity of care for Minnesota's D-SNP enrollees as the Minnesota administrative alignment demonstration phases out. A commenter noted that the proposal would reduce potential barriers to integrated care for Medicare and Medicaid, allow for the expansion of coverage options in other geographies, and ease administrative burden on States. Another commenter expressed general support for policies that address barriers to integration across States, particularly in rural areas, and those that apply best practices from demonstrations.

Response: We thank the commenters for their support of this proposal and agree it would reduce barriers to integration of Medicare and Medicaid.

Comment: A commenter expressed support for CMS's close monitoring of

enrollment, should we finalize the proposed regulation.

Response: We appreciate the commenter's statement. We will monitor patterns of dually eligible enrollment and disenrollment in applicable cost contract plans and D-SNPs. To the extent we see any pattern that suggests that plan sponsors are persuading D-SNP enrollees to move into cost contract plans, we would investigate and pursue corrective actions or additional rulemaking, potentially removing or restricting the exemption finalized in this rule.

Comment: A commenter suggested that organizations should be permitted to offer both a national MA Employer Group Waver Plan (EGWP) option and continue to offer an individual cost contract plan in certain rural areas of the Midwest with limited Medicare options. The commenter posited that cost contract plans and EGWPs would not compete for the same beneficiaries since, unlike cost contract plans, EGWPs are offered specifically to Medicare-eligible retirees of a particular employer.

Response: We thank the commenter for this suggestion. We note that we limited our proposal to D-SNPs operating in the same area as a cost contract plan to remove regulatory obstacles to the availability of D-SNPs that further Medicare-Medicaid integration. Therefore, this comment is not strictly within the scope of the rulemaking, as the proposed rule does not discuss limitations on EGWPs. Although we are not offering an opinion on the merits of the commenter's suggestion, we would clarify that EGWPs need not restrict enrollment to the Medicare-eligible retirees of a particular employer. For example, Chapter 9 of the Medicare Managed Care Manual provides that professional or other types of group associations with members that do not all have the same employer are not precluded from enrolling Medicare beneficiaries in EGWPs, provided the members of the association are eligible for employment-based health coverage. Further, our regulations do not preclude a Medicare beneficiary who would be eligible for an MA EGWP from electing to enroll in a different coverage option, like a cost plan offered in the area where the beneficiary lives. As a result, it is not as clear as the commenter suggests that the concerns underlying our original adoption of § 422.503(b)(5) would not apply in the context of an EGWP.

After consideration of the comments and for the reasons provided in the proposed rule and our responses to the comments, we are finalizing without

modification our proposal to allow a parent organization to accept new enrollees in a cost contract plan it offers in the same service area as the entity offers a D-SNP, or seeks to offer a new D-SNP.

9. Requirements To Unify Appeals and Grievances for Applicable Integrated Plans (§§ 422.629, 422.631, 422.633, and 422.634)

Section 50311 of the BBA of 2018 amended section 1859 of the Act to add new requirements for D-SNPs to unify Medicare and Medicaid appeals and grievance procedures for integrated D-SNPs. We codified the regulations for unified appeal and grievance procedures §§ 422.629 through 422.634 (84 FR 15720). These procedures apply to applicable integrated plans, which are currently defined at § 422.561 as FIDE SNPs and HIDE SNPs with exclusively aligned enrollment. We are finalizing an amendment to the definition of applicable integrated plan in section II.A.7. of this final rule, which will add new categories of applicable integrated plans beginning January 1, 2023. Based on our initial implementation experience and feedback from stakeholders, we proposed several adjustments, clarifications, and corrections to the regulations governing unified appeal and grievance procedures at §§ 422.629 through 422.634.

Comment: Numerous commenters expressed general support of our proposals for updates to the unified appeals and grievance rules with commenters noting the benefits to enrollees of having a single pathway for Medicare and Medicaid appeals and grievances, integrated notices, and access to continuation of benefits while the appeal is pending for Medicare.

Response: We appreciate the broad support for unified appeals and grievance processes and agree that the unified process is simpler and provides more protections for enrollees.

Comment: Several commenters requested that we delay implementation of the proposed changes until at least 2024 to give plans more time to implement the updates, and to provide more time for CMS to release additional guidance and best practices on the unified appeals and grievance processes.

Response: While we acknowledge the commenters' concern, the updates we proposed are relatively minor, so we are not delaying the implementation date.

Comment: We received several comments requesting that CMS work with States to ensure State-specific requirements are clear and conveyed

timely, and additional guidance to plans is released. Commenters also requested that CMS share best practices and additional materials about integrated appeals and grievance processes.

Response: We appreciate the commenters' request for clarity. We will make timely updates to the *Addendum to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance*⁵⁴ to incorporate the updates made in this rule. CMS is also committed to continuing to engage States, plans, and other stakeholders as we gather and disseminate best practice information, providing technical assistance on integration issues as needs arise.

Comment: Several commenters proposed changes to the existing unified and grievance rules. A commenter suggested that CMS revise § 422.629(e) to require plans to assist providers in filing appeals. A commenter suggested additional information should be required to be included in each organization determination, some of which is already included (for example, the enrollee's right to get a free copy of the information used in making the decision and how to get it and how to continue services while an appeal is pending, and receiving the notice in alternate formats), and details on the second level appeals process (to the Independent Review Entity (IRE) or a State fair hearing). A commenter requested that we add additional specificity on how plans should consider, approve, and provide for appeals of reasonable accommodation requests. A commenter requested clarification on how continuation of benefits work while an appeal is pending. A commenter requested changes to § 422.633(e)(3) to no longer allow circumstances where an enrollee's payment request appeal may be expedited. A commenter requested clarification related to the language in § 422.633(e)(3) on how a plan should determine if non-payment will create material life or health consequences and how quickly decisions and payments must be processed in these cases.

Response: We appreciate the commenters' suggestions. We note, generally, that these comments are on regulations for which we did not propose changes and therefore are

⁵⁴ The Addendum to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, Coverage Decision Letter (Form CMS-10716), Letter about Your Right to Make a Fast Complaint, and Appeal Decision Letter can be found at [https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination-Office/D-SNPs](https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/D-SNPs).

beyond the scope of this rulemaking. We included an extensive discussion of the unified appeals and grievance process in the April 2019 final rule (84 FR 15727 through 15744) and in the Addendum to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. We direct readers to those documents for additional information and explanation of the existing appeals and grievance system rules for applicable integrated plans, and how to operationalize them.⁵⁵ We also direct commenters to the current model notices for applicable integrated plans for reference as to what is currently covered in the notices.⁵⁶ We also note that this rule does not impact the requirements for applicable integrated plans to continue benefits while an appeal is pending (please see the April 2019 final rule (84 FR 15737) for more information on how continuation of benefits works in the unified process). These continuation of benefits requirements will be applied to additional applicable integrated plans and their enrollees, per our discussion related to the revised, expanded definition of applicable integrated plans in section II.A.7.

We urge commenters to review the April 2019 final rule (84 FR 15741) for a discussion of expedited payment appeals, which provides the rationale for inclusion of the right for an enrollee to request one. In addition, with respect to the language in § 422.633(e)(3) related to considering whether the standard timeframe could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function, we note that all MA organizations and Medicaid managed care organizations must apply this standard today in various contexts of appeals cases, since this language also exists in §§ 422.566, 422.570, 422.584, 438.210, and 438.410.

Finally, we note that MA plans, including D-SNPs, must comply with applicable Federal civil rights authorities. Section 504 of the Rehabilitation Act prohibits disability discrimination and includes requirements for effective communication for individuals with disabilities (45 CFR 84.52), accessibility

standards for buildings and facilities (45 CFR 84.22, 84.23), and filing of grievances and complaints (45 CFR 84.61, 84.7).

a. Providing Enrollees Information on Presenting Evidence and Testimony (§ 422.629(d))

We proposed adding additional language to § 422.629(d) to codify in regulation a provision from existing sub-regulatory guidance.⁵⁷ We proposed to revise § 422.629(d) to require that, as part of its responsibilities pertaining to an enrollee's presenting evidence for an integrated grievance or appeal, an applicable plan provide an enrollee with information on how evidence and testimony should be presented to the plan. In addition, our proposal would reorganize § 422.629(d) to improve the readability of the provision.

Comment: Several commenters requested that CMS clarify when, in the appeals process, applicable integrated plans should offer enrollees the opportunity to provide live testimony, and how long such testimony should be allowed to be.

Response: We note that the requirement to provide enrollees with an opportunity to present evidence and testimony is an existing rule, at § 422.629(d). This same requirement to provide an opportunity for evidence and testimony also exists in both the Medicaid managed care requirements at § 438.406(b)(4) for appeals, and for MA plans at § 422.586 for reconsiderations. Our proposed update is to require that applicable integrated plans provide enrollees information on how to present the evidence and testimony. For the evidence and testimony to be meaningful to the plan's decision, it must be accepted prior to the plan's decision and taken into account in that decision. The regulation does not set forth a specific amount of time that must be provided for an enrollee to provide evidence, including testimony, but enrollees must be provided a reasonable opportunity and sufficient flexibility in terms of what is presented as needed to provide relevant information.

After consideration of the comments and for the reasons provided in the proposed rule and our response to the comments, we are finalizing this provision as proposed without modification.

b. Technical Correction (§ 422.629(k))

We proposed technical changes to § 422.629(k)(4)(ii) to correct a minor error from the April 2019 final rule (84 FR 15835). We proposed to replace the word "organization" with "reconsideration" and remove the word "decision" from the end of the sentence in § 422.629(k)(4)(ii) for clarity and consistency in the text.

We received no comments on this proposal. For the reasons outlined in the proposed rule, we are finalizing the proposed change without modification.

c. Accommodate State Medicaid Representation Rules (§ 422.629(l))

At § 422.629(l)(1), we proposed adding additional language to codify in regulation current sub-regulatory guidance⁵⁸ regarding the appointment of a representative. We proposed to add language to clarify that an enrollee's representative includes any person authorized under State law to accommodate State Medicaid program appointments. We proposed to reorganize paragraph (l)(1) as part of this amendment. Specifically, we proposed to revise paragraph (l)(1)(i) to list the enrollee and to revise paragraph (l)(1)(ii) to list the enrollee's representative, including any person authorized under State law. We also proposed to move the content of current paragraph (l)(1)(ii) that deals with rights of assignees to a new § 422.629(l)(4) as discussed in section II.A.9.d. of this final rule.

Comment: A commenter requested that CMS clarify the types of documentation applicable integrated plans should accept, and if the documentation requirements would be different depending on whether the underlying benefit is covered by Medicaid or Medicare.

Response: We appreciate the commenters' requests for clarity. Applicable integrated plans should treat all appeals and grievances subject to the rules at §§ 422.629 through 422.634, and authorization of representation documentation, the same whether the underlying benefit is covered by Medicare, Medicaid, or both. If the documentation that the applicable integrated plan receives from a representative meets either State Medicaid or Medicare standards for representation, the plan should accept the documentation. For example, even if the underlying benefit at issue in the

⁵⁵ The guidance can be found at <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/DSNPs>.

⁵⁶ The Coverage Decision Letter (Form CMS-10716), Letter about Your Right to Make a Fast Complaint, and Appeal Decision Letter can be found at <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/D-SNPs>.

⁵⁷ CMS, "Addendum to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for Applicable Integrated Plans". Retrieved from: <https://www.cms.gov/files/document/dsnpartscdgrievancesdeterminationsappealsguidanceaddendum.pdf>.

⁵⁸ CMS, "Addendum to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for Applicable Integrated Plans". Retrieved from: <https://www.cms.gov/files/document/dsnpartscdgrievancesdeterminationsappealsguidanceaddendum.pdf>.

appeal is covered only by Medicare, and the representation documentation meets State Medicaid representation requirements, the plan should accept the authorization as sufficient. This is consistent with how the appeal processes for applicable integrated plans were designed to take into account differences in Medicaid State programs, be easily navigable by enrollees, and provide unified procedures and processes.

We did not receive any comments recommending changes to this proposal. For the reasons outlined in the proposed rule, we are finalizing this provision without modification.

d. Clarifying the Role of Assignees and Other Parties (§ 422.629(l))

In the April 2019 final rule, we finalized § 422.629(l)(1)(ii) to include assignees of the enrollee and other providers with appealable interests in the proceedings as individuals who could file an integrated grievance, request an integrated organization determination, or request an integrated reconsideration to clarify the rights of non-contracted providers. We therefore proposed to move the content of § 422.629(l)(1)(ii) to new paragraph (l)(4). As noted in section II.A.9.c. of this final rule, we proposed to add new language at § 422.629(l)(1)(ii) in its place addressing who can be an enrollee's representative.

In new paragraph (l)(4) we proposed to clarify which individuals or entities can request an integrated reconsideration and are considered parties to the case but who do not have the right to request an integrated grievance or integrated organization determination. In paragraph (l)(4)(i), we proposed to permit an assignee of the enrollee (that is, a physician or other provider who has furnished or intends to furnish a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service) to request an integrated reconsideration. In paragraph (l)(4)(ii) we proposed to permit any other provider or entity (other than the applicable integrated plan) who has an appealable interest in the proceeding to request an integrated reconsideration.

Comment: A few commenters requested that CMS clarify what an appealable interest means and clarify the language in § 422.629(l)(1)(ii) that provides that “parties with appealable interest” may appeal.

Response: We appreciate the commenters' request for clarity and note that we did not propose any changes to the language in § 422.629(l) related to appealable interest (that is, any other

provider or entity—other than the applicable integrated plan—who has an appealable interest). This is existing language in § 422.629(l) and in the longstanding MA appeal rules at § 422.574(d). We point commenters to the discussion on § 422.574 in the June 1998 final rule titled “Medicare Program; Establishment of the Medicare+Choice Program” (63 FR 35026) which noted that the phrase includes not just the enrollee, but also allows other parties to exercise appeal rights (excluding the MA organization). As noted in that discussion, parties who may have an appealable interest in a case may include certain physicians and other providers who are assignees of the enrollee, legal representatives of a deceased enrollee's estate, and the broad category of any other entity determined to have an appealable interest in the proceeding. These parties can continue to have an interest in the proceedings throughout each level of an appeal. We decline to add a definition for this phrase in this rule. In our proposal we are only reorganizing where this language is in § 422.629(1).

We did not receive any comments recommending changes to this proposal. After consideration of the comments and for the reasons outlined in our responses, we are finalizing this provision without modification.

e. Timelines for Processing Payment Requests (§ 422.631)

In the April 2019 final rule, we neglected to specify how the MA “prompt payment” rules at § 422.520 governing payment of claims apply to applicable integrated plans.

Accordingly, at § 422.631(d), we proposed to add a new paragraph (d)(3) to require applicable integrated plans to process payment requests according to the prompt payment provisions set forth in § 422.520, which would mirror the current provision at § 422.568(c).

We did not receive any comments recommending changes to this proposal. For the reasons provided in the proposed rule, we are finalizing the proposed amendment without modification.

f. Clarifying Integrated Reconsideration Request (§ 422.633(e) and (f))

We proposed changes to § 422.633(e)(1) to clarify who may file a request for an expedited post-service integrated reconsideration (that is, one that is related to payment). Our proposal would clarify that an enrollee may request an expedited integrated reconsideration related to payment that can qualify as expedited, but a provider's right to request an expedited

integrated reconsideration on behalf of an enrollee is limited to pre-service integrated reconsideration requests. We proposed to specify in § 422.633(e)(1)(i) that expedited post-service integrated reconsideration requests are limited to those requested by an enrollee, and in § 422.633(e)(1)(ii) that providers acting on behalf of an enrollee may only request pre-service expedited integrated reconsiderations.

We solicited comment regarding whether allowing a 60-day timeframe for non-contracted provider payment requests where the provider has obtained a waiver of liability from the enrollee would simplify plan operations without adversely affecting beneficiaries or access to care. We noted that any changes to this timeframe would impact § 422.633(f), and the timing for applicable integrated plans to make integrated reconsideration determinations in cases involving payment requests from providers where the provider has obtained and filed a waiver of liability from the enrollee. We also solicited comment regarding whether adopting such a timeframe for non-contracted provider payment requests would conflict with any State-specific Medicaid rules or processes concerning provider appeals.

Lastly, we proposed at § 422.633(f)(3) to add language to clarify that extensions of up to 14 days are available for any integrated reconsiderations (either standard and expedited) other than those regarding Part B drugs. We proposed to exclude integrated reconsiderations about Part B drugs from the authority for extensions in order to be consistent with current § 422.633(f), which provides that integrated reconsidered determinations regarding Part B drugs must comply with the timelines governing Part B drugs established in §§ 422.584(d)(1) and 422.590(c) and (e)(2). Our current sub-regulatory guidance addresses this as well.

Comment: A few commenters requested that CMS add language clarifying that when providers are appealing on behalf of enrollees, and the services have been rendered and the enrollee is not financially responsible, they should not be doing so for purposes of their own (provider) reimbursement. A commenter also requested that CMS confirm whether enrollees would need to provide a waiver of liability in these cases.

Response: We appreciate the commenters' perspective on this issue, but we decline to add further detail in the rule on this issue. If a provider is acting on behalf of the beneficiary in the appeals process, the provider's motive

for assisting the enrollee is not relevant; beneficiaries are permitted to have a provider act on their behalf consistent with these rules. In addition, a non-contract provider may appeal in their own right consistent with these rules when a waiver of liability is properly filed. If the provider is acting on behalf of the enrollee, the enrollee does not need to provide a waiver of liability. A waiver of liability would only be provided if the non-participating provider is appealing on their own behalf (not on behalf of the enrollee). We decline to add the suggested additional detail to the regulation at this time.

After consideration of the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the amendments to § 422.633(e) and (f) as proposed without substantive modification. We are finalizing a grammatical revision to paragraph (e)(1)(ii).

g. Timeframes for Service Authorization After a Favorable Decision (§ 422.634(d))

We proposed changes, in § 422.634(d), to more clearly describe timeframes for authorizing services in all situations where an applicable integrated plan's decision is reversed. We proposed reorganizing § 422.634(d) to more explicitly address each scenario that an applicable integrated plan would face when effectuating a reversal. In proposed paragraph (d)(1), we proposed to address cases where the applicable integrated plan reverses its own decision in an appeal for services that were not furnished while the appeal was pending. We proposed that an applicable integrated plan must authorize or provide the service as expeditiously as the enrollee's condition requires and within the sooner of: (1) 72 hours from the date of the reversed decision; or (2) 30 calendar days (7 calendar days for a Part B drug) after the date that the applicable integrated plan received the integrated reconsideration request.

We also proposed to include the Part B drug timeframe from § 422.618(a)(3) in § 422.634(d)(1)(ii)(B) to ensure enrollees of applicable integrated plans get the same timely effectuation of a favorable appeal decision on coverage of a Part B drug; this is consistent with how current § 422.633(f) provides that integrated reconsidered determinations regarding Part B drugs must comply with the timelines governing reconsidered determinations regarding Part B drugs established in §§ 422.584(d)(1) and

422.590(c) and (e)(2), which apply to other MA plans.

In proposed paragraph (d)(2), for the sake of clarity we proposed to place in its own paragraph the requirement for the applicable integrated plan to authorize or provide a Medicaid-covered service no later than 72 hours from the date the plan is notified of a decision reversed by a State fair hearing. We proposed no changes to this effectuation timeline.

Lastly, we proposed to add a new paragraph (d)(3) to require the same timelines for an applicable integrated plan to effectuate reversals by the Medicare IRE, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council as apply to other MA plans at §§ 422.618 and 422.619.

We requested comment on whether the additional language provides clarity to applicable integrated plans on their responsibility to provide a service after an integrated organizational determination or integrated reconsideration is overturned.

Comment: A commenter recommended that § 422.634 more fully integrate the Medicare and Medicaid processes, specifically requesting that the regulations parallel the integrated process in the Massachusetts One Care FAI demonstration since some services are covered by both programs. The commenter further noted, as an example, that the One Care contract requires the IRE to review both the Medicare and MassHealth medical necessity criteria.

Response: We thank the commenter for this suggestion, but we did not propose, and therefore will not finalize, a further integration of the appeals process at this time. We leave open the future possibility of furthering the integration of the unified appeals and grievance process to include the post-plan appeal procedures, as we noted in the April 2019 final rule (84 FR 15743). With respect to the unique aspects of the One Care demonstration three-way contract, though the IRE cannot review Medicaid cases for Medicaid benefits, it does use Medicaid medical necessity criteria, along with Medicare criteria, when reviewing Medicare supplemental benefit cases under One Care because, in the One Care demonstration, Medicare supplemental benefits are defined by State Medicaid criteria. Applicable integrated plans are not subject to the same requirements in designing and offering MA supplemental benefits. We would need to further evaluate whether there are any viable scenarios in which the IRE

may be required to review any particular State's Medicaid coverage criteria in reviewing coverage for a Medicare benefit.

Comment: A commenter requested that CMS clarify whether the timeframes in § 422.634 apply to expedited appeal decisions, and whether CMS intends to issue further guidance on timelines for effectuating reversals after the plan has issued an authorization and when the plan seeks next-level review of the initial appeal decision.

Response: Timeframes for applicable integrated plans to effectuate all decisions are covered in § 422.634; this includes effectuation after reversal by the applicable integrated plan, the IRE, a State fair hearing, or at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council. With the amendments made by this final rule, timeframes for effectuation are as follows:

As expeditiously as the enrollee's health condition requires, but no later than:

1. For a reversal by the applicable integrated plan (reversing its integrated organization determination), no later than the earlier of: (1) 72 hours from the date it reverses its decision or, (2) with the exception of a Part B drug, 30 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration (or no later than upon expiration of an extension described in § 422.633(f)). For a Part B drug, 7 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration.

2. For reversals by the IRE, in accordance with MA requirements at § 422.618 the applicable integrated plan must, for standard, non-Part B drug, and non-payment cases, authorize the service under dispute within 72 hours from the date it receives notice reversing its determination, or provide the service under dispute as expeditiously as possible no later than 14 calendar days from that date; for standard Part B drug cases, 72 hours from the date it receives notice reversing the determination; and payment cases, pay for the service no later than 30 calendar days from the date it receives notice reversing the integrated organization determination; and, in accordance with MA requirements at § 422.619, for expedited, non-Part B drug cases, authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination, and for expedited Part B

drug cases, authorize or provide the Part B drug no later than 24 hours from the date it receives notice reversing the determination.

3. If a State fair hearing reverses the applicable integrated plan's integrated reconsideration regarding a Medicaid benefit not furnished while the appeal was pending, the applicable integrated plan must provide or authorize the item or service as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination for all cases, both standard and expedited, in accordance with § 422.634(d)(2) (which is the same timeframe as required under Medicaid regulations at § 438.424).

4. For a reversal by an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council, the applicable integrated plan must effectuate a reversal under same timelines applicable to other MA plans as specified in §§ 422.618 and 422.619.

With respect to a MA plan's appeal rights, these proposed changes do not impact plans' appeal rights, and CMS does not anticipate issuing guidance on that topic as a result of this rule. Sections 422.592 and 422.600 of the MA rules apply to applicable integrated plans that have issued an integrated reconsideration that is adverse, in whole or in part, to the enrollee with regard to coverage or provision of a Medicare benefit. We note that § 422.634(b) addresses adverse integrated reconsiderations; this rulemaking does not revise § 422.634(b). An applicable integrated plan, like all other MA plans, must effectuate a decision in favor of the enrollee from the IRE; the plan does not have the authority to appeal the decision to an administrative law judge.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed amendment to § 422.634(d) without modification.

10. Technical Update to State Medicaid Agency Contract Requirements (§ 422.107)

Section § 422.107(c) lists minimum requirements for State Medicaid agency contracts. Paragraph (c)(6) requires that the contract document the verification of an enrollee's eligibility for "both Medicare and Medicaid." We proposed to strike the reference to Medicare in paragraph (c)(6) as it is not essential for the contract between the State Medicaid agency and the D-SNP to document how the D-SNP verifies Medicare eligibility. All MA plans, including D-

SNPs, already verify Medicare eligibility as part of accepting beneficiary coverage elections under § 422.60. See also Chapter 2 of the Medicare Managed Care Manual for additional details.⁵⁹

Comment: Several commenters expressed support for this technical update as it is a logical simplification of the State Medicaid agency contract minimum requirements.

Response: We thank the commenters for their support of this technical update.

Comment: A few commenters recommended that CMS should not finalize this proposal but should retain the contract requirement that a D-SNP must verify an enrollee's Medicare eligibility. These commenters believed that the existing regulatory text clarifies the State's obligation to identify dually eligible individuals and provide MA organizations with information that distinguishes between types of dual eligibility, such as full-benefit, and partial-benefit dually eligible individuals. A few commenters recommend that CMS require States to provide a crosswalk or translations to category identifiers, such as eligibility for Medicare Savings Programs (MSP), needed to manage benefits for enrollees. This would also serve as a tool to better understand differences in dual eligibility categories for D-SNPs, including partial-benefit dually eligible individuals.

Response: We thank commenters for raising their concerns. We note that we did not propose a change to the contract requirement that the D-SNP validate the enrollee's Medicaid eligibility. As noted in our proposal, all MA plans, including D-SNPs, already verify Medicare eligibility as part of accepting beneficiary coverage elections under § 422.60. See also Chapter 2 of the Medicare Managed Care Manual for additional details. Therefore, it is not essential for the contract between the State Medicaid agency and the D-SNP to document how the D-SNP verifies Medicare eligibility.

We note that § 422.107(c)(2) states that the contract must document the categories and criteria for eligibility for dually eligible individuals to be enrolled under the SNP, including as described in sections 1902(a), 1902(f), 1902(p), and 1905 of the Act. Therefore, the D-SNP contracts with States should describe how States provide D-SNPs with information needed to enroll dually eligible individuals. For example, if a State limits D-SNP enrollment to full-benefit dually eligible

individuals, that State should note in the contract with a D-SNP how the D-SNP will determine an enrollee's status. We encourage D-SNPs to discuss with States any issues in obtaining this information.

After consideration of the comments we received and for the reasons outlined in the proposed rule, we are finalizing our proposed amendments to § 422.107(c)(6) to strike the reference to Medicare.

11. Compliance With Notification Requirements for D-SNPs That Exclusively Serve Partial-Benefit Dually Eligible Beneficiaries (§ 422.107(d))

We codified minimum Medicare-Medicaid integration requirements for D-SNPs at § 422.2, stating that a D-SNP must either (i) be a HIDE SNP or FIDE SNP or (ii) meet the additional requirement specified in § 422.107(d) that requires that the D-SNP notify the State Medicaid agency, or individuals or entities designated by the State Medicaid agency, of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dually eligible individuals, as determined by the State Medicaid agency.

While implementing these minimum integration standards, CMS identified some MA organizations that have separate D-SNP PBPs for partial-benefit and full-benefit dually eligible individuals, which enable the MA organizations to more clearly explain and coordinate the Medicaid benefits that those enrollees are entitled to receive. However, the D-SNP PBPs for partial-benefit dually eligible individuals (hereinafter referred to as "partial-benefit-only D-SNPs") have no explicit pathway to meaningfully meet one of the three integration standards under § 422.2. In a partial-benefit-only D-SNP, no plan enrollees are eligible for the minimum set of Medicaid services that a D-SNP must cover to qualify as a HIDE SNP or FIDE SNP. Additionally, there are no full-benefit dually eligible individuals that the plan could identify for notification of hospital and SNF admissions (and no Medicaid services to coordinate post notification) as required by § 422.107(d).

We proposed to largely codify the guidance issued in January 2020⁶⁰ that would allow the partial-benefit-only D-

⁵⁹ See <https://www.cms.gov/medicare/health-plans/healthplansgeninfo/downloads/mc86c02.pdf>.

⁶⁰ CMS Medicare-Medicaid Coordination Office, "Additional Guidance on CY 2021 Medicare-Medicaid Integration Requirements for Dual Eligible Special Needs Plans", January 17, 2020. Retrieved from: <https://www.cms.gov/htpseditcmgovresearch-statistics-data-and-systemscomputer-data-and-systemshpms-hpms-memos-archive/hpms-memo-5>.

SNP to be considered as meeting the integration requirements. We proposed revising § 422.107(d) to provide that partial-benefit-only D-SNPs are not required to meet the notification requirement in § 422.100(d) when the MA organization also offers a D-SNP with enrollment limited to full-benefit dually eligible individuals that meets the integration criteria at § 422.2 and is in the same State and service area and under the same parent organization.

As discussed in the proposed rule, we believe our proposal is consistent with the minimum integration required by section 1859(f)(8) of the Act because it achieves the same level of coordination with State Medicaid agencies for partial-benefit dually eligible enrollees as would be achieved if there were one D-SNP PBP covering both full-benefit and partial-benefit dually eligible individuals. Additionally, for full-benefit dually eligible enrollees, the two-PBP structure facilitates a higher level of integration of Medicare and Medicaid benefits (for example, where the two-PBP structure would result in more applicable integrated plans with unified appeals processes). We did not anticipate any negative impact for beneficiaries or partial-benefit-only D-SNPs as a result of this rule.

Comment: Some commenters supported this provision, and no commenters opposed it. A few commenters noted the proposal supports continued enrollment of partial-benefit dually eligible beneficiaries in D-SNPs where they have access to additional care coordination. A commenter noted that partial-benefit dually eligible individuals often can experience a change in circumstances making them eligible for the full Medicaid benefit; this proposal that a plan sponsor also operate a D-SNP serving full-benefit dually eligible individuals could be helpful for care continuity in a transition. Another commenter noted that this provision would allow D-SNP sponsors to continue providing supplemental benefits to partial-benefit dually eligible enrollees.

Response: We thank the commenters for their support.

Comment: A commenter noted CMS should continue to allow States the option to authorize an MA organization to offer a D-SNP that enrolls only partial-benefit dually eligible individuals, with the inclusion of the notification requirement in the State Medicaid agency contract, to meet the integration requirements outlined in the BBA of 2018. This commenter noted that as States move to more integrated FIDE SNP or HIDE SNP models for full-

benefit dually eligible individuals, they continue to seek opportunities for partial-benefit dually eligible individuals that provide the best level of care for this population, including by allowing these beneficiaries to remain with carriers that do not have a Medicaid contract.

Response: We appreciate the commenter's concern and confirm that a D-SNP that serves partial-benefit dually eligible individuals without a corresponding full-benefit-only D-SNP in the same service area would be able to continue operating as long as the contract with the State Medicaid agency includes the notification requirement at § 422.107(d)(1).

Comment: Another commenter questioned whether, if the proposal is adopted, States could continue to require MA organizations to submit hospital or skilled nursing facility admissions for partial-dually eligible enrollees if such a requirement in the State Medicaid agency contract.

Response: We thank the commenter for their question and confirm that States remain able to use their contracts with D-SNPs to require MA organizations to notify the State Medicaid agency of admissions for partial-benefit dually eligible enrollees.

Comment: A commenter noted that they have concerns about D-SNPs' ability to comply with this requirement due to Federal and State health information privacy laws regarding the disclosure of particular sensitive health information without an individual's consent. The commenter requested that CMS provide comprehensive guidance on how D-SNPs should reconcile the admission notification requirement with the limitations presented by 42 CFR part 2 and State health information privacy laws, especially as they relate to substance use disorder and mental health services. Alternatively, the commenter suggested that CMS amend § 422.107(d) to relieve D-SNPs of the obligation to submit admission notifications when doing so is not authorized by applicable law or would require an enrollee's consent.

Response: We thank the commenter for expressing their concerns. We emphasize that States must implement the notification requirement at § 422.107(d) in a way that complies with all applicable State and Federal laws. We acknowledge there are limitations to D-SNPs' ability to notify States of certain inpatient admissions for high-risk enrollees with substance use disorder, as well as to their ability to coordinate these individuals' care, absent enrollee consent for the disclosure of such information. We

encourage D-SNPs to collaborate with their States to identify and address concerns regarding compliance with other statutes and regulations, including the Health Insurance Portability and Accountability Act HIPAA of 1996 and 42 CFR part 2.

We are still gathering information on the initial implementation of the data notification requirement at § 422.107(d). We will use feedback received in response to the request for information described in section III.C. of this final rule and our work with States and D-SNPs to update technical guidance and consider any needed changes to the regulation.

Comment: A commenter expressed concern with enrolling partial-benefit dually eligible individuals in D-SNPs. This commenter noted that there has not been an analysis to determine if the supplemental benefits offered by some D-SNPs are relevant to partial-benefit dually eligible individuals. The commenter urged CMS to undertake such an analysis and establish minimum criteria to ensure that D-SNPs have relevance and value to partial-benefit dually eligible enrollees.

Response: We thank the commenter and will consider an analysis on the relevance of supplemental benefits to partial-dually eligible individuals enrolled in D-SNPs to determine if establishing minimum criteria through rulemaking is warranted.

After consideration of the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed amendments to § 422.107(d) to provide that partial-benefit-only D-SNPs are not required to meet the notification requirement in new § 422.107(d)(1) when the MA organization also offers a D-SNP with enrollment limited to full-benefit dually eligible individuals that meets the integration criteria at § 422.2 and is in the same State and service area and under the same parent organization.

12. Attainment of the Maximum Out-of-Pocket (MOOP) Limit (§§ 422.100 and 422.101)

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. Under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act, CMS added §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3), effective for

coverage in 2011, to require all MA plans (including employer group waiver plans (EGWPs) and special needs plans (SNPs)) to establish limits on enrollee out-of-pocket cost-sharing for Parts A and B services that do not exceed the annual limits established by CMS (75 FR 19709 through 19711). Section 1858(b)(2) of the Act requires a catastrophic limit on in-network and out-of-pocket expenditures for enrollees in Regional Preferred Provider Organization (RPPO) MA plans. In addition, MA Local PPO plans, under § 422.100(f)(5), and RPPO plans, under section 1858(b)(2) of the Act and § 422.101(d)(3), are required to have two maximum out-of-pocket (MOOP) limits (also referred to as catastrophic limits) established by CMS annually, including (a) an in-network and (b) a total catastrophic (combined) limit that includes both in-network and out-of-network items and services covered under Parts A and B. After the MOOP limit is reached, the MA plan pays 100 percent of the costs of items and services covered under Parts A and B.

In the April 2011 final rule (76 FR 21508), CMS established the approach MA organizations must use to track an enrollee's progress toward the plan MOOP limit. Under this policy, the in-network (catastrophic) and combined (total catastrophic) MOOP limits consider only the enrollee's actual out-of-pocket spending for purposes of tracking the enrollee's progress toward the plan MOOP limit. This approach also applies to D-SNPs. Thus, for any D-SNP enrollee, MA plans currently have the option to count only those amounts the individual enrollee is responsible for paying net of any State responsibility or exemption from cost-sharing toward the MOOP limit rather than the cost-sharing amounts for services the plan has established in its plan benefit package. As a result, in practice, the MOOP limit does not cap the amount a State could pay for a dually eligible MA enrollee's Medicare cost-sharing, nor does it cap the amount of Medicare cost-sharing that remains unpaid for providers serving dually eligible enrollees because of the prohibition on collecting Medicare cost-sharing from certain dually eligible individuals and the limits on State payments of Medicare cost-sharing under State lesser-of policies.⁶¹ Thus,

MA plans are paying amounts for non-dually eligible enrollees that they do not pay for dually eligible enrollees, even when different enrollees use the same volume of services; States, in certain circumstances, pay cost-sharing for dually eligible enrollees that is otherwise covered by the MA plans for non-dually eligible enrollees; and providers serving dually eligible MA enrollees are systemically disadvantaged relative to providers serving non-dually eligible MA enrollees, which we believe, based on the evidence described below, may negatively affect access to Medicare providers for dually eligible enrollees.

We proposed to revise the regulations governing the MOOP limits for MA plans to require that all costs for Medicare Parts A and B services accrued under the plan benefit package, including cost-sharing paid by any applicable secondary or supplemental insurance (such as through Medicaid, employer(s), and commercial insurance) and any cost-sharing that remains unpaid because of limits on Medicaid liability for Medicare cost-sharing under lesser-of policy and the cost-sharing protections afforded certain dually eligible individuals, is counted towards the MOOP limit. This would ensure that once an enrollee, including a dually eligible individual with cost-sharing protections, has accrued cost-sharing (deductibles, coinsurance, or copays) that reaches the MOOP limit established by the plan (whether at the annual limit set by CMS under § 422.100(f) or some lesser amount), the MA plan must pay 100 percent of the cost of covered Medicare Part A and Part B services. As a result, the State Medicaid agency and other secondary payers would no longer be billed for any Medicare cost-sharing for the remainder of the year. To ensure clarity in the regulation text for the policy on what costs are tracked for purposes of the MOOP limit, we proposed to amend the regulations to specify that MA organizations are responsible for tracking out-of-pocket spending accrued by the enrollee, and must alert enrollees and contracted providers when the MOOP limit is reached. In addition, we proposed to amend § 422.101(d)(4) to substitute "accrued" for "incurred" in the description of how regional plans must track beneficiary out-of-pocket spending

towards the MOOP limit. We intend this amendment to have only the substantive affect described here: That cost-sharing paid by any applicable secondary or supplemental insurance (such as through Medicaid) and any cost-sharing that remains unpaid because of limits on Medicaid liability for Medicare cost-sharing under lesser-of policy and the cost-sharing protections afforded certain dually eligible individuals, is counted towards the MOOP limit by MA plans. This proposal was not intended to and would not change how the word "incurred" is otherwise used in the regulation. We believe that using a different term in the regulation text is appropriate to mark this change in policy from the policy, first adopted in the April 2011 final rule, permitting MA organizations not to count towards the MOOP limit any Medicare cost-sharing amounts paid by Medicaid programs and cost-sharing that remains unpaid under current law because the enrollee is a dually eligible individual. We noted that the specific regulatory amendments would have to change if we finalized the MOOP limit provisions from the proposed rule titled "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" which appeared in the **Federal Register** on February 18, 2020 (85 FR 9002).

For the reasons discussed in the proposed rule (87 FR 1884), we proposed to amend §§ 422.100(f)(4) and (5) and 422.101(d)(4) to provide that MA organizations are responsible for tracking out-of-pocket spending accrued by enrollees and must alert both the enrollee and the contracted provider(s) if an enrollee has reached the MOOP limit. For purposes of this amendment, accrued cost-sharing includes all Medicare Parts A and B cost-sharing under the plan, regardless of whether the enrollee or another party or entity pays the cost-sharing, and regardless whether the cost-sharing is actually paid. Our proposed regulation text did not distinguish between cost that is left unpaid because the provider is prohibited from collecting cost-sharing from certain dually eligible enrollees or for other reasons. As noted in the proposed rule, in our experience, MA organizations do not impose additional cost-sharing liability above the MOOP limit on their Medicare-only enrollees if some of the pre-MOOP cost-sharing remains unpaid. We received 58 comments on the proposal.

⁶¹ Section 1902(n)(2) of the Act permits the State to limit payment for Medicare cost-sharing for QMBs to the amount necessary to provide a total payment to the provider (including Medicare, Medicaid State plan payments, and third-party payments) equal to the amount a State would have paid for the service under the Medicaid State plan. For example, if the Medicare (or MA) rate for a

service is \$100, of which \$20 is beneficiary coinsurance, and the Medicaid rate for the service is \$90, the State would only pay \$10. If the Medicaid rate is \$80 or lower, the State would make no payment. See Chapter II, sections E.4 through E.6 of the Medicaid Third Party Liability Handbook at <https://www.medicaid.gov/medicaid/eligibility/downloads/cob-tpl-handbook.pdf>.

Comment: We received broad support, including from State Medicaid agencies, beneficiary advocacy organizations, and providers of primary, specialty, hospital, and long-term services and supports, for our proposal to require MA plans to calculate attainment of the MOOP limit based on the accrual of cost-sharing in the plan benefit. The reasons commenters gave for their support mirror the rationale we provided for the proposal in the NPRM.

Supportive commenters noted the proposal would increase payments to providers serving dually eligible MA enrollees with cost-sharing above the MOOP limit and thereby mitigate disincentives to serve dually eligible MA enrollees and increase provider incentives to join D-SNP provider networks. One State commenter noted that the proposal would make it more financially sustainable for physicians to serve dually eligible MA enrollees. One provider commented that the proposed requirement would reduce the amount of bad debt that providers incur when MA plan cost-sharing goes unpaid due to the combination of limits on State cost-sharing payments and prohibitions on providers collecting cost-sharing from certain dual eligible individuals. Another provider organization commented that the proposed revision to how attainment of the MOOP limit is calculated would capture more dually eligible enrollees with very high medical costs and thereby reduce the administrative burden on providers of having to seek State payment of cost-sharing once the MOOP limit was attained. Numerous commenters wrote that they expected the financial benefits to providers from the proposal would improve provider access for dually eligible MA enrollees.

Many commenters supportive of our proposal stated that it would improve health equity by requiring that dually eligible MA enrollees, and the providers who serve them, are treated the same as non-dually eligible MA enrollees under the MOOP policy. A commenter noted that the proposal would effectively ensure that MA plans face the same liability to pay 100 percent of the cost of services over the MOOP limit just as they are required to do for non-dually eligible enrollees.

A number of commenters supported the proposal because they expect it would reduce State expenditures by ensuring the MOOP limit for dually eligible enrollees would be attained by high cost enrollees, thereby limiting State responsibility for payment of cost-sharing. One beneficiary advocacy organization wrote that current policy, by allowing MA organizations to

exclude State paid or unpaid cost-sharing by dually eligible enrollees toward attainment of the MOOP limit, represented an unfair burden on State budgets.

Response: We thank the commenters for their support of this proposal. In particular, we are grateful for their comments, based on their experience serving dually eligible individuals as providers, advocates, or State Medicaid agencies, that finalizing the proposal would reduce provider disincentives to serve dually eligible MA enrollees and potentially improve access to care. We agree with commenters that the proposal results in more equitable treatment of dually eligible MA enrollees in administration of the MOOP protection.

Comment: Both MedPAC and MACPAC supported this proposal. MedPAC wrote that MA organizations should administer the MOOP limit in a consistent manner for all MA enrollees. MedPAC also noted that dually eligible beneficiaries may benefit from improved access to care in MA plans that change how they administer the MOOP to be consistent with the proposed requirement. MACPAC supported the proposal as it would ensure that MA organizations rather than States cover cost-sharing for dually eligible MA enrollees above the MOOP limit.

Response: We thank MedPAC and MACPAC for their comments and value their expertise on this issue.

Comment: Many of the opposing comments stated that dually eligible enrollees would receive no benefit from the proposal because providers in MA plans are already prevented from charging QMBs and full-benefit dually eligible individuals for Medicare cost-sharing for Parts A and B services. Rather, these commenters stated that the result of implementing the proposal would be a reduction in supplemental benefits for dually eligible enrollees, particularly enrollees in D-SNPs, as MA organizations would have to increase their bids to pay for effectively providing a MOOP to dually eligible enrollees and as a result have fewer rebate dollars available to fund supplemental benefits. According to these commenters, if CMS finalized the proposal, the supplemental benefits that MA organizations would have to reduce or eliminate as a result would include dental, hearing, vision, transportation, health food and meals benefits, over-the-counter medical items, health home services and care managers, benefits for individuals with serious mental illness, adult day care, tele-physical health, and benefits addressing health care disparities and social determinants of

health. A commenter in particular noted an MA organization had recently added a service to address social isolation and, through an Innovation Center model,⁶² cash benefits being provided to enrollees in select D-SNPs in contract year 2022. Several commenters also wrote that the additional cost of implementing the MOOP proposal would make it difficult for D-SNPs to offer zero-premium plans as it would reduce rebate revenues now used to pay down Part D premiums.

Commenters provided a range of estimates for the increases in bid costs and rebate reductions that would flow from implementation of the proposal. A commenter cited analysis estimating that the additional cost for Part A and B benefits for D-SNPs if implemented in 2022 would be \$23.90 per member per month or a 2.3 percent increase in plan bids. A commenter estimated that its per member costs would be 20 to 25 percent higher than this estimate, while another commenter stated this level additional costs would be shouldered by all D-SNPs. Another D-SNP sponsor projected the proposal would reduce by half the available funds for supplemental benefits. A commenter estimated the added cost could be as high as 2 percent of plan revenue. Another commenter cited the cost of the MOOP proposal estimated in the proposed rule. Some commenters noted that smaller, regional D-SNPs would be less able to absorb these added bid costs than larger MA organizations.

Response: We recognize that implementation of this proposal would raise MA bids for basic benefits, especially for D-SNPs and other MA plans with a high percentage of dually eligible enrollees, and thereby potentially reduce rebates available for a range of supplemental benefits to the extent MA organizations are unable or unwilling to reduce profit margins or other costs to account for the added MA plan costs for services provided after an enrollee meets the MOOP limit. Along with many of the commenters who supported our proposal, we appreciate the value to dually eligible enrollees of certain supplemental benefits offered through D-SNPs and other MA plans. We disagree that the MOOP proposal provides no benefit to dually eligible enrollees. We address the potential benefit to improved provider access later in this rule.

In the proposed rule, using contract year 2022 bid data to estimate the Medicare cost-sharing accrued by dually

⁶² For information on the Value Based Insurance Design Model, see <https://innovation.cms.gov/innovation-models/vbid>.

eligible beneficiaries with cost-sharing protections (full-benefit dually eligible and QMB enrollees) above the mandatory MOOP level (\$7,550 in 2022), we estimated the cost of Medicare cost-sharing above this MOOP level to be on average \$22.99 per member per month. This estimate is very similar to the \$23.90 estimate provided by an analysis cited, but not provided, by several commenters. Both estimates are based on D-SNP bid data, and as such already reflect the higher medical costs of dually eligible enrollees.

We believe that for most MA organizations, most (if not all) of the added costs for implementation of the MOOP proposal could be absorbed by reductions in plan profit margins and still allow MA organizations to achieve D-SNP profit margins that are comparable to the overall MA profit margins. According to MedPAC, D-SNPs had average profit margins of 7.8 percent for the 2019 contract year, while the overall MA plan profit margin averaged 4.5 percent.⁶³ A 2 percent increase in bid costs represents a less-than-two percent increase in revenue, as plan revenue also includes rebate dollars and increases due to risk adjustment of MA payments. Thus, based on recent years of experience, a 2 percent increase in bid costs could be fully absorbed in D-SNP profit margins while still allowing average D-SNP profit margins to exceed average MA plan margins.

We recognize that MA organizations with smaller D-SNP margins, including some regional and nonprofit organizations, may have more difficulty absorbing the full costs of the proposal by reducing margins. MedPAC noted that nonprofit D-SNPs had lower average 2019 gain/loss (profit) margins of 2.5 percent (still higher than the overall nonprofit MA margin of 0.9 percent).⁶⁴ Although we value the participation of these organizations in the D-SNP program, we believe that the benefits of our proposal outweigh the downsides, including the differential difficulty that smaller, nonprofit MA organizations may face to come into compliance. Such organizations also have less revenue to comply with a range of MA requirements, including provision of the Part A and B benefit, yet we do not differentiate between the types of MA organizations in requiring

delivery of such benefits. In sum, we are not convinced that the added bid costs attributable to the proposal would necessarily translate into reductions in valuable supplemental benefits for dually eligible enrollees. We also do not believe the costs of implementing the MOOP proposal would jeopardize the ability to pay down Part D premiums and offer zero-premium plans. For contract years 2021 and 2022, D-SNPs allocated an average of \$7.50 per member per month to pay down the Part D premium to the amounts covered by the Part D Low Income Premium Subsidy, amounts that we believe D-SNPs would be able to continue to allocate as they implement this proposal. Finally, since promulgation of our proposed rule, we issued a final rule with comment period to finalize regulations regarding the MA MOOP and cost-sharing limits for Medicare Parts A and B services titled “Medicare Program; Maximum Out-of-Pocket (MOOP) Limits and Service Category Cost-Sharing Standards” (CMS-4190-FC4; 87 FR 22290, April 14, 2022) (“MOOP April 2022 final rule”), which will raise the in-network mandatory MOOP limit to \$8,300 starting in 2023. This regulatory change will reduce the costs of this proposal to D-SNPs and other MA plans that adopt the mandatory MOOP limit.

Comment: Many commenters opposing this proposal disagreed with CMS that its implementation would improve access to providers in D-SNPs and other MA plans and noted that CMS had provided no evidence of dually eligible MA enrollees having problems with access to providers. A commenter cited data from the Medicare Current Beneficiary Survey that showed that a higher percentage of dually eligible MA enrollees than dually eligible individuals in Original Medicare had a usual source of care (91 percent compared to 86 percent). Other commenters believed that, because D-SNPs and other MA plans must meet CMS provider network access requirements, CMS’s concerns about dually eligible enrollees’ access to care were misplaced. Another commenter opined that, to the extent that there are problems with access to specialists for dually eligible MA enrollees, the reasons underlying such access problems are more complicated than whether MA plans pay providers 100 percent of the cost of services above the MOOP level, as they do for non-dually eligible enrollees.

Response: We thank the commenters for their input. We recognize that D-SNPs and other MA plans must meet CMS network requirements but note

that the number of providers who are participating in Original Medicare is much larger than the number of providers in the network typical of MA plans, and the access problems facing dually eligible individuals in Original Medicare in States where lesser-of policies limit payment of Medicare cost-sharing are well established.⁶⁵

According to one study, the reductions in Medicare cost-sharing under these policies decreased the odds that a dually eligible individual would have an outpatient physician visit or mental health treatment visit in comparison to non-dually eligible Medicare beneficiaries.⁶⁶ MACPAC found that, relative to non-dually eligible Medicare beneficiaries, lower payment of cost-sharing correlated with a decreased likelihood of evaluation and management visits, use of outpatient psychotherapy, and increased likelihood of using a safety net provider such as an FQHC or rural health clinic.⁶⁷ A third study found decreased use of outpatient services among QMB-only beneficiaries and decreased utilization of office evaluation and management services and hospital outpatient services among QMB-plus beneficiaries compared to non-dually eligible Medicare beneficiaries.⁶⁸

Although these studies all draw from Medicare FFS data, they establish that Federal and State policies on coverage of Medicare cost-sharing, and the amounts paid providers for Medicare cost-sharing, impact access to care for dually eligible individuals. Our current policy on attainment of the MOOP limit allows for a disparity in MA plan payment of cost-sharing for dually eligible compared to non-dually eligible MA enrollees. We believe that, to the extent that D-SNPs and other MA plans replicate the Medicare FFS structure, including by effectively never providing a MOOP above which the MA organization pays 100 percent of costs, that similar differences in access

⁶⁵ See <https://www.kff.org/medicare/report/medicare-advantage-how-robust-are-plans-physician-networks/> MA plan networks on average include 46 percent of physicians in a county, with lower averages for some specialists, such as oncologists, and for “narrow-network” plans. By contrast, 97 percent of physicians participate in Original Medicare. See: <https://www.kff.org/medicare/issue-brief/how-many-physicians-have-opted-out-of-the-medicare-program/>.

⁶⁶ <https://www.rti.org/sites/default/files/resources/StatePaymentLimits.pdf>.

⁶⁷ <https://www.macpac.gov/publication/effect-of-state-medicare-payment-policies-for-medicare-cost-sharing-on-access-to-care-for-dual-eligibles/>.

⁶⁸ https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Access_to_Care_Issues_Among_Qualified_Medicare_Beneficiaries.pdf.

⁶³ See chapter 12 of Medicare Payment Advisory Committee, *March 2021 Report to the Congress: The Medicare Advantage Program: Status Report*. Retrieved from: https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch12_sec.pdf.

⁶⁴ Ibid.

between dually eligible and non-dually eligible would be replicated in MA plans, and especially in D-SNPs that largely replicate Original Medicare in their plan benefits. We are under no illusion that implementation of our MOOP proposal would eliminate all access barriers facing dually eligible MA enrollees, but, to the extent it provides greater parity in plan benefits between dually eligible and non-dually eligible MA enrollees, we are confident that it would at least incrementally improve dually eligible MA enrollees' access to care. As previously noted in this rule, a range of providers commented that they expected parity in payment over the MOOP limit between non-dually eligible MA enrollees and dually eligible MA enrollees would improve access to care.

Because of the strong evidence, cited above, of access challenges for dually eligible beneficiaries (relative to non-dually eligible beneficiaries) in Original Medicare, we are unpersuaded by the MCBS data showing a four percentage point differential between dually eligible MA enrollees who have a usual source of care and their counterparts in Original Medicare. We think the more salient comparison for access to care is between dually eligible and non-dually eligible MA enrollees. We acknowledge that the body of evidence directly comparing access to care in MA between the two cohorts is limited. This is because one important source of data on this issue, the self-reported beneficiary experience measures in the MA CAHPS surveys, is reported at the contract level and thereby often comingles data on D-SNP performance within larger contracts that include non-D-SNP MA plans as well. We are finalizing a policy that can begin to address the scope of available quality measurement data in section II.A.6.a. in this final rule in our discussion of D-SNP-only contracts under proposed § 422.107(e). We note, however, that in the 2022 Star Ratings, 14 percent of the universe of D-SNP-only MA contracts had a low star rating—one or two stars—compared to 10 percent of MA contracts with no D-SNP enrollment on the CAHPS measure C18—Getting Appointments and Care Quickly. Fifty percent of MA contracts with 100 percent D-SNP enrollment had high star ratings on this measure—4 or 5 stars—but 65 percent of contracts with no D-SNP enrollment had high star ratings on this measure. Although imperfect, this data substantiates our concerns that access to and availability of healthcare for dually eligible individuals in D-SNPs is less than that for MA enrollees

who are not dually eligible. These concerns support finalizing this provision as proposed.

Comment: A commenter wrote that implementation of this proposal would have a significant impact on D-SNP enrollees, who constitute 35 percent of Medicare beneficiaries in Puerto Rico, and would result in higher premiums and/or reductions in supplemental benefits such as dental coverage and other benefits that address social barriers to health.

Response: We appreciate the commenter drawing our attention to the issues affecting D-SNP enrollees in Puerto Rico but do not agree with this assessment of the potential impact to these enrollees. All Puerto Rico D-SNPs, in the Platino contracts they sign with ASES (Puerto Rico's Medicaid agency), certify that they have no cost-sharing for Medicare Parts A and B services. Unlike States, Puerto Rico does not have a QMB program under which the State pays Medicare cost-sharing for Medicare services provided by these D-SNPs or that provides protections against providers billing for unpaid Medicare cost-sharing under the D-SNP benefit. That means the full cost of Medicare services, both before and after attainment of the MOOP limit, is already paid by the D-SNPs and funded by a combination of Medicare bid and rebate payments for the D-SNP bids and payments from ASES. Therefore, we do not believe this proposal will have an impact on the Puerto Rico D-SNPs' costs for covering Medicare services.

Comment: A commenter noted that there would be minimal to no impact on its provider payments above the MOOP limit because the D-SNP does not charge cost-sharing and pays providers a set percentage of the Medicare fee schedule regardless of the claim. Another commenter stated that FIDE SNPs with a negotiated single fee schedule for providers would also see no impact on provider payments under the MOOP provision.

Response: We thank the commenters for this analysis as it provides an opportunity to better explain our proposal. FIDE SNPs and other D-SNPs that are capitated by the State for Medicare cost-sharing for all their full-benefit dually eligible QMB members have the ability to negotiate a single fee schedule for providers that encompasses both the Medicare and Medicaid responsibility for any claim. If implementation of the proposal has no impact on these D-SNPs' payments to providers above the MOOP, then there should be no increase in these D-SNPs' bids unless there is a reduction in the capitation rate that the Medicaid agency

pays for coverage of Medicare cost-sharing and MA organizations must make up the difference in their bids. We note that less than one third of total D-SNP enrollment are in D-SNPs with exclusively aligned enrollment that are capitated by the State Medicaid agency for Medicaid payment of cost-sharing for Medicare Part A and B benefits, and a smaller proportion still of dually eligible enrollees in all MA plans are in such D-SNPs. We do not know, however, whether all these D-SNPs with exclusively aligned enrollees negotiate a single fee schedule for Medicare services encompassing both Medicare and Medicaid payments.

Comment: A few commenters believed implementation of the proposal would have a negative impact on MA organizations' ability to negotiate value-based payment arrangements with providers or implement State-directed value-based payment initiatives in connection with Medicaid managed care contracts also held by the MA organizations. Another commenter wrote that the MOOP provision would incentivize providers to run unnecessary tests and procedures to speed their patients' progress toward the MOOP limit, after which the providers would receive full payment from the MA plan for the care they provide. A separate commenter stated that the chief beneficiaries of the proposal would be dialysis providers that have a duopoly on dialysis clinics and providers of Part B drugs and CMS should determine which providers would benefit from the MOOP proposal and whether access to these providers would be improved.

Response: We thank commenters for this input but do not find it persuasive. We do not believe changes to the calculation of the MOOP to take into account the particular cost-sharing circumstances for dually eligible enrollees and making effective the requirement that MA plans pay 100 percent of the cost of services above the MOOP limit would in any way limit the ability of MA plans to negotiate value-based payment structures with their providers. As proposed and finalized, this policy would in no way restrict the ability of MA organizations to negotiate payment rates with their providers, including the ability to negotiate capitated or semi-capitated payment arrangements. Regarding incentives for providers to perform unnecessary tests and procedures to advance patients towards the MOOP, we expect that MA organizations would employ appropriate utilization management and fraud prevention techniques to prevent any such provider behavior, both to ensure program integrity and for the

health of their dually eligible enrollees. Lastly, we are not in a position to judge whether special classes of providers are deserving of the extra payments that may flow to them under this new policy, but do not believe the evidence supports the belief that dialysis providers and providers of Part B drugs will be the primary recipients of additional MA payments above the MOOP limit. Nor does this amendment to how costs are counted toward the MOOP impact the relative market power of MA organizations and providers in connection with their respective ability to negotiate payment arrangements.

Finally, we note that skilled nursing facilities may also be recipients of higher payments for their dually eligible patients that have exceeded the MOOP limit. These higher payments may reduce SNF incentives to encourage their patients to disenroll from their MA plan, despite the prohibition on such provider interference with beneficiary plan choice, a practice described to CMS in anecdotal reports.⁶⁹ To the extent dually eligible enrollees remain in their MA plan, particularly in FIDE SNPs, after a SNF admission, the MA organization would be better able to participate in discharge planning and ensure the individual has the appropriate supports to return to the community.

Comment: A few commenters objected to the proposal, citing their belief that it would use Medicare funds to subsidize Medicaid, by requiring MA organizations to pay 100 percent of the costs of care after cost-sharing in the plan benefit had accrued to reach the MOOP limit, substituting Medicare dollars in the form of MA capitation payment for the state Medicaid dollars that now continue to pay cost-sharing for dually eligible enrollees with no effective limit provided by the MOOP.

Response: We disagree that the provision constitutes an inappropriate subsidization of Medicaid by Medicare. Any policy that impacts Medicare coverage of services or payment rates for which Medicaid is responsible to pay dually eligible individuals' cost-sharing necessarily has the impact of increasing or decreasing the amount of cost-sharing paid by Medicaid. The fact that this proposed Medicare policy does result in significant savings to States should not by itself constitute a reason not to pursue it.

Comment: A commenter disagreed with the concern we expressed in the proposed rule that the current policy may not be fully consistent with section

1902(a)(25)(G) of the Act by allowing MA organizations to calculate attainment of the MOOP limit differently for non-dually eligible beneficiaries, for whom MA organizations accrue all cost-sharing in the plan benefit towards the MOOP limit, from dually eligible enrollees, for whom no cost-sharing in the plan benefit, whether paid by the State or unpaid because of prohibitions on collection of such cost-sharing, counts toward attainment of the MOOP. As the commenter notes, section 1902(a)(25) of the Act requires Medicaid State plans to prohibit any insurer from taking into account that an individual the insurer covers is eligible for or receives assistance from Medicaid. The commenter acknowledges that the current policy does allow MA organizations to take into account dually eligible enrollees' receipt of Medicaid assistance by disregarding any the cost-sharing actually paid by the State. However, the commenter stated that dually eligible enrollees' cost-sharing is similarly not counted towards attainment of the MOOP, not because of the enrollee's eligibility for Medicare, but because it is in fact not owed by the enrollee or ever paid, in contrast to other MA enrollees who typically are billed for cost-sharing and pay those bills. The commenter suggested that CMS's proposal was internally inconsistent by requiring MA plans to count towards the MOOP limit cost-sharing that remains unpaid because the enrollee is also eligible for Medicaid, which requires the MA plan to take into consideration Medicaid eligibility in a way that is not aligned with section 1902(a)(25) of the Act. The commenter also suggested, if CMS should change the basis on which MA plans calculate attainment of the MOOP limit, the agency should only require MA organizations to count amounts the State actually pays in cost-sharing toward attainment of the MOOP.

Response: We appreciate the commenter's acknowledgement that MA organizations' disregard of Medicaid cost-sharing does in fact "take into account" their enrollees' receipt of Medicaid benefits in administration of the MOOP limit. We do not agree that the disregard of cost-sharing that is unpaid because of the protection afforded dually eligible beneficiaries does not similarly raise concerns about section 1902(a)(25)(G) of the Act, which also requires the State plan to prohibit insurers' administration of plan benefits because of an individual's eligibility for Medicaid. As the commenter recognizes, the protection against being billed

Medicare cost-sharing is conferred on the individual by virtue of their eligibility for QMB or full Medicaid benefits. Further, disregarding unpaid cost-sharing in calculating attainment of the MOOP has the effect of delaying attainment of the MOOP and shifting costs onto Medicaid that would not be borne by non-Medicaid enrollees, which is the very scenario that section 1902(a)(25)(G) is designed to prevent. For this reason, we disagree with the alternative suggested to have MA organizations count only Medicaid-paid amounts toward the MOOP limit. This would undermine the goal of providing the same plan benefit under the MOOP policy for both dually eligible and non-dually eligible MA enrollees; the limits of State cost-sharing payments under lesser-of policies would mean that the effective MOOP limit for dually eligible MA enrollees in most States would be much higher than for non-dually eligible MA enrollees. Finally, we note that, while it is true that MA beneficiaries typically do pay their MA cost-sharing, it is also true that dually eligible beneficiaries, despite the prohibition against providers billing them for cost-sharing, do get billed and do pay such cost-sharing.⁷⁰ The current policy, under which MA organizations assume no dually eligible enrollee pays cost-sharing, might not result in counting these vulnerable beneficiaries' payment of improperly billed cost-sharing toward the MOOP limit.

Comment: A few commenters questioned whether CMS's proposal was usurping the authority Congress granted States to establish lesser-of policies. Other commenters questioned whether, by changing the method MA plans must use to calculate the MOOP limit, CMS was superseding the authority granted by Congress in MIPPA to establish state Medicaid agency contracts with D-SNPs.

Response: We respectfully disagree with the commenters' assertions that this proposal would usurp or supersede authority granted States by Congress. Our proposal would not limit State flexibility to establish rates, including lesser-of rates, that set limits on state Medicaid payment of Medicare cost-sharing. Instead, we proposed requirements for the MOOP limits established by MA plans and how cost-sharing is counted toward the MOOP limit, particularly with regard to cost-sharing for dually eligible enrollees. As Medicare is primary to Medicaid, the policy necessarily impacts Medicaid as

⁶⁹ <https://www.cms.gov/files/document/lcfdisenrollmentmemo.pdf>.

⁷⁰ See: https://www.cms.gov/sites/default/files/repo-new/42/Access_To_Care_Issues_Among_Qualified_Medicare_Beneficiaries.pdf.

a secondary payer. We are not superseding State authority to establish the methods a State requires D-SNPs that operate in the State to employ in the administration of Medicaid's responsibility for cost-sharing. Again, our proposal is focused on how MA organizations administer the MOOP limit, which is a benefit required, under §§ 422.100(f) and 422.101(d), from MA plans in connection with basic benefits (that is, the Medicare Part A and Part B benefits covered by MA plans). The authority Congress has granted under section 1859(f) of the Act States for their D-SNP contract is not limited to administration of Medicaid benefits that D-SNPs are contracted to provide. Such contracts can include requirements on D-SNPs relative to the Medicare cost-sharing they impose in plan benefits; our proposal does not impinge on or limit that authority.

Comment: A few commenters questioned whether CMS has the legal authority to impose a mandatory MOOP limit on any MA plan other than regional PPOs, which are the only MA plans that the Part C statute specifically requires to have MOOP limits. A commenter wrote that CMS instituted a MOOP requirement for all plans on the basis of its authority to ensure MA organizations do not design plan benefits to discourage enrollment by Medicare beneficiaries with higher costs. The commenter notes that CMS provides no evidence that the current policy on dually eligible individuals' attainment of the MOOP is discouraging enrollment in MA plans or D-SNPs. Moreover, the commenter argues that the rationale we provided for this proposal is not the same as the rationale underlying the MOOP requirement.

Response: The overall legal underpinning for the current MOOP rules, established through notice-and-comment rulemaking over a decade ago, is beyond the scope of this final rule. In adopting the MOOP requirements in the April 2010 final rule titled "Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (75 FR 19804), CMS also relied on its authority in section 1856(b)(1) of the Act to establish standards for MA organizations and MA plans and 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's authority under the statute for the MA program is not limited to implementing only the specific requirements listed in the statute.

Regarding the assertion that CMS has provided no data to support the claim that the current way that some MA organizations calculate attainment of the MOOP limit for dually eligible individuals substantially discourages enrollment by these individuals, our proposed rule makes no such claim to justify our proposal. In addition to the responsibility to deny an MA plan design that we determine is likely to substantially discourage enrollment by certain beneficiaries, CMS also has authority under section 1854(a) of the Act to negotiate MA bids similar to the authority given the Office of Personnel Management to negotiate health benefits plans under the Federal Employees Health Benefits Program, and we are not obligated to accept every bid. CMS also has established the authority, under § 422.100(f)(2) to review and approve MA benefits and cost-sharing to ensure that MA organizations are not designing benefits to discriminate against beneficiaries or inhibit access to services. Our MOOP proposal, which requires that MA organizations' MOOP limit is administered the same way for dually eligible enrollees and non-dually eligible enrollees, is consistent with this authority. In addition, by preventing a method of adjudicating the MOOP benefit that now results in providers serving dually eligible enrollees never receiving the same level of payment as providers serving non-dually eligible enrollees, our proposal prevents MA organizations from implementing a cost-sharing structure that has the potential to inhibit access to services for dually eligible enrollees. In addition, § 422.100(d)(2)(i) requires MA organizations to offer uniform benefits and level of cost-sharing through the plan's service area. This is not the case when the MA organization adjudicates attainment of the MOOP one way for non-dually eligible beneficiaries (by accruing all cost-sharing in the plan benefit) and another way for dually eligible beneficiaries (by accruing none of the cost-sharing accrued by dually eligible beneficiaries with cost-sharing protections). Similarly, D-SNPs that enroll both dually eligible individuals with cost-sharing protections and dually eligible individuals whose only Medicaid benefit is payment of their Part B premiums, also do not adjudicate the MOOP uniformly. For the dually eligible enrollees with cost-sharing protections, none of the cost-sharing accrues toward the MOOP limit; for the dually eligible enrollees without such protections, all of the cost-sharing in the plan benefit accrues toward the MOOP limit.

Finally, we have learned since promulgation of the proposed rule that some MA organizations have used the flexibility afforded to MA organizations with a lower voluntary plan MOOP to design a benefit with higher service-specific cost-sharing, even though the MOOP limit is never attained because no cost-sharing in the D-SNP plan benefit counts toward the MOOP. For example, some MA organizations have established D-SNPs with a lower, voluntary MOOP and subsequently raised cost-sharing for other Part A and B services above levels that are actuarially equivalent to the Original Medicare benefit for those services. These MA organizations have raised cost-sharing for services including inpatient and mental health hospital stays and imposed cost-sharing for home health services. In D-SNPs for which the bid information shows no cost associated with payment of cost-sharing above the MOOP limit, indicating that the MOOP is almost never attained by enrollees, these MA organizations have raised cost-sharing for emergency and post stabilization services. We believe this practice is manipulative of our benefit review process and has the potential to violate the requirement at § 422.254(b)(4) that MA plans provide a benefit that is at least actuarially equivalent to Original Medicare. Implementation of our MOOP proposal would ensure that the flexibility we allow to raise service-specific cost-sharing to encourage use of the lower, voluntary MOOP would ensure that use of the MOOP limit actually limited cost-sharing under the plan benefit.

Comment: A few commenters stated that they were grateful that the proposal did not exclude charitable contributions to cost-sharing from applying toward the MOOP limit. A commenter asked CMS to identify what beneficiary costs may be waived by providers. Another commenter noted that the proposal did not specifically exclude cost-sharing paid by pharmaceutical manufacturer patient assistance programs from counting as cost-sharing toward the MOOP limit and requested that similar pharmaceutical manufacturer assistance count toward the MOOP limit employed by Marketplace plans.

Response: Although it is accurate that charitable contributions to MA enrollees' cost-sharing would count toward the MOOP limit for MA plans under our proposal, we remind commenters that the reduction or waiver of cost-sharing by providers implicates the Federal Anti-kickback Statute (AKS), found in section 1128B(b) of the Social Security Act

(Act), and the civil monetary penalties provision prohibiting inducements to beneficiaries (Beneficiary Inducements CMP), found in section 1128A(a)(5) of the Act. Whether any particular arrangement violates the AKS or the Beneficiary Inducements CMP would be based on the specific facts and circumstances. Similarly, subsidies provided by pharmaceutical manufacturer assistance programs that induce the purchase of federally reimbursable items, such as drugs paid for by Medicare Part B, also implicate the AKS. A subsidy for cost-sharing obligations provided by a pharmaceutical manufacturer assistance program may implicate the Beneficiary Inducements CMP, if the subsidy is likely to influence a Medicare or State health care program beneficiary's selection of a particular provider, practitioner, or supplier. The comments seeking CMS guidance on what beneficiary costs may be waived by providers and seeking to require that pharmaceutical manufacturer patient assistance counts toward the MOOP limit used by Marketplace plans are out of the scope of this rule.

Comment: Other comments we received asked for the MA MOOP protection to be extended to Part D, that CMS increase payment rates to MA plans, that CMS change the cost-sharing applicable to physical therapy and that CMS allow hospitals to collect bad debt for unpaid cost-sharing under MA plans.

Response: These comments are outside the scope of this rulemaking.

Comment: Several commenters asked CMS to prohibit States from using lesser-of policies in establishing the amounts paid for Medicare cost-sharing.

Response: We do not have the statutory authority to prohibit States from using lesser-of policies in establishing the amounts paid for Medicare cost-sharing.

Comment: We received numerous comments concerning how MA organizations would operationalize the proposal and how States would know when the MOOP limit was attained and should no longer be billed by providers for dually eligible MA enrollees' cost-sharing. Several commenters questioned how they would obtain information on non-Medicaid secondary coverage in accruing cost-sharing toward the MOOP limit. A few commenters questioned how the cost-sharing that has accumulated toward the MOOP would be transferred to another MA organization if enrollees switch plans mid-year. A commenter objected to the proposed requirement to notify dually eligible beneficiaries when the MOOP

limit is reached, stating that it would be confusing to these enrollees because they do not themselves owe cost-sharing. The commenter also opposed a requirement that MA organizations notify providers that an enrollee has reached the MOOP limit because providers have other means to access MOOP information.

Response: We thank the commenters for this input. MA organizations would not need to engage in tracking non-Medicaid secondary coverage because all cost-sharing, whether or not paid by secondary coverage, that is in the plan benefit package for Parts A and B services would accumulate toward the MOOP limit. MA organizations can rely entirely on the claims for services they receive from providers and accumulate the cost-sharing in the plan benefit for those services toward the MOOP limit.

Longstanding CMS guidance, as described at 50.1 of Chapter 4 of the Medicare Managed Care Manual, is that when an enrollee switches to another plan of the same type (for example, from one HMO to another HMO) offered by the same MA organization, their accumulated annual contribution toward the annual MOOP limit in the previous plan to date is to be counted towards their MOOP limit in the new MA plan. As applicable, this transfer of MOOP applies to both in-network and out-of-network MOOP. The MOOP limit is not now a transferrable benefit when a MA enrollee changes to a plan offered by a different MA organization. The cost-sharing that counts toward the MOOP limit starts anew with the cost-sharing that is incurred or accrued under the new plan offered by the different MA organization. Our proposal does not change that.

We disagree that we should eliminate the requirement to alert dually eligible enrollees and providers when enrollees have reached the MOOP limit. We note that this requirement is already in § 422.101(d)(4) (and has been for several years) and was explicitly added to § 422.100(f)(4) and (5) in a recent MOOP April 2022 final rule, CMS-4190-FC4. Our proposal only changes how attainment of the MOOP limit is calculated. We will consider for future rulemaking whether there are circumstances where alerting enrollees may be unnecessary. In the interim, we believe providing the identical notification to a dually eligible beneficiary with cost-sharing protections as is provided to a non-dually eligible enrollee has the potential to be confusing. The notification to dually eligible enrollees should be tailored to their circumstance. If the dually eligible enrollee should not

ever be charged cost-sharing by MA plan providers, any notification alerting these enrollees that they attained the MOOP limit should reflect that. Attainment of the MOOP limit can be accurately described by telling enrollees they have reached the stage in their benefit when their plan will pay all the cost of your care, and that their providers no longer need to bill Medicaid.

We disagree that providers serving dually eligible enrollees should not be alerted when the MOOP limit is attained, a requirement that was finalized in CMS-4190-FC4 at § 422.100(f)(4) and (f)(5)(iii). Alerting providers that the MOOP limit has been attained, that the MA organization will cover 100 percent of the cost of services for the remainder of the year, and that State Medicaid agencies should no longer be billed for Medicare cost-sharing, is essential for administration of the MOOP limit. Remittance advice indicating attainment of the MOOP limit and the absence of any additional cost-sharing charges may fulfill the requirement. If providers have accurate remittance advice from MA organizations, they will have no claim for Medicaid payment of Medicare cost-sharing over the MOOP limit to submit for State payment.

We note that remittance advice to providers serving dually eligible MA enrollees with cost-sharing protections under the MA plan—QMBs, SLMB+, and other full-benefit dually eligible enrollees—should explain that no cost-sharing may be billed whether the enrollee has attained the MOOP limit or not.

Comment: Numerous commenters urged CMS, if we finalize the proposal, to delay the effective date until 2024 or 2025.

Response: We disagree that a delay is necessary for MA organizations to implement the proposal or to submit accurate bids for contract year 2023 that take this change into account. MA organizations already have experience projecting costs and utilization for their enrollees for purposes of bids and accumulating the cost-sharing accrued under the plan benefit; annual bids require projections of cost and utilization and MA plans must accumulate cost-sharing and process claims after the MOOP limit is reached now for non-dually eligible enrollees. There is also sufficient time before the start of the plan year to develop tailored notices for dually eligible enrollees and their providers.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to

comments, we are finalizing the provision as proposed with technical changes to reflect changes to regulation text made by the MOOP April 2022 final rule, CMS-4190-FC4. Specifically, in paragraphs § 422.100(f)(4) and (f)(5)(iii) and in paragraph § 422.101(d)(4), we are removing the word “incurred” and adding in its place the word “accrued”.

13. Comment Solicitation on Coordination of Medicaid and MA Supplemental Benefits

Section 422.107 requires each MA organization offering a D-SNP to have a contract with the State Medicaid agency that describes, among other things, the organization’s responsibility to coordinate Medicaid benefits. State Medicaid agencies have broad flexibility to include provisions in their D-SNP contracts.

In the proposed rule, we described a number of ways that State Medicaid agencies can use their D-SNP contracts under § 422.107 to coordinate D-SNP supplemental benefits with Medicaid benefits. The proposed rule described specific examples of potential coordination of MA supplemental benefits and Medicaid coverage, including Medicaid benefits that are delivered through Medicaid FFS, through a separate Medicaid managed care contract, or by the State capitating the D-SNP for delivery of these benefits. The examples demonstrated how this coordination can ensure the overlapping D-SNP supplemental benefits are primary to Medicaid, how to ensure D-SNPs and Medicaid providers do not receive duplicative payments for delivery of the identical benefits to the same individuals, how D-SNP supplemental benefits can extend or expand on similar Medicaid benefits, and how D-SNP enrollees can have a more integrated experience of care. The examples included discussion of typical D-SNP supplemental benefits, such as coverage of dental services and non-emergency transportation, as well as delivery of supports for community living. We described how CMS considers a FIDE SNP’s supplemental benefits as meeting the uniformity requirements in cases where some dually eligible individuals receive the benefit under the FIDE SNP’s Medicaid managed care contract while other enrollees receive the benefit as an MA supplemental benefit because they are not eligible for Medicaid benefits under State Medicaid eligibility criteria. We noted that we were considering whether an amendment to § 422.100(d)(2) would be appropriate regarding this approach to uniformity for supplemental benefits when a FIDE SNP arranges

supplemental benefits this way and sought comments on that issue. We also solicited comment on other potential ways that D-SNPs and States can work together to coordinate Medicare and Medicaid benefits in order to improve D-SNP enrollee experiences and outcomes.

Comment: Several commenters supported the use of D-SNP contracts to coordinate MA supplemental benefits with Medicaid. A few commenters expressed concerns with operationalizing the coordination of supplemental benefits because of the complexity and limitations in data sharing and inadequate data systems. Other commenters recommended increasing information sharing to better integrate coordination of Medicare and Medicaid services. Several commenters also requested more oversight and data collection of supplemental benefits. A commenter believed that the use of D-SNPs to coordinate Medicare and Medicaid benefits would place much of the responsibility on the D-SNPs and would require expensive sophisticated integrated IT systems for the exchange of data. A few commenters raised concerns with enrollee access to services and enrollee confusion about D-SNP supplemental benefits when they overlap with Medicaid benefits.

Response: We appreciate the commenters’ perspectives and thank the commenters for their input. These comments will inform our collaboration with States on D-SNP integration.

(a) Using the D-SNP MOC To Coordinate Medicaid Services

As described in the proposed rule, the D-SNP MOC, required by § 422.101(f), also provides a vehicle for State Medicaid agencies to work with D-SNPs to meet State goals to improve quality of care and address social determinants of health. State Medicaid agencies may work with D-SNPs with service areas in the State to include (and, through the State Medicaid agency contract at § 422.107, require inclusion of) specific elements in the MOC and how the D-SNP delivers covered items and services consistent with the MOC. There is no prohibition on a State Medicaid agency imposing specific requirements for the D-SNP MOC that are in addition to the minimum requirements at § 422.101(f); compliance with the approved MOC is included in the D-SNP’s bid to provide basic benefits under § 422.101(f). For example, the State Medicaid agency contract under § 422.107 could require the D-SNP to have specific community-based providers involved in development of individualized care plans, deploy nurse practitioners for in-

home care for high-risk enrollees when in-home services are required by the individualized care plans, use health care providers (rather than plan staff) for care coordination functions, and/or set minimum payment amounts for such providers. We solicited comments on CMS guidance or regulations that may warrant clarification, and whether using D-SNP MOC to coordinate Medicaid services create any unintended obstacles to accessing services among dually eligible beneficiaries.

Comment: A few commenters supported using the D-SNP MOC to coordinate Medicaid services and a commenter supported more transparency by incorporating the MOC process into the regulatory and contractual oversight regime. Several plan sponsors and their trade associations expressed concern with the State’s ability to leverage the MOC with Medicaid requirements and the possible addition of any State requirements that may be duplicative or in conflict with the MOC-specific requirements. A few commenters suggested potential ways to improve coordination such as training for States on Federal requirements, a national State specific requirements repository, and better alignment of MOC reviews.

Response: We appreciate the commenters’ support and will take into consideration the additional comment on enhancing transparency. We also thank the commenters for suggesting ways to improve MOC alignment with the State coordination process and will take these into consideration in future rulemaking and guidance.

(b) Coordinating Coverage of Medicare Cost-Sharing

As stated in the proposed rule (87 FR 1887), the same prohibition on duplicate Medicare and Medicaid payments for identical benefits applies when a D-SNP covers MA supplemental benefits that reduce Medicare Parts A and B cost-sharing, such as deductibles and coinsurance, as described for overlapping coverage of other Medicaid and MA supplemental benefits. How it works depends on whether the State Medicaid agency pays for Medicare cost-sharing through the Medicaid FFS program or pays the D-SNP a capitated amount to cover the State’s obligation to pay MA cost-sharing. The proposed rule included examples (87 FR 1887) of both State payment arrangements for MA cost-sharing. We solicited comments on State and MA organization experiences and challenges in coordinating benefits, CMS guidance or regulations that may warrant clarification, and whether our current policies create any unintended

obstacles to accessing services among dually eligible beneficiaries.

Comment: A few commenters supported coordinating coverage of Medicare cost-sharing and noted that Medicaid capitation for coverage of Medicare cost-sharing will need to be projected accurately and actuarially sound.

Response: We thank commenters for raising this issue. We will consider opportunities for future Medicaid rate-setting guidance on the issue.

14. Solicitation of Comment on Converting MMPs to Integrated D-SNPs

In the 10 years since the creation of the FAI, the integrated care landscape

has changed substantially. Congress made D-SNPs permanent in 2018 and established, beginning in 2021, new minimum integration standards and directed the establishment of unified appeals and grievance procedures (which we tested through the MMPs). Changes in MA policy have also created a level of benefit flexibility that did not previously exist outside of the capitated model demonstrations, with MA plans increasingly offering supplemental benefits that address social determinants of health and long-term services and supports.⁷¹ These factors, in combination with the proposals discussed earlier in this final rule, offer

the opportunity to implement integrated care at a much broader scale than existed when MMPs were first created. As a result, we described in the proposed rule at 87 FR 1888 our intent, contingent on finalizing other proposals in the rule, to work with the States participating in the capitated financial alignment model during CY 2022 to develop a plan for converting MMPs to integrated D-SNPs. Table 1 summarizes how our proposals finalized in this rule relate to MMP policies.

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TABLE 1: PROPOSALS FINALIZED IN THIS RULE THAT APPLY MMP FEATURES TO D-SNPs

MMP Characteristic	FIDE SNP	HIDE SNP	Coordination-only D-SNP
Enrollee advisory committee	Required	Same as FIDE	Same as FIDE
HRA to include social risk factors	Required	Same as FIDE	Same as FIDE
Exclusively aligned enrollment	Required starting 2025	Not addressed in this rulemaking	Not addressed in this rulemaking
Capitation for LTSS and behavioral health	Required starting 2025	Not addressed in this rulemaking	Not addressed in this rulemaking
Capitation for Medicare cost-sharing	Required starting 2025	Not addressed in this rulemaking	Not addressed in this rulemaking
Unified appeals & grievances ¹	Required starting 2025 for all FIDE SNPs	Not addressed in this rulemaking	Required for certain plans
Continuation of Medicare benefits pending appeal ²	Required starting 2025 for all FIDE SNPs	Not addressed in this rulemaking	Required for certain plans
Integrated member materials	Finalized a new pathway for States to require for certain plans	Same as FIDE	Same as FIDE
Contract only includes within-State plans limited to dually eligible individuals	Finalized a new pathway for States to require for certain plans	Same as FIDE	Same as FIDE
Quality data/ratings based solely on performance in contracts that only include within-State plans limited to dually eligible individuals ³			
Mechanisms for joint Federal-State oversight	Finalized for States meeting specified criteria at § 422.107(e)	Same as FIDE	Same as FIDE
State HPMS access	Finalized for States meeting specified criteria at § 422.107(e)	Same as FIDE	Same as FIDE

NOTES: HPMS: Health Plan Management System; LTSS: long-term services and supports

¹The requirement for unified appeals and grievances was already in place for those FIDE SNPs and HIDE SNPs that are applicable integrated plans, as defined at § 422.561. Our requirement for exclusively aligned enrollment for FIDE SNPs beginning 2025 means that all FIDE SNPs will be applicable integrated plans subject to the requirements for unified appeals and grievance systems. In addition, this final rule revises the definition of applicable integrated plans to extend requirements for unified appeals and grievance systems to a subset of coordination-only D-SNPs.

²The requirement for continuation of Medicare benefits pending appeal was previously adopted at § 422.632 for those FIDE SNPs and HIDE SNPs that are applicable integrated plans, as defined at § 422.561. Our requirement for exclusively aligned enrollment for FIDE SNPs beginning 2025 will mean that all FIDE SNPs will be applicable integrated plans subject to this requirement of a unified appeals system.

³CMS calculates Star Ratings at the contract level. Star Ratings will become specific to plans serving dually eligible individuals where the MA contract is limited to a one or more D-SNPs. We did not propose or finalize changes to require Star Ratings to be calculated at the plan level *per se*. (See §§ 422.160 through 422.166.)

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We described in the proposed rule at 87 FR 1888 the process for transitioning MMPs to D-SNPs and the potential advantages and disadvantages of such a

transition. In order to mitigate any disruptions that could result from converting MMPs to D-SNPs, we intend to work closely with States and other

stakeholders to ensure the transition is as seamless as possible for MMP enrollees, including facilitating the transition of MMP enrollees to D-SNPs

⁷¹ ATI Advisory. *New, Non-Medical Supplemental Benefits in Medicare Advantage in*

2021. May 2021. [https://atiadvisory.com/wp-](https://atiadvisory.com/wp-content/uploads/2021/06/2021-Special-Supplemental-Benefits-for-the-Chronically-Ill.pdf)

[content/uploads/2021/06/2021-Special-Supplemental-Benefits-for-the-Chronically-Ill.pdf](https://atiadvisory.com/wp-content/uploads/2021/06/2021-Special-Supplemental-Benefits-for-the-Chronically-Ill.pdf).

operated by the same parent organization, subject to State approval, unless enrollees choose otherwise. This could minimize disruption of services and ensure continuity of care to the greatest extent possible. As discussed in the proposed rule, we already have experience with similar transitions at the end of the Virginia⁷² and New York MMP demonstrations⁷³ and are working closely with the California Department of Health Care Services and MMPs to facilitate such a transition when the Cal MediConnect demonstration concludes at the end of 2022.⁷⁴ We solicited comment on this contemplated approach to working with States to convert MMPs to integrated D-SNPs.

Comment: Several commenters expressed support for our approach to work with States to develop a plan for converting MMPs to integrated D-SNPs. A few commenters stated that this approach would simplify the number of products offered to dually eligible individuals and would be easier for States to administer and for beneficiaries and providers to understand while providing long-term predictability for stakeholders. Another commented that D-SNP models have been effective at managing hospitalizations and providing access to primary care and MLTSS services even without the promise of shared savings offered through MMPs.

Response: We appreciate the support we received for our intended approach. As discussed in the proposed rule, current law as well as the new and amended regulations finalized in this rule provide opportunities and potential for streamlining and strengthening integrated care options for dually eligible beneficiaries. We look forward to working with States to address their unique circumstances in planning for a transition of MMPs to integrated D-SNPs.

⁷² Centers for Medicare & Medicaid Services and Virginia Department of Medical Assistance Services. *Commonwealth Coordinated Care (CCC) Phase-Out Plan*. <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/VAPhaseOutPlan.pdf>.

⁷³ Centers for Medicare & Medicaid Services and New York Department of Health. *New York Fully Integrated Dual Advantage Demonstration Phase-Out Plan*. September 2019. <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/NYFIDAPhaseOutPlan.pdf>.

⁷⁴ California Department of Health Care Services. *Expanding Access to Integrated Care for Dual Eligible Californians*. March 2021. <https://www.dhcs.ca.gov/provgovpart/Documents/6422/Expanding-Access-to-Integrated-Care-for-Dual-Eligible-Californians-03-01-21.pdf>.

Comment: Numerous commenters opposed our approach to work with States to develop a plan for converting MMPs to integrated D-SNPs and instead asked to continue the FAI. Many commenters expressed concern that certain aspects of integrated coverage in the MMPs may be hard to replicate or are otherwise not currently available in integrated D-SNPs, including integrated enrollment processing in which enrollment and disenrollment functions are operationalized through State Medicaid agencies; the ability to passively enroll beneficiaries into integrated plans; integrated financing that blends Medicare and Medicaid capitation payments; and/or opportunities for States to share in Medicare savings. Several commenters recommended CMS provide additional guidance and opportunities for comment on how such a transition would work in States where D-SNPs are not offered or where certain benefits are carved out before making a final decision regarding the future of MMPs. A number of commenters, including States, plan sponsors, and advocates, expressed concern that ongoing funding for dedicated ombudsman and one-on-one options counseling services would be lost as part of the transition out of the FAI and urged CMS to continue support for these programs.

Response: We thank the commenters for the feedback on our intended approach for working with States. Several of the new and amended regulations adopted in this final rule create mechanisms and new requirements to replicate much of the programmatic or administrative integration found in MMPs including integrated member materials, unified appeals and grievances, continuation of Medicare benefits pending appeals, elements of joint CMS/state oversight, and contract-specific quality ratings. States can also use their State Medicaid agency contracts with D-SNPs, as described throughout this final rule, to establish parameters that promote person-centered and integrated care, including exclusively alignment enrollment, additional requirements for care planning and self-direction, and enrollment limited to certain age groups or other variables. Other aspects of integration tested in the FAI will not be possible under current law or the new and amended regulations adopted here, and we acknowledge commenters' concerns to that end. However, we believe that the ability to maintain most, if not all, aspects of integration outside the confines of time-limited demonstrations outweighs the potential

loss in the identified areas. Although outside the scope of this rule, we will consider whether there are additional opportunities to further integrate enrollment and/or financing in the future.

We intend to work closely with States and other stakeholders not only to develop a transition plan that would allow States to preserve the integration currently available through MMPs to the greatest extent possible but also to provide subsequent technical assistance and resources to support these efforts, including in scenarios where States do not currently contract with D-SNPs or where certain benefits are carved out.

We agree with commenters that dedicated ombudsman and one-on-one options counseling services provide important beneficiary protections. Existing grant awards already include a transition period as part of the cooperative agreements currently in place, and we will work closely with States on potential sustainability plans. We note that Virginia, for example, was able to continue its ombudsman services at the end of its FAI demonstration without grant assistance.

Comment: We received numerous comments in support of the Massachusetts One Care demonstration. Several commenters expressed concern that the elements unique to this demonstration would not be applied to the D-SNP model of care or contracting requirements and, as a result, key attributes of the One Care model would be lost in such a transition. Several commenters highlighted the value the consumer-led Implementation Council provides in plan oversight and to ensure the demonstration retains its person-centric, independence-driven approach, and expressed concerns that the Council would be diminished or eliminated in an integrated D-SNP environment.

Response: We appreciate the ongoing support for the One Care demonstration. We look forward to working with the State and other stakeholders, including the Implementation Council, on how to sustain and strengthen the person-centric, independence approach for which One Care is known.

Comment: Numerous commenters, including States, plan sponsors, and advocates, urged CMS to take steps to ensure a smooth transition for enrollees if CMS moves forward with transitioning MMPs to integrated D-SNPs. Such steps included: Use of passive enrollment to transition MMP enrollees to corresponding D-SNPs; requiring continuity of care provisions to ensure stability of coverage and access to providers; and/or ongoing stakeholder engagement that includes

advocates, MMPs, and D-SNPs to promote collaborative discussion on the planning and implementation of integrated D-SNPs and ensure aligned messaging and coordination. Many commenters recommended that CMS provide technical assistance and resources for States on topics related to Medicaid managed care authorities, contracting options, and operational steps to assist with the transition from MMPs to D-SNPs. A few commenters strongly supported using 1115A authority to facilitate the transition of MMP enrollees to D-SNPs operated by the same parent organization, subject to State approval, unless enrollees choose otherwise.

Response: We appreciate the feedback on the necessary transition steps, and we agree that ensuring an MMP to D-SNP transition is as seamless as possible for MMP enrollees is critical to successfully implementing this approach. We continue to think through our ability to use waiver authority under section 1115A of the Act as part of any MMP transition. We are committed to working closely with States and other stakeholders and intend to utilize and build from the technical assistance resources we already have in place, including the Integrated Care Resource Center.

Comment: The majority of commenters on this section of the proposed rule, including States, advocates, and plan sponsors, stated that additional time would be needed beyond the current end date in order to allow sufficient runway for a seamless transition of operations and enrollment. Commenters made this statement regardless of whether or not they supported the overall approach. Most suggested at least two additional years would be needed for States to evaluate options and obtain necessary authorities, vet policy proposals with stakeholders, make necessary State system changes, and conduct procurements, if necessary, in order to ensure that MMP enrollees experience a seamless and easy transition from their MMP to a successor FIDE SNP or HIDE SNP.

Response: We thank the commenters for these comments. We acknowledge the commenters' concerns about the time necessary to ensure a seamless transition for all parties involved.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we intend to adjust our approach to working with the States participating in the capitated financial alignment model to develop a plan for converting MMPs under the FAI model

test to integrated D-SNPs. We will offer States the opportunity to continue demonstrations under the FAI, under conditions described in this section and where authorized by section 1115A of the Act.

States interested in this opportunity will need to convert all MMPs to integrated D-SNPs as early as possible, but no later than December 31, 2025. This timeframe reflects the perspectives expressed in public comments related to the time needed for a smooth transition.

States pursuing converting their MMPs into integrated D-SNPs should submit a transition plan to CMS by October 1, 2022. This transition plan should reflect each State's individual circumstances and outline, for example, the State's commitment to (a) maximize integration attained through the capitated financial alignment demo and a seamless transition to integrated D-SNPs, (b) sustain dedicated ombudsman support without Federal grant funding, and (c) a stakeholder engagement process to promote collaborative discussion on the planning and implementation of the transition to integrated D-SNPs. The transition plan should also identify specific policy and/or operational steps that need to occur to fulfill the commitments. These could include, but are not limited to, executing Medicaid procurement and/or D-SNP contracting processes; obtaining necessary State legislative or additional Medicaid authorities, if applicable; and/or identifying and executing system changes and processes to implement exclusively aligned enrollment.

If a State chooses not to convert MMPs to integrated D-SNPs, CMS will work with the State on an appropriate MMP conclusion by December 31, 2023. In all cases, we look forward to working with States, beneficiaries, advocates, and other stakeholders to continue our work to improve outcomes and experiences for dually eligible individuals.

B. Special Requirements During a Disaster or Emergency for Medicare Advantage Plans (§ 422.100(m))

In the February 12, 2015, final rule titled "Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (80 FR 7959) (hereinafter referred to as the 2015 final rule), CMS finalized a new paragraph (m) in § 422.100 to codify and clarify an MA organization's responsibilities when health plan services are affected by disasters or emergencies, including public health emergencies (PHEs), to ensure that MA enrollees continue to

have access to care when normal business operations are disrupted and to ensure out-of-network providers are informed of the terms of payment for furnishing services to affected enrollees during disasters or emergencies. During the Coronavirus 2019 Disease (COVID-19) PHE, we have received questions about the applicability of the special requirements at § 422.100(m), which prompted us to review the regulation and the laws related to the declaration of disasters and emergencies. In light of this review, we proposed changes to clarify potential ambiguities in the regulation text, to further clarify the basis for determining the end of an MA organization's obligations to comply with special requirements during a disaster or emergency and codify our previous guidance in Chapter 4 of the Medicare Managed Care Manual (MMCM). Specifically, we proposed to revise § 422.100(m) to more clearly specify when MA organizations must begin ensuring access to covered benefits by meeting the requirements in paragraphs (m)(1)(i) through (iv) and when MA organizations are permitted to stop meeting those requirements.

Section 1852(d) of the Act requires MA organizations to provide continued availability of and access to covered benefits, including making medically necessary benefits available and accessible 24 hours a day and 7 days a week; the ability to limit coverage to benefits received from a plan's network of providers is contingent on fulfilling this obligation. When a disaster or emergency occurs, enrollees may have trouble accessing services through network providers or sometimes must physically relocate to locations that are outside of their MA plan's service area. Currently, § 422.100(m) requires MA organizations to ensure access, at in-network cost-sharing, to covered services even when furnished by noncontracted providers when disruption in their MA plan's service area during a state of disaster or emergency impedes enrollees' ability to access covered healthcare services from contracted providers. Consistent with uniformity requirements for MA plans at § 422.100(d) and other regulations, these special requirements must be uniformly provided to similarly situated enrollees who are affected by the state of disaster or emergency.

First, we proposed to amend the regulation to explicitly limit the application of the special requirements to when there is a disruption in access to health care. In the 2015 final rule, we stated in the preamble that the regulations at § 422.100(m) were added to require MA organizations to ensure

access, at in-network cost-sharing, to covered services even when furnished by noncontracted providers “when a disruption of care in the service area impedes enrollees’ ability to access contracted providers and/or contracted providers’ ability to provide needed services.” (80 FR 7953) We proposed to revise § 422.100(m)(1) to include that there must also be a disruption of access to health care in addition to a disaster or emergency declaration for the MA organization to be required to ensure access to covered benefits consistent with the special requirements described in § 422.100(m)(1). We proposed to define “disruption of access to health care” for purposes of these special requirements by adding a new paragraph (m)(6); as proposed, a “disruption of access to health care” for the purpose of § 422.100(m) is an interruption or interference in access to health care throughout the service area such that enrollees do not have the ability to access contracted providers or contracted providers do not have the ability to provide needed services causing MA organizations to fail to meet the prevailing patterns of community health care delivery in the service area under § 422.112(a). The intent of these modifications is to clarify that if there is a current state of disaster or emergency that is not contributing to a disruption in health care services, then MA organizations would not be required to follow the requirements at § 422.100(m)(1)(i) through (iv). During a state of disaster or emergency, MA organizations must continue to meet MA access and availability requirements consistent with the normal prevailing community pattern of health care delivery in the areas where the network is being offered. During a state of disaster or emergency, disruptions caused by the disaster or emergency may prevent contracted providers from providing services to enrollees. If enough contracted providers are unavailable to enrollees, then the MA plan would not have enough contracted providers consistent with the normal prevailing community pattern of health care delivery in the service area. Per the proposed definition, this would indicate that there is a disruption in access to health care in the service area, and MA organizations would be required to follow the special requirements at § 422.100(m)(1). This definition is not intended to be limited to physical barriers to access (such as electrical outages or transportation difficulties caused by hurricanes or wildfires) but to be broad enough to encompass any interruption or interference caused by a

disaster or emergency such as a lack of available hospital beds or quarantine restrictions. Therefore, under our proposal, when a disaster or emergency interrupts that level of access to and availability of services, MA organizations must ensure access by covering basic and supplemental benefits furnished at non-contracted facilities; waiving, in full, requirements for gatekeeper referrals where applicable; providing in-network cost-sharing even if the enrollee uses out-of-network providers; and making changes that benefit the enrollee effective immediately without the 30-day notification requirement at § 422.111(d)(3). Limits in other regulations, such as §§ 422.204(b)(3) and 422.220 through 422.224, on which healthcare providers may furnish benefits remain in place and are not eliminated by § 422.100(m).

In the definition, we refer to the normal prevailing community pattern of health care delivery in the service area as it usually is when a state of disaster or emergency does not exist, not the prevailing community pattern of health care delivery in the service area during the state of disaster or emergency. During a state of disaster or emergency, it is possible that access to health care will be disrupted affecting more than MA enrollees, including access to care for enrollees in commercial plans and Original Medicare. To provide an extreme example, an MA organization could indicate that its MA plans are meeting the prevailing community pattern of health care delivery when all of the primary care providers in the service area are closed due to a state of disaster, and the MA plans are therefore meeting the standard because everyone in the service area, no matter the type of insurance they have, cannot access primary care providers. As explained above, this would not be acceptable, as CMS is measuring the prevailing community pattern of health care by reference to the pre-disaster period. Under the proposed regulation, MA organizations would be required to ensure access for their enrollees by complying with the special requirements listed at § 422.100(m)(1)(i) through (iv). While we consider the standard to be the normal prevailing community pattern of health care delivery, we understand this standard broadly in the context of disasters and emergencies. Some examples that would constitute a disruption in access to health care include physical barriers to accessing health care such as road disruptions or electrical outages, as well as other barriers to accessing health care

such as provider offices being closed due to quarantine requirements from the Centers for Disease Control and Prevention (CDC) or state or local health departments, or hospitals beds being unavailable as occurred during the COVID-19 pandemic. This list is not intended to be exhaustive as many unforeseen circumstances may arise during states of disaster or emergencies that may cause enrollees to have trouble accessing services through normal channels or force them to move to safer locations that are outside of their plan’s service areas. A disruption in access to health care could include disruptions in access to Medicare Part A or Part B services or to supplemental benefits offered by the plan, or any combination of those. Our proposal is intended to be broad and to focus on actual access to and availability of services for enrollees in a service area affected by a disaster or emergency. Whether the MA plan network continues to meet evaluation standards specified in § 422.116 is not the only relevant consideration. For example, regarding a hospital with beds or other equipment unavailable to treat additional patients (as has occurred during COVID-19 pandemic), the hospital remains part of the MA organization’s network, and therefore the network may be consistent with CMS’s network adequacy standards for MA plans, but enrollees would not be able to access the hospital and may need to go to out-of-network providers to access their covered benefits. Similarly, physical barriers that enrollees may experience during a disaster or emergency (road closures, flooding, etc.) may affect enrollees unevenly, preventing some enrollees from accessing in-network providers. The provider may be part of the MA organization’s network and therefore the network may meet the time and distance evaluation standards in § 422.116 and appear to be capable of furnishing services consistent with the prevailing community pattern of health care, but some enrollees may experience difficulty accessing that provider to obtain needed health services. Further, if an enrollee had to leave their home to move to a different location due to a disaster or emergency, the MA organization may still have a network that meets the prevailing community pattern of health care in the service area of the enrollee’s home, but the enrollee may not be able to access health care in their different location without being able to access out-of-network care. We requested comments from stakeholders on our proposed definition to determine whether there are circumstances CMS is

not considering or additional standards that we should be using to identify when a disruption of access to health care is occurring.

We proposed to add a disruption of access to health care as a condition that must be met before the special requirements in § 422.100(m)(1) apply in order to ensure that this regulation is not overly broad and is appropriately tailored to address our concerns that MA enrollees have adequate access to medically necessary care and are not unduly restricted to the MA plan's network of providers. As an illustrative example of a situation where a disruption of access to health care was not present even though a state of emergency was in effect, the Governor of Hawaii issued a state of emergency⁷⁵ to fight the Zika virus in February of 2016. This state of emergency did not require all MA organizations operating in Hawaii to comply with the requirements at § 422.100(m)(1) because all provider offices were operating as usual, contracted providers continued in their ability to provide needed services, and enrollees did not face barriers in accessing needed services. The Opioid PHE, which began in 2017, is another example where there is a declared PHE by the Secretary that has been ongoing, but it does not necessarily constitute a disruption of access to health care. However, in 2017, Hurricane Maria in Puerto Rico led to substantial issues with access to covered services for MA enrollees. In connection with the Hurricane Maria, there was a Presidential declaration of a major disaster under the Stafford Act on September 20, 2017⁷⁶ and a Public Health Emergency declaration by the Secretary as of September 17, 2017.⁷⁷ Under our proposal, MA organizations would be required to meet the special requirements at § 422.100(m)(1) for the duration of similar disasters and emergencies where access to covered benefits is disrupted.

We proposed that MA organizations would be initially responsible for evaluating whether there is a disruption of access to health care under § 422.100(m). We believe MA organizations are best positioned to evaluate if a state of disaster or emergency is disrupting access to health care for enrollees in their service area. MA organizations would know the

status of their in-network providers (for example, whether they are operational or not, how many beds are filled, etc.) and would be in communication with their providers as issues at the provider's facilities or with an MA organization's enrollees arise. MA organizations should be guided by the explanations here, including the examples, as well as their particular and detailed knowledge and understanding of their enrollees, service areas, and networks, to reasonably assess if there is a disruption in access to health care in the service area. CMS expects that MA organizations should be aware of these and other facts regarding access to health care in the service areas where they offer plans, and should be able to evaluate those facts and apply the standard in the regulation to know when they must comply with the special requirements at § 422.100(m). CMS will monitor access during disasters or emergencies to ensure MA organizations are applying the standard in § 422.100(m)(1) correctly and complying with this regulation to avoid any disruptions in access to care. As we monitor, we will evaluate whether and when the standard in § 422.100(m)(1) as proposed to be amended here is met. If CMS discovers that there are problems with access for enrollees, we will direct MA organizations in the affected area to comply with § 422.100(m). However, we reiterate that an MA organization should be able to apply the standard in the regulation to the relevant facts related to a potential disruption in access to care during a disaster or emergency and to know the regulatory standard with regard to disruption in access to care during a disaster or emergency and when compliance with the special requirements during a disaster or emergency at § 422.100(m) is required. MA organizations are required to meet the network adequacy requirements at §§ 422.112(a) and 422.116 at all times to ensure enrollees have sufficient access to covered benefits. MA organizations that fail to meet network adequacy requirements must ensure access to specialty care by permitting enrollees to see out-of-network specialists at the individual enrollee's in-network cost-sharing level under § 422.112(a)(3). In addition, MA organizations may need to make alternate arrangements if the network of primary care providers is not sufficient to ensure access to medically necessary care under § 422.112(a)(2). This proposal would not change these existing and continuing regulatory requirements.

Similar to what was experienced by MA enrollees during the COVID-19

PHE, CMS expects that there will be situations where disruptions are intermittent and access to health care is disrupted for some period of time during a disaster or emergency, but not at other times. Under our proposed regulation, MA organizations would follow the special requirements imposed by § 422.100(m)(1) for 30 days after the disruption of access to health care ends while the disaster or emergency is ongoing and for 30 days after the end of the disaster or emergency if the disruption of access to health care, as defined in § 422.100(m)(6), continues until the end of the disaster or emergency. MA organizations may also find that at a later time period, during the same declared disaster or emergency, there is another disruption of access to health care and therefore that the MA organization must again follow the special requirements imposed by § 422.100(m)(1). We also recognize that there may be circumstances when a state of disaster or emergency is declared for an area containing multiple service areas (for example, the entire United States), but the disaster or emergency may unequally affect the various service areas contained in the larger area for which it is declared. It may be that some service areas experience a disruption of access to health care, but other service areas do not, or that the disruption in care ends for certain service areas but continues in others. Under our proposed regulation, in situations where a disruption of access to health care ends in a particular service area, but the state of disaster or emergency continues to be in effect for an area that includes that particular service area, the special requirements imposed by § 422.100(m)(1) would be in effect for the service areas in which there is a disruption of access to health care (until 30 days after the disruption of access to health care ends) and would not be in effect for services in which there has not been any disruption of access to health care.

We also proposed two technical changes to our regulations at § 422.100(m)(2) to correct some numbering issues that occurred in the 2015 final rule. First, we proposed to move the text from the fourth-level paragraph at (m)(2)(ii)(A) to the third-level paragraph at (m)(2)(ii), which currently does not have text associated with it. As amended, the regulation at § 422.100(m)(2)(ii)(A) would state that the Secretary of Health and Human Services (hereinafter referred to as the Secretary) may declare a PHE under section 319 of the Public Health Service

⁷⁵ https://governor.hawaii.gov/wp-content/uploads/2016/02/160212_EmergencyProclamation_Dengue.pdf.

⁷⁶ <https://www.govinfo.gov/content/pkg/FR-2017-10-06/pdf/2017-21649.pdf>.

⁷⁷ <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Puerto-Rico-and-US-Virgin-Islands-PHE-Determination.pdf>.

Act. Second, we proposed to remove the fourth-level paragraph at (m)(2)(ii)(B) because this paragraph only provides information about the Secretary's section 1135 waiver authority which is not an authority under which the Secretary may declare PHEs. In addition to these technical changes, we proposed several clarifying revisions to our language in § 422.100(m) to ensure that we are consistently referring to disasters and emergencies. Currently, the language sometimes refers only to disasters (as in the introductory text to paragraphs (m)(1) and (2)), but also refers to disasters and public health emergencies (as in the text to paragraphs (m)(3) and (4) and (m)(5)(i)). We therefore proposed to update the language throughout to reference disasters and emergencies with the aim of being consistent in referring to the various types of declarations listed at § 422.100(m)(2).

Lastly, we proposed revisions to clarify the basis for determining when MA organizations are no longer required to comply with the special requirements for a disaster or emergency. We proposed to modify the text at § 422.100(m)(3) to clarify that it refers to the end of the special requirements for a state of disaster or emergency stipulated at § 422.100(m)(1), not to the end of the state of disaster or emergency itself. We also proposed to add a 30-day transition period to § 422.100(m)(3). Our current regulation at § 422.100(m)(3)(iii) provides a period of 30 days from the initial declaration for the special requirements imposed by § 422.100(m)(1) to be in effect if the initial declaration of the disaster or emergency does not contain a specific end date or if the official or authority that declared the disaster or emergency does not separately identify a specific end date, and CMS has not indicated an end date to the disaster or emergency. This means that, under the current regulation, there is usually a 30-day minimum period during which MA plans are providing access to covered benefits with the additional beneficiary protections specified in paragraphs (m)(1)(i) through (iv), unless an explicit announcement of the end of the disaster or emergency has been declared sooner than the end of the 30 days. We believe that having a minimum period for these protections is important and appropriate. A transitional period from when an MA organization must comply with the access requirements in § 422.100(m)(1) to when the MA organization must furnish services are required by normal coverage rules will protect enrollees who need time and

assistance from the MA organization to find a contracted provider after having been treated by a non-contracted provider during the disaster or emergency. We intend for this period to serve as a protection for enrollees so they are not immediately responsible for the total cost of services received from a non-contracted provider that they have been seeing for a period of time due to the state of disaster or emergency. MA organizations may also find a transitional period helpful if they must contract with additional providers or otherwise make changes to their network to assist with their return to normal operations. We therefore proposed to revise the regulation text at § 422.100(m)(3) to require a 30-day transition period after the points in time identified in the regulation for the end of the special requirements. Specifically, we proposed to revise paragraph (m)(3) to provide that the applicability of the special requirements for a disaster or emergency in paragraphs (m)(1)(i) through (iv) end 30 days after the latest of the events specified in paragraph (m)(3)(i) or (ii) occur (that is, the latest end date in a case where there are multiple disasters/emergencies) or end 30 days after the condition specified in paragraph (m)(3)(iii) occurs (that is, there is no longer a disruption of access to health care).

In the 2015 final rule, we finalized three circumstances as determining the end of the special requirements for a disaster or PHE in the regulations at § 422.100(m)(3). First, as currently provided in § 422.100(m)(3)(i), the source that declared the disaster or PHE declares an end to it. As explained in § 422.100(m)(2), disasters or emergencies may be declared by the President of the United States under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) or the National Emergencies Act, by the Secretary who may declare a PHE under section 319 of the Public Health Service Act, or by Governors of States or Protectorates. We intend paragraph (m)(3)(i) to address circumstances when the initial declaration contains a specific end date or when the official or authority who declared the disaster or emergency separately identifies a specific end date. We proposed to revise § 422.100(m)(3)(i) to address situations that may arise where there is more than one declaration of a disaster or emergency at the same time for the same service area(s). This proposed revision clarifies that MA organizations must follow the special requirements until the latest applicable end date when

multiple declarations apply to the same geographic area by specifying that all sources that declared a disaster or emergency that include the service area have declared an end. For example, if a Governor of a State declares a state of disaster or emergency and the President also later declares a state of disaster, both the state and Federal disasters must be declared at an end to trigger § 422.100(m)(3)(i). If the President's disaster declaration ends after 20 days, but the Governor maintains the state of disaster for 30 days, then the special requirements imposed by § 422.100(m)(1) would apply for MA plans in that area through the end of the emergency declared by the Governor, plus an additional 30 days for the transition period we proposed.

Second, the regulation currently provides that CMS may declare an end to the state of disaster or PHE per § 422.100(m)(3)(ii). Upon review, we intended for this regulation text to refer to the Secretary's authority, which is consistent with the current practice of the Secretary to declare an end to PHEs. However, since the Secretary is already considered a source under § 422.100(m)(3)(i), we believe that modifying this requirement to refer to the Secretary is unnecessary and therefore we proposed to remove this text.

Third, our current regulation at § 422.100(m)(3)(iii) addresses circumstances where a state of disaster or PHE is declared with no end date identified. Because § 422.100(m)(3) provides that the end of the emergency or state of disaster ends when "any" of the three listed, if the declaration disaster or emergency timeframe has not been identified by the authority or official who declared the disaster or emergency and CMS has not indicated an end date to the disaster or emergency, MA plans should resume normal operations 30 days from the initial declaration. However, this does not properly account for how declarations of disasters or emergencies may be renewed with continued disruptions to access to health care services for enrollees. Further, our experiences with declarations of disasters and emergencies have demonstrated that the 30-day timeframe for the special requirements in § 422.100(m)(1)(i) through (iv) may not be enough time to address concerns about enrollees being able to access benefits during disasters or emergencies, especially in cases where a disaster or emergency declaration has been renewed. There are circumstances where a 30-day time period does not cover the full length of a declared

disaster or emergency and the current regulation is not well suited to ensure access for enrollees during the entire period of a disaster or emergency. For example, a PHE declared by the Secretary under section 319 of the Public Health Service Act is in effect for 90 days unless the Secretary terminates it earlier, and the Secretary may renew the declaration at the end of the 90-day period.

We proposed to revise § 422.100(m)(3)(ii) to address when no end date is identified under § 422.100(m)(3)(i); in such cases, the applicability of the special requirements ends 30 days after the expiration of the declared disaster or emergency and any deadline for renewing the state of disaster or emergency. This modification clarifies that when a state of disaster or emergency is declared without an end date, § 422.100(m)(1) will continue to apply for the entire duration of the declared disaster or emergency, as determined under the relevant authority under which it was declared, if a disruption of access to health care continues. Stafford Act declarations do not have a defined end date. When the President declares a national emergency under the National Emergencies Act, the declaration of a national emergency lasts for a year unless terminated earlier by the Presidential proclamation or a joint resolution of Congress. The President can renew the declaration for subsequent one-year periods. When the Secretary declares a PHE under section 319 of the Public Health Service Act, it lasts for 90 days unless the Secretary terminates it earlier, and it can be renewed for 90-day periods. For example, if the Secretary declared a PHE under section 319 of the Public Health Service Act, then the end date of the PHE would be in 90 days, unless renewed. If the Secretary chose to declare an end before the 90-day period ended, then the public health emergency would end according to the declared end date. CMS does not have the expertise to know whether all state declarations of emergency have a defined end date. Therefore, we did not propose specific time periods but proposed to amend § 422.100(m)(3)(ii) to account for extensions or renewals of declarations of the type identified in paragraph (m)(2).

Lastly, we proposed to add the disruption of access to health care as a limitation under revised § 422.100(m)(3)(iii) to indicate that the special requirements associated with a state of disaster or emergency may end when the disruption of access to health care ends, even if one of the

circumstances in § 422.100(m)(3)(i) or (ii) to end the state of disaster or emergency has not yet occurred.

We intend to continue to issue sub-regulatory guidance as appropriate for MA organizations to explain how § 422.100(m) works, both through the HPMS system and through the CMS Current Emergencies web page at <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies.-page>. Further, we note that the Secretary may exercise the waiver authority under section 1135 of the Social Security Act during an emergency period (defined in section 1135(g) of the Act), which exists when the President declares a disaster or emergency pursuant to the National Emergencies Act or the Stafford Act, and the Secretary declares a PHE pursuant to section 319 of the Public Health Service Act. Under the Secretary's section 1135 waiver authority, CMS may authorize DME and A/B Medicare Administrative Contractors (MACs) to pay for Part C-covered services furnished to MA enrollees and seek reimbursement from MA organizations for those health care services, retrospectively. Detailed guidance and requirements for MA organizations under the section 1135 waiver, including timeframes associated with those requirements and responsibilities, would be posted on the Department of Health and Human Services website, (<https://www.hhs.gov/>) and the CMS website (<https://www.cms.hhs.gov/>). MA organizations are expected to check these sites frequently during such disasters and emergencies.

We proposed the following changes to our regulations at § 422.100(m):

- Revise § 422.100(m)(1) to state that when a disaster or emergency is declared as described in § 422.100(m)(2) and there is disruption of access to health care as described in § 422.100(m)(6), an MA organization offering an MA plan must, until one of the conditions described in § 422.100(m)(3) of this section occurs, ensure access to benefits as described in § 422.100(m)(1)(i) through (iv).
- Revise § 422.100(m)(2) to refer to emergencies and disasters.
- Move the current text of § 422.100(m)(2)(ii)(A) to § 422.100(m)(2)(ii).
- Remove § 422.100(m)(2)(ii)(B).
- Revise § 422.100(m)(3) to specify that it addresses the end of the applicability of the special requirements rather than the end of the disaster or emergency.

- Revise § 422.100(m)(3) to add a transition period of 30 days after the earlier of the conditions described in § 422.100(m)(3)(i) and (ii) occurs or after the condition described in § 422.100(m)(3)(iii) occurs; during the transition, MA organizations must continue to comply with § 422.100(m)(1).

- Revise § 422.100(m)(3)(i) to clarify that MA organizations must follow the special requirements until all of the sources that declared a disaster or emergency in the service area declare it ended.

- Revise § 422.100(m)(3)(ii) to state that no end date was identified in § 422.100(m)(3)(i) of this section, and all applicable disasters or emergencies have ended, including through expiration of the declaration or any renewal of such declaration.

- Revise § 422.100(m)(3)(iii) to state that the special requirements identified in § 422.100(m)(1) of this section may also end if the disruption in access to health care services ends.

- Revise § 422.100(m)(4) to refer to disasters and emergencies.

- Revise § 422.100(m)(5)(i) to refer to disasters and emergencies.

- Add a new paragraph at § 422.100(m)(6) to define “disruption of access to health care” as an interruption or interference throughout the service area such that enrollees do not have ability to access contracted providers or contracted providers do not have the ability to provide needed services, resulting in MA organizations failing to meet the normal prevailing patterns of community health care delivery in the service area under § 422.112(a).

We thank commenters for helping inform Special Requirements during a Disaster or Emergency. We received approximately 35 comments on this proposal; we summarize them and our responses follow:

Comment: Comments were very supportive of our proposal that there must also be a disruption of access to health care in addition to a declared disaster or emergency for special requirements during a disaster or emergency to apply.

Response: CMS thanks comments for their feedback.

Comment: Some commenters agreed that MA plans are in the best position to determine when there is a disruption in care and supported our proposal. Many of these commenters requested CMS release further guidance providing additional examples and objective criteria for MAOs to use in further determining “disruption of access to care.”

Response: We thank commenters for their feedback. We proposed that a “disruption of access to health care” for the purpose of § 422.100(m) mean an interruption or interference in access to health care throughout the service area such that enrollees do not have the ability to access contracted providers or contracted providers do not have the ability to provide needed services causing MA organizations to fail to meet the prevailing patterns of community health care delivery in the service area under § 422.112(a). We are finalizing this definition with a slight change to provide that a disruption of access to health care occurs when the interruption or interference in access to health care occurs “in” the service area such that the standard we proposed is met. This revision is to be more consistent with our intent and discussion in the proposed rule that a disruption of access to health care may be targeted or specific to a limited area. Service areas are generally a county or larger and while many disruptions of access to health care may be county-wide or cover multiple counties, not all emergencies or disasters will result in such scope. Specific disruptions, such as those involving physical access (such as road damage or flooding that block access to or damage a hospital or larger provider group serving many enrollees) or damage to electrical supply or utilities, may be more limited in scope. So long as interruption or interference in access to health care in the service area is such that enrollees do not have the ability to access contracted providers or contracted providers do not have the ability to provide needed services causing MA organizations to fail to meet the prevailing patterns of community health care delivery in the service area under § 422.112(a) during a declared emergency or disaster as described in § 422.100(m)(2), it does not matter if that interruption or interference is limited to a specific area. In addition, we are clarifying in the regulation text that the term “service area” has the meaning provided in § 422.2.

Under this final rule, MA organizations must interpret and apply this regulatory standard (for when the special coverage requirements in § 422.100(m)(1) apply) by the explanations in the proposed rule and this final rule, including the examples, as well as their particular and detailed knowledge and understanding of their enrollees, service areas, and networks. Applications of § 422.100(m) are to be based on reasonable assessments whether and when there is a disruption

in access to health care in the service area for enrollees in an MA plan. MA organizations must take into account available information regarding access to health care in the service areas where they offer MA plans and must reasonably evaluate those facts and apply the standard in the regulation to know when they must comply with the special requirements at § 422.100(m). CMS will similarly be guided by the same things when evaluating MA organization compliance with § 422.100(m) and when issuing instructions if CMS has determined that a disruption of access to health care has occurred in an area where a declaration of disaster or emergency has been made as described in § 422.100(m)(2).

As previously stated in this final rule, per § 422.112(a), MA plans must ensure that all covered services are available and accessible to enrollees under the plan. Additionally, we note CMS quantifies the prevailing patterns of care standard in network adequacy with the specific time and distance and minimum number of provider requirements at § 422.116. Per CMS regulations at § 422.112, MA plans are currently required to maintain and monitor a network of appropriate providers, supported by written arrangements, that is sufficient to provide adequate access to covered services to meet the needs of the population served. The delivery of services in particular geographic areas must be consistent with local community patterns of care. Simply put, MA plans must currently ensure that contracted providers are distributed so that no enrollee residing in the service area must travel an unreasonable distance to obtain covered services. Given that MA plans must already follow and monitor these existing requirements, we believe that MA organizations are in the best position to determine when and whether access to network providers has been compromised. We also encourage plans to look at how they ensure compliance with current access requirements when determining whether and when access to health care services has been disrupted.

Finally, to provide greater clarity, we are changing the term “throughout the service area” to “in the service area” at in the regulation text at § 422.100(m)(6). If the service area is several counties or an entire state but the natural disaster is limited to one county, “throughout the service area” could be interpreted to signify that there has not been a disruption sufficient to trigger § 422.100(m) if only one county is affected. That is not our intention. As

discussed in the proposed rule, some examples that would constitute a disruption in access to health care include physical barriers to accessing health care such as road disruptions or electrical outages, as well as other barriers to accessing health care such as provider offices being closed due to quarantine requirements from the Centers for Disease Control and Prevention (CDC) or state or local health departments, or hospitals beds being unavailable as occurred during the COVID-19 pandemic. Any disruption of service within a given service area, whether it is multiple counties or one county, is sufficient to trigger the requirements at § 422.100(m). MA plans must follow 422.100(m) for all impacted enrollees. Additionally, we added a reference to the statutory definition of “service area” to provide further clarity on what CMS means by service area. Specifically, we define “service area” as it is defined at 42 CFR 422.2: a geographic area that for local MA plans is a county or multiple county, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization.

Comment: Some commenters expressed concern that allowing plans to determine whether there is a disruption in care may not sufficiently guarantee beneficiary protections. A few expressed concern that allowing each plan to make their own determination may lead to inconsistency (for example, different determinations by different plans) and confusion among enrollees. Others expressed concern that providers and MA plans in the same service area may disagree and asked CMS for clarification if these scenarios were to occur. Some commenters expressed concern that MA plans may have financial incentive to not apply or delay compliance with these special requirements.

Response: We thank commenters for expressing their concern. We reiterate that MA plans must provide enrollees health care services through a contracted network of providers that is consistent with the prevailing community pattern of health care delivery in the network service area (42 CFR 422.112(a)). Further, we note that that MA plans must meet current network adequacy requirements as defined under 42 CFR 422.116. Per § 422.112(a)(1), CMS requires that organizations monitor their contracted networks throughout the respective contract year to ensure compliance with the current network adequacy criteria. Given that plans are already required to ensure adequate access, we believe that

plans are best equipped to determine whether these existing standards have been compromised in a given service area or not.

Additionally, MA organizations must consider the extent to which services are accessible in the network (meaning, from network providers) and whether that access is consistent with normal community patterns of health care delivery and with access during periods when there is no declaration of disaster or emergency in effect. For example, if a plan has a sufficient network per CMS requirements, but enrollees are not able to access those contracted providers or those providers are unavailable or otherwise unable to furnish services to enrollees, this would be a disruption in access. As stated in the proposed rule, some examples of a disruption in access to health care include physical barriers to accessing health care providers, road disruptions or electrical outages, as well as other barriers to accessing health care such as provider offices being closed due to quarantine requirements from the Centers for Disease Control and Prevention (CDC) or state or local health departments, or hospitals beds being unavailable as occurred during the COVID-19 pandemic. A disruption of access has occurred if the existing network adequacy requirements and requirements for access to and availability of services cannot be met and/or enrollees cannot access the providers in this network. Given that plans are already required to monitor adequate access as discussed above, we believe MA plans are already in a position to determine if a disaster or emergency has compromised or disrupted normal patterns of access to, availability of, and delivery of covered services when those services are medically necessary. We encourage plans to evaluate whether an emergency or disaster has compromised their ability to meet these existing requirements when determining whether a disruption of access to health care as defined in § 422.100(m)(6) is occurring for purposes of meeting the special requirements in § 422.100(m).

Comment: A commenter suggested CMS change the 30-day transition period to one full month for additional clarity and to better align with plans' claims processing systems. Some suggested CMS extend the 30-day transition period, suggesting that 30 days may not be sufficient for enrollees to find new or alternative care. A commenter suggested 60 days instead of 30 days.

Response: We thank commenters for their feedback. Under our current regulations there is no explicit

transition period but the general minimum period of time when an MA organization must comply with the special requirements in § 422.100(m)(1) is 30 days, and we believe that 30 days is sufficient in establishing how long an MA plan must continue to provide access to services as described in § 422.100(m)(1) after the end of an emergency or disaster period or end of a disruption of access to health care. However, we will consider revising this duration in future rulemaking if we determine that it is necessary. We note that MA organizations that find it more operationally feasible to maintain compliance with the special requirements in § 422.100(m)(1)(i) through (iv) for a full month or until the end of a month when that it is longer than the 30 days transition period are free to do so. As proposed and finalized, the 30-day transition period is the minimum requirement.

Comment: A commenter asked CMS to clarify how to determine the end point from which to begin calculating the 30 days transitional period.

Response: As stated in the proposed rule, MA plans are required to continue to apply special requirements for 30 days (the 30-day transitional period) after the points in time identified in the regulation at § 422.100(m)(3) for the end of the special requirements. For example, if the only applicable declaration of a public health emergency expires without renewal on April 30, the 30-day transition period ends on May 30 of the same year. If an MA organization reasonably determines, consistent with the regulation as it is adopted and explained in this final rule, that a disruption of access to health care has ended on January 1, the 30-day transition period will end on January 31.

Comment: Many commenters supported CMS's intention to continue to issue sub-regulatory guidance to further explain § 422.100(m) as appropriate and requested that CMS release guidance regarding events that might trigger special requirements and timeframes associated with those requirements.

Response: We thank commenters for their comments and plan to release additional sub-regulatory guidance on this subject as appropriate and as needed in the future.

Comments: We received some comments asking CMS to ensure transparency to providers and beneficiaries when these special requirements are put into place.

Response: We thank commenters for their concern. We remind MA plans that in addition to annual disclosure

requirements at § 422.111, plans must follow emergency and disaster disclosure requirements at § 422.100(m)(5), which include indicating the terms and conditions of payment during the public health emergency or disaster for non-contracted providers furnishing benefits to plan enrollees residing in the state-of-disaster area, annually notifying enrollees of information on the coverage requirements related to declarations of emergencies and disasters and providing this information on plan websites. Additionally, per CMS regulations at §§ 422.111 and 422.202(b), MA plans must establish policies and procedures to educate and fully inform contracted health care provider and, as appropriate, to enrollees concerning plan utilization policies, which should include any necessary information related to emergencies and disasters. We reiterate that we believe that MA organizations are generally in the best position to determine when and whether access to network providers in a service area has been compromised, so they will be expected to initiate compliance with § 422.100(m) as necessary and appropriate. We believe that the disaster disclosure requirements at § 422.100(m)(5) and general provider disclosure requirements at § 422.202(b) provide adequate transparency.

Comment: A commenter expressed concern that the special requirements will increase plan costs, noting that out of network coverage for an extended period is not included in plan rates. Another commenter requested OACT provide guidance on whether MA plans should include actuarial assumptions related to disaster and emergency events when developing prices for their contract year bids.

Response: We thank commenters for their feedback. When pricing a bid, the actuary should refer to the Actuarial Standards of Practice (ASOP). For example, ASOP No. 5 *Incurred Health and Disability Claims* says that when estimating incurred claims, the actuary should consider items such as changes in price levels, unemployment levels, medical practice, managed care contracts, cost shifting, provider fee schedule changes, medical procedures, epidemics or catastrophic events, and elective claims processed in recessionary periods or prior to contract termination (section 3.2.2 ECONOMIC AND OTHER EXTERNAL INFLUENCES).

Comment: A few commenters asked CMS to clarify whether special requirements should apply in other situations beyond national or state

emergencies, such as shortage of health care staff or other scenarios that may still impact normal patterns of community health care delivery.

Response: We thank commenters for their feedback. Section 422.112 requires MA plans to provide continued availability of and access to covered benefits for enrollees, including making medically necessary benefits available and accessible 24 hours a day and 7 days a week. Additionally, § 422.113 provides that urgently needed services must be provided when an enrollee is temporarily absent from the plan's service (or, if applicable, continuation) area and therefore cannot obtain the needed service from a network provider and/or when the enrollee is in the service or continuation area but the network is temporarily unavailable or inaccessible. CMS has issued guidance about these requirements in section 20.2 of Chapter 4 of the Medical Managed Care Manual (MMCM). Further, per CMS regulations at § 422.112(a)(3), MA plans are required to arrange for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs. Finally, MA plans are also currently required to meet network adequacy requirements at § 422.116(a)(2) all year, regardless if there is a declared state of emergency or not. Given these existing standards, we do not believe the special requirements discussed in this rule are necessary to apply outside of an emergency or disaster.

Comment: A commenter asked for more information on who has the authority to declare a state of disaster/emergency where these special requirements would apply. Another commenter asked CMS to remind state governors of their authority under 42 CFR 422.100(m). Another commenter stated that CMS should consider the state's role in determining when determinations the special requirements apply.

Response: The relevant types of disasters and emergencies are discussed in the proposed rule and reflected in § 422.100(m)(2) and include: (i) A Presidential declaration of a disaster or emergency under either the Stafford Act or the National Emergencies Act, (ii) a Secretarial declaration of a public health emergency under section 319 of the Public Health Service Act, and (iii) a declaration by the Governor of a State or Protectorate. To further clarify, the special requirements discussed here do not impose any requirements on state governors. Rather, MA organizations are responsible for being aware of events discussed here, including an emergency

or disaster declared by a Governor, in a given service area and knowing the status of their in-network providers and to applying requirements accordingly. We encourage MA plans to liaison with local and state authorities as appropriate when making a determination.

Comment: A commenter asked CMS to clarify whether waiving of "gatekeeper" referrals described at § 422.100(m)(1)(ii) includes the waiving of prior authorization (PA) in hospital discharges to other settings. Another commenter suggested CMS extend the requirements at § 422.100(m) to include waiving prior authorization for hospitals and post-care settings in general.

Response: As discussed in Chapter 4 of the MCM, the primary purpose of a gatekeeper is to ensure compliance with plan requirements for medically necessary referrals to in-network specialists. Under special requirements during an emergency or disaster, MA plans must cover Medicare Parts A and B services and supplemental Part C plan benefits furnished at non-contracted facilities. Thus, such referrals are not applicable and must be waived during a qualifying disaster or emergency as described in this provision. We do not believe that adding a requirement that MA organizations waive prior authorization for hospitals and post-care settings at § 422.100(m)(1) is within the scope of our proposal to clarify and revise the time frame during which § 422.100(m)(1)(i) through (iv) apply. MA plans are permitted and encouraged to waive or relax plan prior authorization requirements at any time during disasters or emergencies in order to facilitate access to services and alleviate burden on enrollees, plans, and providers.

Comment: A commenter asked CMS to release guidance to address the needs of individuals who are required to evacuate from a disaster area, particularly those whose homes are damaged or destroyed in the disaster. Another commenter asked CMS to consider the special needs of the ESRD population.

Response: The emergency requirements at § 422.100(m) currently address coverage for people who have been evacuated or who had to move temporarily as a result of a disaster or emergency declaration by requiring plans to cover Parts A and B services and supplemental Part C benefits out-of-network. Also, § 422.100(b)(1)(iv) requires coverage of renal dialysis services provided while the enrollee was temporarily outside the plan's service area. Further, there is a Special Enrollment Period (SEP) for people who move out of the service area

permanently. Thus, enrollees who cannot move back to the area of the disaster or emergency are permitted to change plans.

Additionally, we remind commenters that § 422.112(b) requires MA plans to ensure continuity of care and integration of services for enrollees through arrangements with contracted providers. Requirements in § 422.112(b)(1) through (6) detail specific methods by which MA organizations are to ensure an effective continuity and integration of health care services. This includes requiring MA plans to have policies and procedures that provide enrollees with an ongoing source of primary care and to have programs for coordination of plan services with community and social services.

Comment: A commenter asked CMS to clarify the rate a non-contracted provider must be paid.

Response: As discussed in section 1852(a)(2) of the Act, CMS regulations at § 422.100(b)(2), and the MA Payment Guide for Out of Network Payments,⁷⁸ MA plans must pay non-contracted providers the amount that the provider would have received from Original Medicare amount for covered services (including balance billing permitted under Medicare Part A and Part B). The total payment must take into account cost-sharing and the MA plan payment to equal cost-sharing and Medicare payment in the Original Medicare program.

Comment: A few commenters suggested CMS align criteria related to special emergency requirements with the conditions for the Star Rating Extreme and Uncontrollable Circumstances adjustment.

Response: We thank commenters for their suggestion and will consider ways to align CMS policies if and when appropriate in the future.

Comment: A few commenters asked CMS to consider staffing, drug, and supply shortage issues to identify when a disruption of access to health care is occurring and when making decisions on timeframes and standards.

Response: We thank commenters for these suggestions and remind MA plans to also consider these conditions when making a determination whether a disruption of access to health care has occurred. The definition we proposed and are adopted in this final rule permits consideration of these conditions and factors when determining whether there is a

⁷⁸ <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/oonpayments.pdf>.

disruption in access. Therefore, we believe that further edits to the proposed regulation text § 422.100(m)(6) is unnecessary.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are changing the term “throughout the service area” to “in the service area” at in the regulation text at § 422.100(m)(6). Also, to provide further clarity on what CMS means by service area, we added a reference to the statutory definition of “service area” in parenthesis at § 422.100(m)(6). Lastly, we edited some repetitive language at § 422.100(m)(1). Specifically, we revised “until one of the conditions described in paragraph (m)(3)” to “until the end date specified in paragraph (m)(3) of this section occurs”, which is a non-substantive, clarifying edit only. We are finalizing all other changes proposed to § 422.100(m) without modification.

C. Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application (§ 422.116)

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 added new § 422.116, which sets forth standards and criteria for determining, whether an MA organization limits the providers from which its MA plan members may receive covered benefits, and satisfies the requirement under section 1852(d)(1) of the Act that such benefits be made available and accessible in an MA plan’s service area with reasonable promptness.⁷⁹ New § 422.116 codified, with some modifications, network adequacy criteria and access standards that CMS had previously outlined in sub-regulatory guidance. In addition, the regulation codified our then-existing policy, that CMS does not deny an application based on CMS’s evaluation of the applicant’s network for a new or expanding service area. Under our policy as set forth in the June 2020 final rule and § 422.116(a)(2), an applicant is required to attest that it has 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.

In the proposed rule (87 FR 1893 through 1895), we proposed to require compliance with applicable network adequacy standards set forth in § 422.116 as part of an application for a new or expanding service area. As indicated in the June 2020 final rule, we currently rely on our existing triennial network review process and timeline to evaluate compliance with network adequacy standards for organizations applying for a new or expanding service area and we removed network adequacy reviews from the application process beginning in 2018 for contract year 2019. We explained in the proposed rule that while the process of reviewing provider networks as part of the triennial review has thus far been adequate and efficient operationally, we have also experienced unintended consequences, and therefore proposed to improve our oversight and effectiveness of network adequacy reviews for initial and services area expansion (SAE) applicants by requiring provider networks be reviewed by CMS when these MA applications are submitted to CMS for consideration.

Currently, consistent with § 422.116(a)(1)(i) and our application process, applicants must attest that they meet provider network standards, but do not have to demonstrate that they meet CMS network requirements before submitting a bid for the following contract year. CMS’s experience has shown that since adopting the attestation-only approach for the 2019 contract year, organizations are requesting to remove a county (or multiple counties) from their service area (that is, service area reduction) after bids are submitted because the organization realizes that it does not have a sufficient network for the entire service area. For example, five organizations have requested to make changes to the service area of a total of 10 plans after bid submission deadlines since 2019.

Bid integrity is a priority for CMS. A request by an organization to make service area reductions related to provider networks after the bid submission deadline, calls into question the completeness and accuracy of the bid(s). The provider network is an important consideration in preparing the bid submission. Permitting the MA organization to make changes to the bid submission because of the inability to establish an adequate network, which is reviewed after the first Monday in June (the bid deadline), would subsequently allow the MA organization to introduce revised information into the bidding process. The introduction of this revised information after the first Monday in

June implies that the initial bid submission was not complete, timely, or accurate. The proposed requirement that MA networks be submitted for review as part of the application mitigates this issue, as CMS’s review of these networks as part of the application is complete before bids are due.

Furthermore, network adequacy reviews are a critical component for confirming that access to care is available for enrollees. Our network evaluations ensure that MA organizations have networks that are sufficient to provide enrollees with access to providers and facilities without placing undue burden on enrollees seeking covered services. We indicated that adding network reviews back to the application process will help ensure overall bid integrity, result in improved product offerings, and protect beneficiaries.

After we adopted the current policy, failures detected during network reviews were not a basis for CMS to deny an application and CMS expected plans to cure deficiencies and meet network adequacy standards once coverage began on January 1 of the following year. In analyzing the network adequacy review determinations for the years since we removed network adequacy requirements from the application, we have observed a pattern across these network review outcomes: Organizations continue to have failures in their networks even after the contract is operational. For example, we found that 19 initial applicants who submitted provider and facility Health Service Delivery (HSD) tables since contract year 2019 continued to have deficiencies upon review of their networks once the MA plans were operational. We explained that by changing the process and reviewing the provider networks as part of the application, CMS will be able to better understand whether the failures are due to the timing of the reviews, which we hope the 10-percentage point credit (discussed later in this section of this final rule) will account for, or whether they are failures that the organization cannot cure. Establishing and maintaining adequate provider networks capable of providing medically necessary covered services to enrollees is fundamental to participation in the MA program.

Our current process and § 422.116(a)(1)(i) do not prohibit us, when evaluating an application, from considering information related to an organization’s previous failure to comply with an MA contract due to previous failures associated with access to services or network adequacy

⁷⁹ As noted in the proposed rule at 87 FR 1893, CMS has also codified network access requirements and standards at §§ 422.112(a) and 422.114(a)(1).

evaluations resulting in intermediate sanction or civil money penalty under to part 422, subpart O, with the exception of a sanction imposed under § 422.752(d). This will continue to be applicable to our evaluation of initial or SAE applications. The changes we proposed, which require compliance with network adequacy standards during the application process, will help us assess which organizations are not capable of meeting CMS standards in a given service area. As a result, we proposed to broaden our ability to safeguard the MA program by permitting evaluations of network adequacy in connection with our review and approval of applications for new and expanding service areas. This ability will help us avoid approving organizations that could have issues providing access to care in these new or expanded service areas.

We found that the current timing of the network adequacy reviews impacts applicants' ability to make timely decisions regarding the service area in which they intend to provide coverage. The operational process for conducting network adequacy reviews is outlined in the "Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance".⁸⁰ The guidance currently directs initial and SAE applicants to upload their HSD tables containing pending service areas into the Health Plan Management System (HPMS) Network Management Module (NMM) in mid-June for CMS review. Regulations under § 422.254(a)(1) require organizations to submit bids no later than the first Monday in June of each year and authorize CMS to impose sanctions or choose not to renew an existing contract if the bid is not complete, timely and accurate. CMS has issued guidance to remind MA organizations of this obligation that bids be complete and accurate at the time of submission, such as in the CY 2014 through CY 2020 Final Call Letters (provided as attachments to the annual Rate Announcements⁸¹) and the CY 2022 MA Technical Instructions, released in an HPMS memo on May 12, 2021. Providing organizations with network adequacy determinations ahead of the bid deadline (within the application timeline) will provide them the opportunity to make decisions regarding their intended service areas before submitting bids. This practice would also help mitigate operational

issues CMS has experienced related to requests for service area changes after the deadline has passed, as these kinds of requests may affect the MA organization's submissions on the bid pricing tool. For these reasons, we are finalizing our proposal to revise paragraph (a)(1)(ii) of § 422.116 to require an applicant for a new or expanding service area to demonstrate compliance with § 422.116 and to explicitly authorize CMS to deny an application on the basis of an evaluation of the applicant's network for the new or expanding service area.

We also proposed to amend § 422.116 by adding a new paragraph (d)(7), which provide applicants with a temporary 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for all of the combinations of county designations and provider/facility types specified in § 422.116(d), for the proposed contracted network for a new service area or a service area expansion (SAE). Current CMS procedures (see "The Part C—Medicare Advantage and 1876 Cost Plan Expansion and 1876 Cost Plan Expansion Application"⁸²) require completed applications to be submitted by mid-February. We understand that organizations may have difficulties meeting this timing for submission of a full provider network that the proposed change in § 422.116(a)(1)(i) would require. We previously separated the network adequacy reviews from the application process due to the potential challenge of applicants securing a full provider network almost a year in advance of the contract becoming operational. In order to provide flexibility to organizations as they build their provider networks, we proposed to allow the 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the contracted network in the pending service area, at the time of application and for the duration of the application review. At the beginning of the applicable contract year (that is, January 1), the 10-percentage point credit would no longer apply, and plans would need to be in full compliance for the entire service area. This aspect of our proposal will balance the burden on applicants of having network contracts in place close to a year before the beginning of the coverage year with the need to ensure that the MA plans have adequate

networks for furnishing covered benefits to their enrollees.

Starting with the contract year 2024 application cycle, initial and service area expansion applicants will be required to submit their proposed contracted networks during the application process. Applicants will upload their HSD tables to the NMM by the application deadline, and CMS will generally follow the current operational processes for network reviews, which include an opportunity to submit exception requests as outlined in § 422.116(f). The disposition of the exception request would be communicated as part of the opportunity to remedy defects found in the application under § 422.502(c)(2). Applicants for SAEs who are also due for a triennial review would be required to submit their pending new service area during the application process, and their existing network service area(s) separately, during the triennial review in mid-June.

We acknowledge and thank commenters for providing their perspectives regarding our proposals to amend our network adequacy policy. We received a number of comments related to these proposals, and have summarized them and included our responses.

Comment: Numerous commenters expressed support for our proposal to require compliance with network adequacy standards as part of an application for a new or expanding service area. Commenters agreed that network adequacy is critical to enrollees' access to care. Commenters noted that improving our oversight of provider networks would strengthen beneficiary protections and ensure timely access to providers without placing undue burden on enrollees. Other commenters also noted that our proposal would hold plans accountable for providing access to care, especially in underserved communities.

Response: We thank the commenters for their support of our proposal. As previously noted, we believe that requiring MA organizations to demonstrate compliance with network adequacy standards during the application process for a new or expanding service area will improve our oversight and effectiveness of network adequacy reviews and our ability to safeguard the Medicare program.

Comment: Some commenters expressed support for our proposal to require that applicants demonstrate compliance with network adequacy standards during the application process because they believed this would help ensure bid integrity, which

⁸⁰ <https://www.cms.gov/files/document/medicareadvantageandsection1876costplannetworkadequacyguidance6-17-2020.pdf>.

⁸¹ <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Announcements-and-Documents>.

⁸² <https://www.cms.gov/files/document/cy-2022-medicare-part-c-application-updated-1-12-2021.pdf>.

the commenters agreed should be a priority for CMS.

Response: We thank the commenters for their comments regarding bid integrity. As indicated in our proposal, we believe that providing MA organizations with information regarding their ability to provide coverage in a proposed service area ahead of the bid deadline would mitigate issues with service area reduction requests and ensure overall bid integrity.

Comment: A commenter suggested that requests to make service area reductions after the bid deadline are relatively rare based on the number of new and service area expansion applications that are submitted, thus our proposal would needlessly increase burden on the entire industry for few occurrences.

Response: While there may be fewer instances of service area reduction requests relative to MA applications submitted, we believe that any such request has the potential to compromise the overall integrity of the bidding process. As we have previously indicated, ensuring overall bid integrity is a priority for CMS. In addition, we note that this provision helps improve our oversight of provider networks, which strengthens beneficiary protections. Therefore, we believe the added burden of requiring applicants to demonstrate compliance with network adequacy standards is justified, particularly in light of the flexibilities, discussed later in this section, that we are adopting for how applicants for new MA contracts or expanded service areas can demonstrate compliance with the network adequacy requirements.

Comment: Many commenters did not support our proposal. Commenters expressed concerns over the proposed timing for the submission and review of initial and service area expansion applicants' networks (during the time of application in mid-February of each year). The commenters believed this timing would be insufficient for MA organizations to build high-quality provider networks, and would negatively impact negotiations with provider groups, giving providers leverage to negotiate higher rates that could increase healthcare costs and reduce benefits. Commenters also suggested that our proposal would disproportionately impact smaller organizations working to expand to certain regional, rural, and medically underserved areas, thereby inhibiting competition among plans and ultimately limiting choice for beneficiaries; some of these commenters also expressed that the proposal would provide an unfair

advantage to large health plans with an existing presence in these areas. Several commenters posited that our proposal would place a substantial administrative burden on MA organizations and on providers, and that establishing contracts with organizations takes a significant amount of time. Finally, a number of commenters asked CMS to consider allowing MA organizations to use Letters of Intent (LOIs) to contract with providers as a means to meet network adequacy standards, and in order to provide flexibility as they work to come into compliance for the coverage year.

Response: We appreciate the commenters' feedback regarding our proposal. As we noted in the proposed rule, we understand that requiring an MA organization to establish a full provider network almost a year in advance of the contract becoming operational will be difficult. We also indicated that we previously separated the network adequacy reviews from the application process due to the potential challenge of applicants securing a full provider network almost a year in advance of the contract becoming operational. While we believe evaluating provider networks at the time of application is important, we agree that some flexibility is appropriate to address this challenge for applicants.

Therefore, based on the comments received, we are modifying the regulation to allow LOIs to be used in lieu of signed provider contracts, at the time of application and for the duration of the application review. The LOI must be signed by both the MA organization and the provider with which the MA organization intends to negotiate. Further, applicants must notify CMS of their use of LOIs to meet network standards and submit copies (upon request) of the LOIs in the form and manner directed by CMS. At the beginning of the contract year, the MA organization must be in full compliance with the section, including having signed provider and facility contracts in place of the LOIs.

CMS would also require any MA organization that utilized LOIs for the application of a new or expanding service area to participate in the triennial review to evaluate compliance with network adequacy standards. This triennial review by CMS will occur during the first year a plan is operational in its new service area.

Comment: Many commenters supported our proposal to allow a 10-percentage point credit at the time of an MA organization's application and during the application review. Some of these commenters recommended that

the credit no longer apply once the contract is operational. Some of the commenters expressed the view that the proposed 10-percentage point credit struck the right balance between showing sensitivity to the challenges for MA organizations in developing and submitting provider networks on a much earlier timeline as part of the application process and demonstrating awareness of the need for CMS to monitor the adequacy of MA organizations' provider networks.

A number of commenters noted that the 10-percentage point credit would not be sufficient to make an impact on meeting network standards, especially in rural and other areas with limited providers. Some commenters suggested that we increase the 10-percentage point credit without specifying what percentage point they would prefer, whereas others suggested that we increase the credit to a 20-, 30-, or higher percentage point credit. A commenter noted that the credit undermines CMS's effort to improve network adequacy. A commenter requested clarification on whether other credits would be affected by the proposed 10-percentage point credit for initial and service area expansion applicants.

Response: We thank commenters for their support of this proposal and acknowledge the concerns that were raised by other commenters. As we indicated in our proposal, we understand that organizations may have difficulties meeting this timing for submission of a full provider network. Therefore, in order to provide flexibility to organizations as they build their provider networks, we proposed to allow the 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the contracted network in the pending service area, at the time of application and for the duration of the application review. We believe a 10-percentage point credit, in conjunction with use of Letters of Intent (LOIs), as discussed above, will provide MA organizations with enough flexibility to meet network adequacy standards within the application timeframe.

We also clarify that the 10-percentage point credit would be separate from and in addition to any other applicable credit established in § 422.116(d).

Comment: A few commenters suggested that CMS allow MA organizations to apply for additional time to meet network adequacy standards for initial and service area expansion applicants. A few commenters suggested that CMS delay

implementation of this proposal until 2025.

Response: We believe that allowing the 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards and allowing the use of LOIs in lieu of signed contracts, as discussed previously in this rule, for the contracted network in the pending service area, at the time of application and for the duration of the application review, provide sufficient flexibility for MA organizations. We also believe that establishing these changes for the 2024 coverage year will allow us to improve our oversight and effectiveness of network adequacy reviews in a timely fashion.

After careful consideration of the comments received from various stakeholders and for the reasons set forth in our responses and in the proposed rule, we are finalizing, with modifications, the following changes to § 422.116:

- Revise § 422.116(a)(1)(ii) to provide that beginning for contract year 2024, an applicant for a new or expanding service area must demonstrate compliance with this section as part of its application for a new or expanding service area and CMS may deny an application on the basis of an evaluation of the applicant's network for the new or expanding service area.

- Add a new paragraph at § 422.116(d)(7), with the heading "New or expanding service area applicants.", to provide that beginning for contract year 2024, an applicant for a new or expanding service area receives a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the contracted network in the pending service area, at the time of application and for the duration of the application review. In addition, applicants may use an LOI, signed by both the MA organization and the provider or facility with which the MA organization has started or intends to negotiate, in lieu of a signed contract at the time of application and for the duration of the application review, to meet network standards. As part of the network adequacy review process, applicants must notify CMS of their use of LOIs to meet network standards, in lieu of a signed contract and submit copies upon request and in the form and manner directed by CMS. At the beginning of the applicable contract year, the credit and the use of the LOIs no longer apply, and if the application is approved, the MA organization must be in full compliance with this section,

including having signed contracts with the provider or facility.

D. Part C and Part D Quality Rating System

This final rule finalizes a technical change at § 422.166(i)(12) proposed in the January 2022 proposed rule to enable CMS to calculate 2023 Star Ratings for three Healthcare Effectiveness Data and Information Set (HEDIS) measures that are based on the Health Outcomes Survey (HOS). It also finalizes provisions adopted in the March 31st COVID-19 IFC and the September 2nd COVID-19 IFC to enable us to calculate the 2021 and 2022 Star Ratings due to the COVID-19 pandemic.

1. Background

CMS develops and publicly posts a 5-star rating system for Medicare Advantage (MA) and Part D plans based on the requirement to disseminate comparative information, including information about quality, to beneficiaries under sections 1851(d) and 1860D-1(c) of the Act and the collection of different types of quality data under section 1852(e) of the Act. The Star Rating system for MA and Part D plans is used to determine quality bonus payment (QBP) ratings for MA plans under section 1853(o) of the Act and the amount of beneficiary rebates under section 1854(b) of the Act. Cost plans under section 1876 of the Act are also included in the MA and Part D Star Rating system, as codified at § 417.472(k). We use different data sources to measure quality and performance of contracts, such as CMS administrative data, surveys of enrollees, information provided directly from health and drug plans, and data collected by CMS contractors. Various regulations require plans to report on quality improvement and quality assurance and to provide data which help beneficiaries compare plans (for example, §§ 417.472(j) and (k), 422.152(b), 423.153(c), and 423.156). The methodology for the Star Ratings system for the MA and Part D programs is codified at §§ 422.160 through 422.166 and 423.180 through 423.186, respectively.

The Star Ratings are generally based on measures of performance during a period that is 2 calendar years before the year for which the Star Ratings are issued; for example, 2023 Star Ratings will generally be based on performance during 2021. For some measures, such as the cross-sectional measures collected through the HOS, Star Ratings are based on performance up to 3 calendar years prior to the Star Ratings year. For example, the HOS

administered in 2021 asked about care received (for example, whether a healthcare provider advised the member to start, increase, or maintain their level of exercise or physical activity) in the 12 months prior to the survey's administration—that is a period of time covering parts of the 2020 and 2021 calendar years—and the data will be used for the 2023 Star Ratings.

In the March 31st COVID-19 IFC (85 FR 19230), we adopted a series of changes to the 2021 and 2022 Star Ratings to address the disruption to data collection and impact on performance for the 2020 measurement period posed by the public health emergency (PHE) for COVID-19. The Star Ratings changes adopted in that rule addressed both the needs of health and drug plans and their providers to curtail certain data collections and adapt their current practices in light of the COVID-19 PHE and the need to care for the most vulnerable patients, such as the elderly and those with chronic health conditions. As explained in the March 31st COVID-19 IFC, we expected to see changes in measure-level scores for the 2020 measurement period due to COVID-19-related healthcare utilization, reduced or delayed non-COVID-19 care due to advice to patients to delay routine and/or elective care, and changes in non-COVID-19 inpatient utilization. The March 31st COVID-19 IFC made some adjustments to account for potential changes in measure-level scores so health and drug plans could have some degree of certainty that the Star Ratings would be adjusted and could continue their focus on patients who were most in need. (See 85 FR 19269 through 19275 for a description of the various adjustments.)

The March 31st COVID-19 IFC amended, as necessary, certain calculations for the 2021 and 2022 Part C and D Star Ratings to address the expected impacts of the COVID-19 PHE on data collection and performance in 2020 that were immediately apparent. As the PHE for COVID-19 progressed in 2020 with ultimately all areas across the country eligible for Star Ratings disaster adjustments for extreme and uncontrollable circumstances under the current regulations (§§ 422.166(i) and 423.186(i)) for the 2022 Star Ratings, it became apparent that a modification to the existing disaster policy was required in order to calculate cut points for non-CAHPS measures for the 2022 Star Ratings.

We adopted regulations for how Star Ratings would be calculated in the event of extreme and uncontrollable circumstances in the April 2019 final rule. Under §§ 422.166(i)(9)(i) and

(i)(10)(i) and 423.186(i)(7)(i) and (i)(8)(i), the numeric scores for contracts with 60 percent or more of their enrollees living in Federal Emergency Management Agency (FEMA)-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance are excluded from: (1) The measure-level cut point calculations for non-CAHPS measures and (2) the performance summary and variance thresholds for the reward factor. The 60 percent rule ensures that any impact of an unforeseen and uncontrollable circumstance on a particular contract (or group of contracts) in a specific geographic area does not affect the ratings for other contracts. As explained in the April 2019 final rule (84 FR 15777), CAHPS measures use a relative distribution and significance testing, rather than clustering, to determine Star Ratings cut points; our testing indicated that when affected contracts were removed from the distribution of measure-level scores, the distribution of the remaining contracts looked very similar, suggesting that the affected contracts are randomly distributed among the rating levels. Additionally, the CAHPS methodology to assign cut points is less sensitive to extreme outliers that may result from the impact of a disaster on contract-level measure scores; thus, the 60 percent rule does not apply to the calculation of cut points for CAHPS measures. When only a small number of counties are designated by FEMA as Individual Assistance areas, application of the 60 percent exclusions means that the performance of other contracts serving larger or other service areas is used to establish the necessary thresholds for Star Ratings for non-CAHPS measures and the reward factor.

Up until the 2022 Star Ratings, disasters for which any Star Rating adjustments had been made were localized, and the 60 percent rule had removed scores from only a small fraction of contracts (that is, less than 5 percent of contracts on average). The unprecedented impact of COVID-19 created a new methodological issue where, without a revision to the existing disaster policy rules for calculating the measure-level cut points for the 2022 Star Ratings, we would not have had enough contracts to reliably calculate the non-CAHPS measure-level cut points. Consequently, CMS would not have been able to assign Star Ratings for all non-CAHPS measures. Similarly, we would not have had enough contracts to reliably calculate the performance summary and variance thresholds for the Reward Factor.

For most measures, the extreme and uncontrollable circumstance adjustment applies for disasters from 2 years prior to the Star Ratings year (that is, a disaster that begins⁸³ during the 2020 measurement period results in a disaster adjustment for the 2022 Star Ratings). For Part C measures derived from the HOS, the disaster adjustment is delayed an additional year due to the timing of the survey and 1 year recall period. (See 84 FR 15772 through 15773 for an example of the timing of disaster adjustments for measures from the HOS.) Although the CAHPS surveys and HEDIS data collection were not completed in 2020 (we did conduct the HOS in 2020 on a later schedule than usual), CAHPS surveys and HEDIS data collection completed in 2021 reflected performance by plans in 2020 during the PHE for COVID-19 and were used in the 2022 Star Ratings.

In the September 2nd COVID-19 IFC (85 FR 54820), we revised the disaster policy rules for calculating the non-CAHPS measure-level cut points for the 2022 Star Ratings so we would be able to calculate the 2022 Star Ratings for these measures (85 FR 54844-47) since all contracts qualified for the extreme and uncontrollable circumstance adjustments due to COVID-19. The change adopted by the September 2nd COVID-19 IFC at §§ 422.166(i)(11) and 423.186(i)(9) removed application of the 60 percent rule and avoided the exclusion of contracts with 60 percent or more of their enrollees living in FEMA-designated Individual Assistance areas from calculation of the non-CAHPS measure-level cut points for the 2022 Star Ratings. The September 2nd COVID-19 IFC also modified the calculation of the performance summary and variance thresholds for the reward factor so that the threshold calculation would not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance. These changes ensured that CMS was able to calculate measure-level cut points for those measures that qualified for the disaster adjustment for the 2022 Star Ratings; calculate measure-level 2022 Star Ratings; apply the “higher of” policy for non-CAHPS measures as described at §§ 422.166(i)(3)(iv), (i)(4)(v), (i)(5), and (i)(6)(i) and (iv) and 423.186(i)(3) and (i)(4)(i) and (iv); calculate the reward factor; and

⁸³ We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period lasts until another calendar year.

ultimately calculate 2022 overall and summary ratings for 2022 Star Ratings and 2023 QBPs. It was critical to adopt these changes to avoid an unworkable result from the current policy in these extraordinary circumstances and so that CMS could measure actual performance for the 2020 measurement period so plans had an opportunity to demonstrate how they were tailoring care in innovative ways to meet the needs of their enrollees during the PHE for COVID-19. Given the unprecedented impacts of the COVID-19 PHE, it was important to be able to calculate the 2022 Star Ratings to help to continue to drive quality improvement for plans and providers.

We proposed in the January 2022 proposed rule a specific provision for 2023 Star Ratings for HEDIS measures derived from the HOS data collection administered in 2021 covering the 2020/2021 period. We address the comments we received on that proposal in section II.D.2. of this final rule. We also address the changes and comments we received in response to the March 31st COVID-19 IFC and the September 2nd COVID-19 IFC in sections II.D.3. and II.D.4., respectively, of this final rule. Per section 1871(a)(3)(C) of the Act, CMS responds to comments on an interim final rule regarding the Medicare program and finalizes the interim rules within 3 years of the issuance of the IFC.

2. Provision Related to the HEDIS Measures Calculated From the HOS From the January 2022 Proposed Rule

In response to the September 2nd COVID-19 IFC, some commenters requested clarification about the measures that come from the HOS and when the disaster policy would be applied in light of how HOS measures receive adjustment after an extreme and uncontrollable circumstance. A few commenters questioned, based on previous logic for disasters and HOS measures, whether we anticipated that the impacted HOS data collection period would not be until 2021 and the “higher of” methodology would be applicable to reporting year 2023 for HOS measures. Another commenter noted that using the 2020 Star Ratings as an example, the contracts affected by 2018 disasters received the “higher of” logic for most measures; however, the HOS and HEDIS-HOS measures used the “higher of” logic only for contracts affected by 2017 disasters. The commenter stated if this timing applies to 2020 disasters, the HOS and HEDIS-HOS measures will receive the higher of current or prior year measure-level Star Ratings in the 2023 Star Ratings. The

commenters requested clarification since the September 2nd COVID-19 IFC adopted a regulatory change to the 60 percent rule for only the 2022 Star Ratings. We proposed in the January 2022 proposed rule to address the HEDIS measures derived from the HOS used in the 2023 Star Ratings.

As described in the April 2019 final rule (CMS-4185-F) (84 FR 15772 through 15773), for measures derived from the HOS, the disaster policy adjustment is for 3 years after the extreme and uncontrollable circumstance. Thus, we noted in the preamble to that rule that the 2023 Star Ratings would adjust measures derived from the HOS for 2020 extreme and uncontrollable circumstances (85 FR 15772 through 15773). Based on the comments received and the timing of the HOS administration, we proposed to amend § 422.166(i) to specifically address the 2023 Star Ratings, for measures derived from the 2021 HOS only, by adding § 422.166(i)(12) to remove the 60 percent rule for affected contracts. This amendment would ensure that we are able to calculate the Star Ratings cut points for the three HEDIS measures⁸⁴ derived from the HOS and are able to include these measures in the determination of the performance summary and variance thresholds for the reward factor for the 2023 Star Ratings. Without removing the 60 percent rule for HEDIS measures derived from the HOS, we would not be able to calculate these measures for the 2023 Star Ratings or include them in the 2023 reward factor calculation. By removing the 60 percent rule, all affected contracts (that is, contracts affected by the 2020 COVID-19 pandemic) with at least 25 percent of their enrollees in FEMA-designated Individual Assistance areas at the time of the disaster will receive the higher of the 2022 or 2023 Star Rating (and corresponding measure score) for each of the HEDIS measures collected through the HOS as described at § 422.166(i)(3)(iv) for the 2023 Star Ratings.

Below we summarize the comments we received and provide our responses.

Comment: Most commenters expressed support for removing the 60 percent rule for the 2023 Star Ratings for the three HEDIS measures (Monitoring Physical Activity, Reducing the Risk of Falling, and Improving Bladder Control) derived from the HOS due to the COVID-19 PHE. Commenters noted the detrimental effects of the COVID-19

pandemic on beneficiaries and health care providers and appreciated that this proposed policy would ensure plans are not penalized on these three measures because of the effects of the pandemic.

Response: We thank commenters for their support of this provision. This change to the calculation of ratings for these three HEDIS-HOS measures will permit CMS to calculate these measures for the 2023 Star Ratings and include them in the 2023 reward factor calculation.

Comment: A few commenters requested that HEDIS measures derived from the HOS be removed entirely from the 2023 Star Ratings. They expressed concern that the proposed policy may be inadequate to account for the impacts of the COVID-19 PHE on these measures and that they would be penalized for factors outside of their control.

Response: These three areas—bladder control, physical activity, and reducing falls risk—are important for beneficiaries' health and well-being, even during a PHE. Removing the 60 percent rule will allow most contracts to receive the higher of the 2022 or 2023 Star Ratings (and corresponding measure score) for each of the HEDIS measures collected through the HOS, following the rules at § 422.166(i). This will minimize the impact of the PHE on these measures. It is CMS's view that including these measures in Star Ratings will provide valuable information for people with Medicare on important areas of focus for avoiding serious health problems. As a reminder, as required at § 422.504(o), MA organizations must develop, maintain, and implement business continuity plans, including policies and procedures for disaster or emergency situations. Therefore, we do not believe it is appropriate to eliminate use of these measures entirely in the Star Ratings.

After considering the comments we received, and for the reasons set forth in the proposed rule and in our responses, CMS is finalizing without modification the provision at § 422.166(i)(12) to codify special rules for the calculation of the 2023 Star Ratings for the three HEDIS measures that are collected through the HOS.

3. Provisions in the March 31st COVID-19 IFC

This final rule also responds to comments on and finalizes a series of changes to the 2021 and 2022 Star Ratings to accommodate the disruption to data collection posed by the COVID-19 pandemic (FR 85 19271-19275) that were established in the March 31st

COVID-19 IFC. The following is a summary of the provisions and the public comments received on those changes to Part C and D Star Ratings policies included in the March 31st COVID-19 IFC.

a. HEDIS, CAHPS, and HOS Data Collection and Submission for 2021 Star Ratings and 2022 Star Ratings

The March 31st COVID-19 IFC eliminated the requirement to submit HEDIS and CAHPS data at § 422.152(b)(6) for MA contracts and at § 417.472(i) and (j) for cost plans, and to submit CAHPS data at § 423.182(c)(3) for Part D contracts. CMS suspended the collection and submission of HEDIS and CAHPS measures to allow health plans, providers, and physician offices to focus on caring for Medicare beneficiaries during the early stages of the PHE for COVID-19. These actions were adopted to minimize the risk of the spread of infection by eliminating travel and in-person work for the collection of HEDIS data and ensure the safety of CAHPS survey vendor staff by aligning with the CDC's social distancing guidance. Both Part C and D plans could use any data already collected for their internal quality improvement efforts.

CMS also delayed the administration of the HOS until late summer. To address the potential that CMS might not be able to complete HOS data collection in 2020 (for the 2022 Star Ratings), the March 31st COVID-19 IFC also adopted a provision at § 422.166(j)(2)(i) to replace, if the HOS was not conducted in 2020, any measures calculated based on HOS data collections with earlier values from the 2021 Star Ratings that were not affected by the public health threats posed by COVID-19. This specific provision was designed to address any gaps in the necessary HOS data if the HOS could not be administered in 2020. The Star Ratings measures from the HOS include the following: Improving or Maintaining Physical Health; Improving or Maintaining Mental Health; Reducing the Risk of Falling; Improving Bladder Control; and Monitoring Physical Activity.

Comment: Some commenters commended CMS for curtailing HEDIS and CAHPS data collection so that plans and providers could focus on providing care and not put their employees at risk. Other commenters appreciated that by completely eliminating the submission requirements and removing the possibility of a competitive disadvantage as a result of ceasing data retrieval efforts, CMS enabled plans to better focus on patient care and the safety of plans' employees. Commenters

⁸⁴ The HEDIS measures derived from the HOS include *Monitoring Physical Activity*, *Reducing the Risk of Falling*, and *Improving Bladder Control*.

expressed a general understanding of the sensitivity around data collection during this time and the need to focus plans and providers on caring for Medicare beneficiaries.

Response: CMS appreciates the support and emphasis on plans' focus on providing care to Medicare enrollees from the onset of the COVID-19 pandemic.

Comment: Some commenters argued that the HEDIS and CAHPS data collections were already well advanced before shutdowns occurred so there would be little risk to personnel involved in finishing data collection. These commenters stated that HEDIS data collection could be done electronically or through claims analysis and not through in-person contact, thus maintaining social distancing guidance. They also argued that CAHPS survey response rates do not increase much in the last few months of data collection.

Response: The intent of these changes was to eliminate some of the data collection requirements given the public health and safety concerns with collecting the data and to enable plans to focus on the care and safety of their employees and Medicare beneficiaries. Given the extraordinary circumstances under which the healthcare system was operating, CMS wanted plans to have some degree of certainty related to Star Ratings program requirements and wanted to make sure plans would be able to focus on ensuring that Medicare beneficiaries received the care and treatment they needed. The issues facing the healthcare system, including significant differences across regions and demographic groups, created unique challenges for the 2021 and 2022 Star Ratings calculations. Given these concerns, CMS believes that, had the 2020 submission requirements for HEDIS and CAHPS data remained in force, we would not have had complete data for HEDIS and CAHPS across all contracts as needed in order to accurately calculate Star Rating measure cut points for the 2021 Star Ratings. Data collection was ongoing for HEDIS, including medical record review, so not all contracts were near completion.

Data collection was curtailed for CAHPS after the first survey mailing so the data were not complete or representative of all enrollees. In general, for the MA and PDP CAHPS Survey, approximately 40 percent of responses come from the second mailing and telephone follow-up. Further, approximately 50 percent of responses from younger beneficiaries (those under age 55) and black beneficiaries, and 60 percent of Spanish language beneficiary responses, come from the second

mailing and telephone follow-up, which were not yet completed at the time the March 31st COVID-19 IFC was issued.

Comment: Commenters were generally supportive of CMS's decision to delay 2020 HOS data collection until late summer 2020, although some commenters wanted all 2020 HOS data collection to be halted. Other commenters recommended CMS move forward with the 2020 administration of HOS, with the stipulation that any data collected be used for internal plan purposes only and not used in the 2022 Star Ratings.

Response: We appreciate the support for delaying the 2020 HOS administration until late summer. The HOS data collection was successfully completed in the fall of 2020. Although the survey was successfully administered, two measures from the HOS, Improving or Maintaining Physical Health and Improving or Maintaining Mental Health, were moved to the display page for the 2022 and 2023 Star Ratings due to data validity concerns as described in the HPMS memorandum "Medicare Health Outcomes Survey (HOS) Outcome Measures Moved to Display for 2022 and 2023 Star Ratings," released on August 5, 2021.⁸⁵

Comment: A few commenters agreed with CMS's plan to replace the 2022 Star Ratings for HOS measures with the 2021 Star Ratings if the HOS could not be administered, but some commenters argued plans should have the choice of receiving either the 2021 or 2022 Star Ratings and corresponding scores.

Response: CMS did not have to replace the 2022 Star Ratings with the 2021 Star Ratings for the measures from the HOS since the survey was administered in fall 2020. CMS could not select the higher measure-level star and corresponding numeric data for the measures from the HOS for the 2022 Star Ratings since HOS measures did not qualify for the extreme and uncontrollable circumstances adjustment due to COVID-19 due to the timing and recall periods for the HOS. We are therefore not finalizing the provision at § 422.166(j)(2)(i) which authorized replacement of measures calculated based on HOS data collections for the 2022 Star Ratings with earlier values from the 2021 Star Ratings. Because the HOS was completed in 2020, the provision at § 422.166(j)(2)(i) is moot and it is not necessary to finalize it permanently.

Comment: Some commenters requested that the HOS measures be

moved to the display page until at least 2023 or 2024. Additionally, some commenters urged CMS to consider the impact of COVID-19 not only on the 2020 and 2021 HOS data but also on the 2022, 2023, and 2024 Star Ratings. Many commenters stated that even if current conditions improved enough to allow HOS to be fielded in 2020, comparisons of previous and future year scores, as well as comparisons across contracts, would not be valid during the COVID-19 pandemic. A few commenters pointed out that trends will likely vary by region or state based on the prevalence of COVID-19 and the presence or absence of state governments' constraints on patient travel and provider operations. Some commenters argued that it would not be feasible for CMS to adjust HOS outcome measures to account for all COVID-associated factors (for example, social isolation, loneliness, fear of death, national rhetoric regarding the value of elders, economic impacts, and decreased opportunity for physical activities) and pointed out that the negative impacts may last for years. Some commenters did not believe HOS data collected in 2020 would be indicative of overall plan quality, but would instead reflect the massive disruption to the healthcare system caused by the COVID-19 pandemic. To avoid unfairly penalizing plans for circumstances outside their control, most commenters recommended that CMS continue to collect HOS data in 2020 but remove the measures from the Star Ratings for up to 3 years. In particular, commenters were concerned about the two HOS outcome measures, Improving or Maintaining Physical Health and Improving or Maintaining Mental Health.

Response: Although the HOS data collection was completed as scheduled in fall 2020, CMS agrees that the COVID-19 PHE significantly impacted the validity of the two HOS outcome measures. CMS issued the HPMS memorandum "Medicare Health Outcomes Survey (HOS) Outcome Measures Moved to Display for 2022 and 2023 Star Ratings," on August 5, 2021 announcing that the Improving or Maintaining Physical Health and Improving or Maintaining Mental Health measures would be moved to the display page on *CMS.gov* with a note that the comparisons were pre- and post-pandemic and that the measures would not be included in the 2022 and 2023 Star Ratings because of validity concerns related to the COVID-19 PHE. These two measures were therefore not included in the 2022 Star Ratings, and

⁸⁵ HPMS Memos for WK 1 August 2-6, 2021. CMS.

they will not be included in the 2023 Star Ratings.

After consideration of the public comments we received, we are finalizing without modification the provisions eliminating for 2020 the requirement to submit HEDIS and CAHPS data for MA contracts at § 422.152(b)(6) and for cost plans at § 417.472(i) and (j), and to submit CAHPS data for Part D contracts at §§ 423.156 and 423.182(c)(3). HOS data collection was completed as scheduled in fall 2020; thus, we are not finalizing the provision at § 422.166(j)(2) to replace any measures calculated based on HOS data collections for the 2022 Star Ratings with earlier values from the 2021 Star Ratings that were not affected by the public health threats posed by COVID-19.

b. Adjustments to the 2021 Star Ratings Methodology Due To Lack of HEDIS and CAHPS Data

The March 31st COVID-19 IFC replaced the 2021 Star Ratings measures calculated based on HEDIS and Medicare CAHPS data collections with earlier values from the 2020 Star Ratings (which were not affected by the public health threats posed by COVID-19) at §§ 422.166(j)(1) and 423.186(j)(1).

Comment: Some commenters agreed with CMS that given the impact of the COVID-19 pandemic, CMS should use the 2020 Star Ratings scores and stars in place of 2021 Star Ratings scores and stars. Some commenters stated that such an approach would lessen the impact of any declines in performance that were driven by the PHE and outside of the control of Part C and D sponsors. Further, given that COVID-19 had differential geographic impacts throughout the country, commenters expressed that keeping all plans to the 2020 ratings would keep scoring more stable.

Other commenters recommended that CMS use the 2021 Star Ratings scores and stars. They stated that to not do so would not align with the goal of the program, which is to provide current unbiased and accurate information on the quality performance of a health or drug plan for consumers to make their best health care decisions.

Some commenters also argued that to not use the 2021 Star Ratings would ignore the efforts plans had made during the previous year to significantly improve their HEDIS and CAHPS measure scores. Some commenters stated they disagreed with CMS's statement that measure scores and stars do not fluctuate significantly year to year. They argued that not using 2021 Star Ratings could negatively impact

contracts demonstrating year-over-year improvement and "new" plans.

Some commenters wanted the choice to use either their 2020 or 2021 Star Ratings. A few commenters suggested that if the 2021 HEDIS and CAHPS measures were not going to be used, these measures should be removed from the 2021 Star Ratings program or moved to the display page.

Response: We believe that the provisions in the March 31st COVID-19 IFC were necessary to ensure public health and safety during this unprecedented time. If we had required plans to collect HEDIS and CAHPS data, plans would have been forced to choose between protecting the safety of those collecting data, potentially diverting resources away from the urgent care needs of Medicare beneficiaries impacted by COVID-19, and collecting data needed by the Star Ratings program.

For the 2021 Star Ratings, there was no reason not to use the most recent data available from all applicable sources. Unlike HEDIS and CAHPS, other data sources for the 2021 Star Ratings were not impacted by COVID-19 and could continue to be used to show recent plan performance. Given that not all data sources were impacted by COVID-19 for the 2021 Star Ratings, and CMS had the ability to calculate the 2021 Star Ratings with the most recent data available for all measures, there was no reason to allow plans to choose if they wanted the 2020 Star Ratings or the 2021 Star Ratings. CMS did not consider moving both HEDIS and CAHPS data to the display page for the 2021 Star Ratings, since that would have resulted in all contracts being rated on only 10 out of 32 Part C measures, which would not reflect the full range of care and services plans provide.

After consideration of the public comments we received, we are finalizing without modification the provisions, as codified at §§ 422.166(j)(1) and 423.186(j)(1), to use the 2020 Star Ratings HEDIS and CAHPS data for the 2021 Star Ratings.

c. Use of 2020 Star Ratings To Substitute for 2021 Star Ratings in the Event of Extraordinarily Compromised CMS Capabilities or Systemic Data Issues

In the March 31st COVID-19 IFC, CMS established a process for the calculation of the 2021 Star Ratings in the event that the impact of the COVID-19 pandemic made it necessary for CMS to focus exclusively on the continued performance of essential agency functions, and the agency did not have the ability to calculate valid and accurate 2021 Star Ratings at

§§ 422.164(i), 422.166(j)(1)(v), 423.184(i), and 423.186(j)(1)(iv).

CMS's top priority at the beginning of the pandemic was to ensure public health and safety, including that of beneficiaries, health and drug plan staff, and providers, and to allow health and drug plans, providers, and physician offices to focus on the provision of care. Adopting this provision to address such extraordinary circumstances before they potentially could come to pass in connection with the COVID-19 pandemic ensured that Medicare health and drug plans were aware of the steps CMS would take if we were unable to calculate the 2021 Star Ratings.

Comment: Some commenters supported CMS's proposal to establish modified methods of calculating or assigning 2021 Star Ratings if needed due to potential concerns over the impact of the COVID-19 pandemic on agency functions and the ability to calculate the Star Ratings.

Response: CMS appreciates commenters' understanding of our proposal to establish modified methods for calculating or assigning 2021 Star Ratings in the event that the impact of the COVID-19 pandemic made it necessary for CMS to focus exclusively on the continued performance of essential agency functions, or there were systematic measure-level data issues.

We are not finalizing the proposed provisions at §§ 422.166(j)(1)(v) and 423.186(j)(1)(iv) in this final rule, as CMS was able to calculate the 2021 Star Ratings. We are also not finalizing the special rules for 2021 Star Ratings at §§ 422.164(i) and 423.184(i), as CMS did not identify any data quality issues for non-HEDIS and non-CAHPS measures for the 2021 Star Ratings.

d. Guardrails

CMS modified §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to delay the application of the guardrails for non-CAHPS measures until the 2023 Star Ratings are issued in October 2022. To increase the predictability of the cut points used for measure-level ratings, in the April 2019 final rule (84 FR 15761), we adopted a rule that, starting with the 2022 Star Ratings, guardrails would be implemented for measures that have been in the program for more than 3 years. As specified at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i), the guardrails ensure that the measure threshold-specific cut points for non-CAHPS measures do not increase or decrease more than 5 percentage points from 1 year to the next. As noted in the April 2019 final rule, the trade-off for the predictability provided by the bi-directional cap is the inability to fully

keep pace with changes in performance across the industry. While cut points that change less than the cap would be unbiased and keep pace with changes in the measure score trends, changes in the overall performance that are greater than the cap would not be reflected in the new cut points. We anticipated that most, if not all, contracts could have had performance changes on certain measures as they dealt with the demands of the COVID-19 pandemic that would result in the guardrails not keeping pace with changes in measure scores across the industry. Given the enormity of the COVID-19 pandemic, CMS believed it was important for plans to be able to focus on patients who were in the most need during the outbreak, and our guardrails, as currently constructed, could have had unintended incentives to the contrary.

Comment: Many commenters agreed with our provision delaying the application of guardrails for non-CAHPS measures until the 2023 Star Ratings. These commenters appreciated that CMS recognized the significant changes in health care utilization that have occurred during the pandemic and that these changes in utilization might persist for some time.

Response: CMS appreciates commenters' support for this provision.

After consideration of the public comments and for the reasons provided in the March 31st COVID-19 IFC and our responses to comments, CMS is finalizing without modification the provisions at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to delay the use of guardrails until the 2023 Star Ratings.

e. Improvement Measures

Another provision of the March 31st COVID-19 IFC expanded the existing hold harmless adjustment for the Part C improvement measures at § 422.166(f)(1)(i) and (g)(3), and for the Part D improvement measures at § 423.186(f)(1)(i) and (g)(3), to include all contracts for the 2022 Star Ratings, not just those with 4 or more stars for their highest rating. At the start of the COVID-19 pandemic, CMS anticipated that the pandemic could cause plan performance during the 2020 measurement period to decline across the nation. Therefore, we believed it was appropriate to adopt a provision to minimize the impact of potential declines in the Part C and D improvement measures. Namely, for the 2022 Star Ratings, if the inclusion of the Part C improvement measure reduced the Part C summary Star Ratings, it would be excluded from the calculation of the summary rating; if the inclusion of the Part D improvement measure

reduced the Part D summary Star Rating, it would be excluded from the calculation of the summary rating; and if the inclusion of the Part C and Part D improvement measures reduced the overall Star Ratings, they would be excluded from the overall rating calculation.

Comment: Many commenters supported the hold harmless provision for the Part C and D improvement measures to include all contracts for the 2022 Star Ratings. Some commenters noted that the chaos and disruption brought about by COVID-19, which created unparalleled uncertainty and fear for members regarding health and health care, were likely to eclipse any quality improvement efforts implemented by MA plans during the performance year.

Response: CMS thanks the commenters for their support of this provision.

After consideration of the public comments and for the reasons outlined in the March 31st COVID-19 IFC, CMS is finalizing without modification the provisions at §§ 422.166(g)(3), 423.186(g)(3), 422.166(f)(1)(i), and 423.186(f)(1)(i), to apply the higher ratings after calculating the overall and summary ratings with and without the Part C and/or D improvement measures for all contracts only for the 2022 Star Ratings.

f. QBP Calculations for New Contracts

For the 2021 Star Ratings only, CMS modified the definition of a new MA plan to treat an MA plan as a new MA plan if it was offered by a parent organization that had not had another MA contract for the previous 4 years. New plans that started in 2019 and reported HEDIS and CAHPS data to CMS for the first time in 2020 for the 2021 Star Ratings, because of our elimination of the HEDIS and CAHPS data submissions to CMS, would not have had enough measures to calculate the 2021 Star Ratings and, consequently, the 2022 QBP. A new contract with an effective date of January 1, 2019 would normally have been treated as new for QBP purposes for 2019, 2020, and 2021. The 2022 QBP rating was based on the 2021 Star Ratings, which these new contracts did not have.

Comment: Some commenters supported the modifications made to the definition of a new MA plan for purposes of 2022 QBPs based on 2021 Star Ratings only. However, some commenters stated this modified definition of a new MA plan would penalize new plans, denying them the potential to receive 2022 QBPs. A commenter stated that with respect to

placement on the Medicare Plan Finder, new plans would not have the option of earning top billing and placement if they are forced to remain unrated for 2021.

Response: Modifying the definition of a new MA plan as we did in the March 31st COVID-19 IFC does not preclude a plan from receiving a QBP. In the March 31st COVID-19 IFC, we modified the definition of a new plan such that, for purposes of 2022 QBPs based on 2021 Star Ratings only, an MA plan is considered a new MA plan if it is offered by a parent organization that has not had another MA contract for the previous 4 years (rather than 3 years). New plans under parent organizations with other MA contracts would continue to get the enrollment-weighted average of the ratings of the other MA contracts under the parent organization, while new plans under parent organizations that did not have other MA contracts with ratings would continue to be treated as qualifying plans for the purposes of QBPs and would be eligible to receive a QBP percentage increase to the county rate of 3.5 percentage points.

In terms of placement on Medicare Plan Finder, we note that plans are currently sorted first by premium, not by Star Rating.

After consideration of the public comments and for the reasons outlined in the March 31st COVID-19 IFC and our response to comments, CMS is finalizing the definition at § 422.252 without modification, such that for only the 2022 QBP ratings that are based on 2021 Star Ratings, a new MA plan is defined as one that is offered by a parent organization that has not had another MA contract for the previous 4 years.

4. Provisions in the September 2nd COVID-19 IFC

In addition to the provisions discussed in section II.D.3. of this final rule, the September 2nd COVID-19 IFC also adopted a modification to the application of the extreme and uncontrollable circumstances policy for calculation of the 2022 Star Ratings to address the effects of the COVID-19 PHE (85 FR 54844-47). The September 2nd COVID-19 IFC revised the current disaster policy, codified at §§ 422.166(i) and 423.186(i), for 2022 Star Ratings only by: (1) Removing the 60 percent exclusion rule for cut point calculations for non-CAHPS measures; and (2) removing the 60 percent exclusion rule for the determination of the performance summary and variance thresholds for the Reward Factor. As established by the IFC, new § 422.166(i)(11) provides that CMS does

not apply the provisions of § 422.166(i)(9) or (10) in calculating the 2022 MA Star Ratings; and new § 423.186(i)(9) provides that CMS does not apply the provisions of § 423.186(i)(7) or (8) in calculating the 2022 Part D Star Ratings. This change ensured that CMS could: (1) Calculate measure-level cut points for the 2022 Star Ratings; (2) calculate measure-level Star Ratings for the 2022 Star Ratings; (3) apply the “higher of” policy for non-CAHPS measures, as described at §§ 422.166(i)(3)(iv) and (i)(4)(v) and 423.186(i)(4)(i), for all contracts with 25 percent or more of their enrollees living in FEMA-designated Individual Assistance areas which included all Part C and Part D contracts operational during the 2020 measurement period; and (4) ultimately calculate overall and summary ratings for 2022 Star Ratings and 2023 QBPs.

The following is a summary of the public comments received on these Part C and Part D Star Ratings policies included in the September 2nd COVID-19 IFC.

Comment: Most commenters supported dropping the 60 percent rule to be able to calculate 2022 non-CAHPS measure cut points and apply the existing adjustment for extreme and uncontrollable circumstances. They expressed support for modifying the disaster policy so that measure-level data for affected contracts with 60 percent or more of their enrollees in FEMA-designated Individual Assistance areas during the 2020 performance and measurement period are not excluded from the measure-level cut point calculations for non-CAHPS measures and the performance summary and variance thresholds for the Reward Factor. Given the enormous impact the COVID-19 pandemic has had on the delivery of health care, commenters noted that allowing plans to receive the higher of their measure-level rating from 2021 or 2022 Star Ratings would help ensure that plans are not penalized for declines in performance due to the pandemic.

Response: We thank commenters for their support of these provisions.

Comment: Some commenters requested clarification as to whether the adjustment for extreme and uncontrollable circumstances would apply to the CAHPS measures for the 2022 Star Ratings.

Response: Under §§ 422.166(i)(9) and 423.186(i)(7), CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable

circumstance from the clustering algorithms. This rule is limited to non-CAHPS measures since CAHPS measures do not use the clustering algorithm. Because the calculation of CAHPS cut points was not impacted by the 60 percent rule, it was not included in the IFC provisions. We did not propose or make any changes to the extreme and uncontrollable circumstance rules for the 2022 Star Ratings for CAHPS measures in §§ 422.166(i)(2) and 423.186(i)(2).

Comment: Some commenters requested clarification about when the disaster policy would apply for the measures from the HOS. A few commenters questioned, based on how the disaster policy has previously applied for the HOS measures, whether CMS anticipated that the impacted HOS data collection period would not be until 2021 and the “higher of” methodology would be applicable to the 2023 Star Ratings for HOS measures. Another commenter noted that for purposes of the 2020 Star Ratings, the contracts affected by 2018 disasters received the “higher of” logic for most measures; however, the HOS and HEDIS-HOS measures used the “higher of” logic only for contracts affected by 2017 disasters. The commenter observed that if this timing applied to 2020 disasters, the HOS and HEDIS-HOS measures would receive the higher of current or prior year measure-level Star Ratings in the 2023 Star Ratings.

Response: We agree with these commenters that the HEDIS-HOS measures should receive the adjustment for extreme and uncontrollable circumstances for the 2023 Star Ratings. We proposed in the January 2022 proposed rule a specific provision for 2023 Star Ratings for HEDIS measures derived from the HOS data collection administered in 2021 covering the 2020/2021 period. In section II.D.2. of this final rule, we finalize these changes for the 2023 Star Ratings for the HEDIS-HOS measures.

Comment: A few commenters suggested that not all plans may be eligible for the extreme and uncontrollable circumstances policy.

Response: All Part C and Part D contracts that were operational during 2020 qualified for the relevant disaster adjustments for the 2022 Star Ratings.

After consideration of the public comments and for the reasons outlined in the September 2nd COVID-19 IFC and our responses to comments, CMS is finalizing without modification the provisions at §§ 422.166(i)(11) and 423.186(i)(9) to codify special rules for the calculation of the 2022 Star Ratings.

E. Past Performance (§§ 422.502, 422.504, 423.503, and 423.505)

CMS has an obligation to ensure the organizations with whom it contracts are able to provide health care services to beneficiaries in a high-quality manner. CMS does not want organizations entering into or expanding in the MA and Prescription Drug programs that are poor performers. Currently, if an organization meets all of the requirements of CMS’ MA or Prescription Drug program application, CMS approves the application.

However, the application requirements do not look at an organization’s prior performance in existing contracts. Therefore, if an organization fails to provide key services or administers the program poorly, their application for a new contract or a service area expansion would still be approved. Allowing poor performers into the MA and Prescription Drug programs puts beneficiaries at risk for inadequate health care services and prescription drugs. To avoid poor performers from entering or expanding, CMS first addressed this issue in the MA and Part D program regulations in 2005. CMS has established, at §§ 422.502(b) and 423.503(b), that we may deny an application submitted by an organization seeking an MA or Prescription Drug program contract, including for a service area expansion, if that organization has failed to comply with the requirements of a previous MA or Prescription Drug contract. In the April 2011 final rule (75 FR 19684 through 19686), we completed rulemaking that placed limits on the period of contract performance that CMS would review (that is, 14 months preceding the application deadline) and established that CMS would evaluate contract compliance through a methodology that would be issued periodically through sub-regulatory guidance. In the April 2018 final rule (83 FR 16638 through 16639), we reduced the review period to 12 months. In the January 2021 final rule (86 FR 5864), we established that CMS would only have the authority to deny applications based on an organization’s past performance if an organization was subject to an intermediate sanction and/or failed to maintain a fiscally sound operation during the performance review period. Up until the January 2021 final rule (86 FR 5864) CMS issued a sub-regulatory methodology consisting of eleven areas of poor performance, including negative net worth and being under intermediate sanctions during the performance timeframe. The prior methodology assigned “performance

points” to organizations for each area the organization failed (for example, had a negative net worth resulted in a performance point). If the total number of performance points reached CMS’ threshold the organization’s application would be denied based on past performance. Historically, only a handful of applications have been denied based on prior past performance, with three denials since 2017. The low number of denials has not impacted access to MA plans nor do we believe expanding the bases for denials will impact access. In fact, the average number of plans that a beneficiary has access to has been increasing since 2015 with approximately 99.7 percent of beneficiaries currently having access to an MA plan. In addition, 97.7 percent of eligible beneficiaries have access to ten or more plans in CY 2022.

As stated in the January 2021 final rule, CMS’ overall policy with respect to past performance remains the same. We have an obligation to ensure MA organizations and Prescription Drug sponsors can fully manage their current contracts and books of business before expanding. CMS may deny applications based on past contract performance in those instances where the level of previous non-compliance is such that granting additional MA or Prescription Drug business to the organization would pose a high risk to the success and stability of the MA and Prescription Drug programs and their enrollees.

The January 2021 final rule limited the bases for denial based on past performance to intermediate sanctions and failure to maintain fiscal soundness. In the proposed rule, CMS sought to expand the bases for application denial to include Star Ratings history, bankruptcy proceedings, and certain CMS compliance actions. CMS also proposed to codify the types of compliance notices which would be used as a factor in CMS’ review of an organization’s past performance. These notices are Notices of Non-Compliance (NONCs), Warning Letters (WLs), and Corrective Action Plans (CAPs).

We are codifying the new bases for application denial based on past contract performance as paragraphs (b)(1)(i)(C)—Bankruptcy filing or under bankruptcy proceedings, (b)(1)(i)(D)—low Star Ratings, and (b)(1)(i)(E)—Compliance Actions. We are also codifying CMS’ compliance actions which are NONCs, WLs, and CAPs in §§ 422.504(m) and 423.505(n). We note that the basis for application denial based on past contract performance is not applicable for MA organizations establishing new D-SNP-only contracts

under § 422.107(e) as described in section II.A.6.a.

We proposed to correct a few technical issues identified since the final rule was published in January 2021 and will be codifying those proposals. Specifically, we proposed to correct a drafting error in § 422.502(b)(1)(i)(A) that did not include enrollment sanctions based on medical loss ratios (MLRs) as a basis for an application denial. The technical correction revises § 422.502(b)(1)(i)(A) to also provide for the denial of an application if the organization failed to meet MLR requirements and was prohibited from enrolling pursuant to § 422.2410(c). Secondly, we proposed to correct a minor technical error in § 423.503(b)(1)(i)(A) to remove the word “to” when referencing subpart O. Finally, we proposed to modify §§ 422.502(b)(1) and 423.503(b)(1) by deleting “. . . or fails to complete a corrective action plan during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications. . . .” References to CAPs in §§ 422.502(b)(1) and 423.503(b)(1) were codified more than 15 years ago. Since the original provisions, CMS’ corrective action process has changed and is no longer a reason, by itself, to deny an application.

As discussed, we proposed to include in §§ 422.502(b)(1)(i)(C) and 423.503(b)(1)(i)(C), as a reason for application denial, organizations that have filed for bankruptcy or are currently in bankruptcy proceedings. Failure to maintain a fiscally sound operation results in enrollees being at risk of not being able to obtain needed medical resources if the organization cannot or will not pay its providers. Similar to being fiscally unsound, an organization that will potentially be declared bankrupt may result in beneficiaries not having access to needed services as providers may terminate contracts when the plan fails to pay for their services or items. Since bankruptcy may result in the closure of an organization’s operations, permitting an organization to expand while under bankruptcy proceedings is not in the best interest of the MA or Prescription Drug program. Based on this, we believe that any organization that has filed or is in bankruptcy proceedings should not be permitted to expand their current service area or enter into a new contract.

We also sought to include, in §§ 422.502(b)(1)(i)(D) and 423.503(b)(1)(i)(D), a recent history of low Star Ratings as a reason for application denial. We proposed that CMS would deny an application for a

new contract or a service area expansion from any organization that received 2.5 or fewer Stars.

CMS’ Star Ratings are provided to beneficiaries to help them make informed health care choices. Moreover, MA organizations and Prescription Drug sponsors are required by §§ 422.504(b)(17) and 423.505(b)(26) to maintain summary Part C and/or Part D Star Ratings of at least 3 Stars. Contracts that have 2.5 or less Stars are considered to be “low performers.” Regulations at §§ 422.510(a)(4) and 423.509(a)(4) permit CMS to terminate a contract for having less than 3 Stars for 3 consecutive years in a row for Part C summary ratings or for having less than 3 Stars for 3 consecutive years in a row for Part D summary ratings. Such a termination carries with it an exclusion from future MA or Prescription Drug application approvals for 38 months under §§ 422.502(b)(3) and 423.503(b)(3), a more significant consequence than the 1-year application denial we are discussing in this rule. We have decided, based on comments, that a 2-year history of low Star Ratings is a better indicator of poor performance. However, we are clarifying that the applicant’ that have 2.5 or less stars for their Part C Summary rating, their Part D Summary rating, or a combination of Part C and Part D Summary ratings for two years be subject to application and service area expansion denials.

Finally, we proposed to codify our practice of issuing compliance notices in §§ 422.504(m) and 423.505(n). CMS also proposed, in §§ 422.502(b)(1)(i)(E) and 423.503(b)(1)(i)(E), to include the receipt of specific types of compliance notices as a reason to deny new applications or applications for service area expansions.

Prior to the January 2021 final rule, CMS included compliance letters as a category in our sub-regulatory past performance methodology. This methodology included NONCs, WLs, Warning Letters with Business Plans, and CAPs. These notices are CMS’ formal way of recording an organization’s failure to comply with statutory and/or regulatory requirements as well as providing notice to the organization to correct their deficiencies or risk further compliance and enforcement actions.

Of these three types of notices, requests for CAPs are the most serious of the notice types. CMS issues these notices pursuant to §§ 422.510(c) and 423.509(c), which require CMS to afford non-compliant organizations the opportunity to develop and implement a corrective action plan prior to terminating an MA or Prescription Drug

contract. CMS may request CAPs for a one-time egregious error or an organization's continued failure to correct previously identified deficiencies. The non-compliance resulting in a CAP request usually has beneficiary impact, such as failure to process appeals timely or marketing misrepresentation. In cases where CMS requests a CAP where there is no beneficiary impact, the majority are for continued non-compliance with requirements.

WLs are an intermediate level of compliance action, between a NONC and a CAP. WLs, similar to CAPs, are issued for more egregious instances of non-compliance or continued non-compliance. However, the egregiousness or continued non-compliance, at the time of the notice, would not warrant a request for a CAP. Examples include continued failure to timely send Explanation of Benefits, multiple cost/benefit errors on required beneficiary communication documents, and instances of unsolicited marketing.

NONCs are the lowest form of a compliance action issued by CMS. These notices are issued for the least egregious failures. These failures are often a first-time offense, affect a small number/percentage of beneficiaries, or issues that have no beneficiary impact. Examples may include failure to submit and/or attest to agent/broker compensation data or failure to upload or correctly upload marketing materials.

In determining the level of severity of a compliance action, CMS considers whether an organization self-reported the non-compliance. CMS considers items self-reported when CMS would not have otherwise known about the issue. In cases where we direct organizations to take a specific action, such as reviewing and reporting errors in Summary of Benefits (SB) and Evidence of Coverage (EOC) documents, CMS does not consider this self-reporting.

As mentioned above, self-reporting can affect the level of compliance action issued. CMS reviews the organization's non-compliance and whether the organization self-reported the issue or CMS found the issue through means such as, complaint reviews, notification by a State entity, or a review of requested data. Based on the issue involved, CMS determines the appropriate level of compliance that should be issued, such as a WL or a NONC. If the organization did self-report, CMS will consider lowering the level of compliance (for example, issuing a NONC instead of a WL). However, CMS is not required to lower the level of compliance action if the

issue was self-reported. This is especially the case with respect to NONCs, where the non-compliance is significant enough to warrant a NONC even if self-reported.

We proposed to assign points to each type of compliance action based on the type of notice and then apply a compliance action threshold to determine if the application should be denied. The following points would be assigned: CAP—6 points, WL—3 points, NONC—1 point. CMS will then total the points accrued for each contract, and those applicants that have any single contract with 13 or more compliance action points may have applications for new contracts or service area expansions denied on the basis of past performance.

CMS determined the threshold, by reviewing compliance actions taken from 2017 through November 2021. In the review of this data no more than three organizations, out of over three hundred organizations, scored 13 or more compliance action points in any one year. When looking at a percentile, based on historical data, an organization would need be in the top 2 percent of plans based on compliance action points to accrue 13 compliance action points.

For these reasons, we are finalizing the regulations as proposed, with clarifications regarding compliance actions and modifications to Star Ratings. Below we summarize the comments received and our responses.

Comment: We received numerous comments supporting our provisions.

Response: We appreciate the support for our proposals.

Comment: A few of the commenters who supported our provisions requested CMS take stronger action against plans including reviewing plan governance, civil and criminal penalties, ensuring plans have enough liquid assets to cover liabilities to providers, and reviews of consumer complaints.

Response: CMS appreciates the recommendations and will continue to review performance areas to determine if additional reasons for service area expansions and application denials should be added to future regulations.

Comment: A few commenters suggested that the overall methodology was too harsh and that it would penalize too many plans. A commenter suggested that we limit denials to one contract per Parent organization and do not deny applications of contracts that have less than 10 percent of the Parent organization's total enrollment.

Response: CMS appreciates the suggestion but does not believe it is in the best interest of the program to limit

denials to one contract per Parent organization or those contracts with less than 10 percent of the Parent organization's enrollment. The purpose of past performance is to limit the expansion of all poor performing applicants, not just one poor performing contract or only those contracts with significant enrollment. The goal of past performance assessments would be undermined should a Parent organization be allowed to choose which contracts are subject to the past performance evaluation and which are not. The purpose of our past performance evaluation is to ensure that all applicants, regardless of enrollment numbers, are sufficiently qualified to expand into a new service area or enter into a new contract.

Comment: A commenter suggested CMS go back to the past performance methodology prior to the January 2021 final rule, specifically using the outlier percentage threshold for compliance letters and requiring poor performance in more than one category.

Response: CMS appreciates the comment. However, we believe the current and proposed methodology sufficiently identifies poor performers. The previous methodology, using an 80 percent and 90 percent outlier resulted in "poor performers" in the compliance category regardless of the number of compliance actions received. A contract with few compliance actions could be considered an outlier based on other contracts having one or two fewer compliance actions. The prior methodology also failed to identify poor performers if many contracts received a significant number of compliance actions. We believe the threshold number appropriately identifies all contracts that are poor performers in the compliance action category. We also do not agree that an applicant should be required to have poor performance in more than one category. We believe failing to meet CMS' requirements for any of our categories is sufficient to determine that the applicant is not qualified to enter into new contracts or expand existing service areas based on their past performance. Therefore, we will continue to deny applications when the applicant fails to achieve sufficient performance in any one category.

Comment: We received a few comments requesting clarification or asking that CMS' Program Audit Corrective Action Plans be excluded from the compliance category.

Response: CMS is clarifying that CAPs resulting from CMS' Program Audits were not included in the compliance action category of our proposal or this final rule.

Comment: We received comments regarding the inclusion of Star Ratings as one of the bases for application denials. A few commenters asked if the Star Ratings used for past performance were the overall Star Ratings or the summary Star Ratings for Part C and Part D. A few commenters requested that CMS use the overall Star Ratings and a few commenters requested that CMS average the parent organization's Star Ratings instead of using the contract-level Star Ratings.

Response: CMS notes that Star Ratings are calculated at the contract level and not the parent organization level. In addition, we note that CMS contracts with a legal entity, not a parent organization. Therefore, averaging all Star Ratings for all contracts under a parent organization would be inconsistent with how CMS contracts with organizations. As for using the overall Star Rating instead of the Part C or Part D Summary rating, CMS notes that our existing termination authority at §§ 422.504(a)(17) and 423.505(b)(26) is based on low ratings for either the Part C or Part D summary rating. Using the overall Star Rating for past performance would be inconsistent with the application of Star Ratings for termination. To ensure clarity, we have modified the regulatory text to clarify that CMS will use the Part C or Part D summary Star rating for past performance purposes.

Comment: Commenters had various concerns regarding Star Ratings in the past performance methodology. A few commenters opposed including Star Ratings in the methodology. Commenters expressed concern that public health emergencies, such as COVID-19, had a negative effect on Star Ratings. A few commenters believe the inclusion of Star Ratings would disincentivize high performing plans from acquiring low performing plans and decrease plan options. Other commenters stated that CMS already has the authority to terminate contracts after three years of low ratings and that should be sufficient. A few commenters suggested that CMS use two years, instead of one year, of Star Ratings in the past performance methodology.

Response: CMS appreciates the commenters' concerns regarding the inclusion of Star Ratings in the past performance methodology. Based on the comments received, we are finalizing our proposal with a modification to require that a contract have two consecutive years of Part C Summary, Part D Summary, or a combination of Part C and Part D Summary ratings of 2.5 or below to receive a denial of new applications or service area expansions.

CMS will use the two most recent Star Ratings period—that is, those that fall in the 12-month lookback period as specified in 42 CFR 422.502(b)(1) and 423.503(b)(1). More specifically, if an organization received a Part C summary rating of 2.5 or below for both of the most recent Star Rating periods, CMS will deny a new application or a service area expansion. The same holds true if an organization received a Part D summary rating of 2.5 or below for both of the most recent Star Rating periods. If an organization received a Part C summary rating of 2.5 or below for one of the Star Rating periods during the most recent lookback period and received a Part D summary of 2.5 or below for the other Star Rating period during the most recent lookback period, CMS will also deny new applications or service area expansions. For example, for a 2024 application submitted in February 2023, the lookback period will be March 1, 2022 through February 28, 2023, which includes the 2022 and 2023 Star Ratings periods. If the applicant received a summary Star Rating of 2.5 or below for Part C or Part D for the 2022 Star Rating period AND for the 2023 Star Rating period, then the application will be denied. If the organization received a Part C/or Part D summary Star Rating of 2.5 or below only for the 2022 Star Rating period or only for the 2023 Star Rating period, then the application will not be denied.

With respect to commenters' concern that emergencies, such as the COVID-19 pandemic, negatively affect Star Ratings, we note that CMS addresses emergencies, such as COVID-19, in the calculation of Star Ratings using an adjustment for extreme and uncontrollable circumstances policy codified at §§ 422.166(i) and 423.186(i) to mitigate the impact of the disaster on Star Ratings. CMS adopted a number of changes to address expected changes in plan performance due to the COVID-19 public health emergency (PHE) on Star Ratings in the March 31st COVID-19 IFC (85 FR 19230) and September 2nd COVID-19 IFC (85 FR 54820). Although we expected a decline in measure scores across Star Ratings measures for the 2020 measurement year, we did not see a decline across all measures and saw an increase in scores for a number of measures (see the Fact Sheet—2022 Part C and D Star Ratings⁸⁶). Based on CMS's authority to account for extreme and uncontrollable circumstances, such as the COVID-19, we do not believe the methodology needs to be modified based on issues related to disasters.

Finally, in response to the commenters who believe that plan choices will decrease as a result of our proposed inclusion of low Star Ratings as a basis for application denial, we believe the commenters do not fully understand the proposed methodology. The purpose of the methodology is to prohibit expansions of contracts, not to terminate or decrease the service area of contracts. Based on this, beneficiaries will still be able to enroll or stay enrolled in an existing contract, even though the contract has low Star Ratings. However, the legal entity will not be able to expand into new service areas or add new contracts.

Comment: A few commenters were unsure if the methodology was at the Parent organization level, the legal entity level, or the contract level.

Response: CMS' contract and past performance methodology is calculated at the legal entity level. CMS contracts with a legal entity that covers one or more contracts. If any one of the contracts under the legal entity meets any one of the reasons for denial, all new applications and service area expansions under that legal entity will be denied.

Comment: A few commenters suggested CMS provide MA organizations with an appeal process for compliance actions.

Response: CMS appreciates the need to ensure that compliance actions taken against MA organizations are accurate and appropriate. However, we do not believe an appeal process is necessary. The majority of our compliance actions are data driven, with formal thresholds that define whether an organization receives a compliance action and what level of action is issued. CMS also has an organized process which all potential compliance actions must go through, resulting in greater consistency in the issuance of compliance actions. In addition, when requested by an organization, CMS reviews information provided by the organization and re-reviews the compliance action to determine if the action was appropriate. CMS has a long-standing history of discussing compliance actions with organizations and retracting or modifying compliance actions when necessary. Based on our existing process we do not feel a formal appeals process is necessary for compliance actions. CMS notes that a formal appeal process is available for applicants whose application has been denied for past performance reasons specified in this rule.

Comment: A few commenters were unsure if the compliance action threshold was at the contract level or if

⁸⁶ Part C and D Performance Data CMS.

all contract points for the legal entity were added together.

Response: The compliance action point threshold of 13 is at the contract level. We have modified the regulatory text to ensure clarity regarding the point threshold. CMS will review all of the compliance actions and total the points for each contract. If any particular contract under a legal entity has 13 or more compliance action points new applications and service area expansions for that legal entity will be denied.

Comment: A few commenters were concerned that one small contract could affect the entire organization.

Response: CMS acknowledges that one poor performing contract could prohibit an applicant from service area expansions of other contracts or prohibit the applicant from entering into a new contract. As previously stated, if an organization has a poor performing contract it is in the best interest of the program for that organization to focus on improving the performance of the poor performing contract, no matter how small or how few enrollees are in the contract, instead of expanding their footprint. CMS believes all contracts under a legal entity should meet our requirements before that legal entity is permitted to expand into new service areas or add new contracts.

Comment: A commenter stated that CMS should only consider the financial health of the acquiring organization and not of the financial health of the organization being acquired.

Response: Organizations that acquire a poor performing organization are provided a 24-month grace period preceding the subsequent application deadline, after which the performance of the acquired organization will be factored into the acquiring organization's performance. Based on this, if a fiscally sound organization acquires an organization that fails to meet CMS' net worth requirements, the acquiring organization will not be denied the opportunity to expand into new service areas or add new contracts, if the entity was acquired within the 24-month period prior to the application deadline. However, the acquired organization will still be denied. Given the acquired organization has significant fiscal soundness issues, the acquiring organization should be putting all necessary resources into the acquired organization's fiscal soundness issues, rather than trying to expand or enter into new contracts under that legal entity.

Based on the comments received, we are finalizing as proposed with a few modifications. The first modification is

to use 2 years of Star Ratings for Part C Summary, Part D Summary, or a combination of Part C and Part D Summary ratings. The second modification is to clarify that CMS is using the Part C Summary and Part D Summary Star ratings. The final modification is to clarify that the 13 compliance action points are allotted on a per contract basis.

F. Marketing and Communications Requirements on MA and Part D Plans To Assist Their Enrollees (§§ 422.2260 and 423.2260, 422.2267, and 423.2267)

As discussed in the proposed rule, sections 1851(h) and (j) of the Act provide a structural framework for how MA organizations may market to beneficiaries and direct CMS to adopt standards related to the review of marketing materials and limitations on marketing activities. Section 1860D–1(b)(1)(B)(vi) of the Act directs that the Secretary use rules similar to and coordinated with the MA rules at section 1851(h) of the Act for approval of marketing material and application forms for Part D plan sponsors. Section 1860D–4(l) of the Act applies certain prohibitions under section 1851(h) of the Act to Part D sponsors in the same manner as such provisions apply to MA organizations. In addition, sections 1852(c) and 1860D–4(a) of the Act provide that MA organizations and Part D sponsors must disclose specific types of information to each enrollee. Based on these authorities, CMS has promulgated regulations related to marketing and mandatory disclosures by MA organizations and Part D sponsors in 42 CFR part 422, subparts C (at § 422.111) and V; as well as 42 CFR part 423, subparts C (at § 423.128) and V, as directed in the statutory authority granted to the agency. Additionally, as we noted in the proposed rule, under 42 CFR 417.428, most marketing requirements in subpart V of part 422 also apply to section 1876 cost plans. Finally, CMS has authority to adopt additional contract terms for cost plans (section 1876(i)(3)(D) of the Act), MA plans (section 1857(e)(1) of the Act), and Part D plans (section 1860D–12(b)(3)(D) of the Act) where such terms are not inconsistent with the Medicare statute and that we determine are necessary and appropriate.

As we did in the proposed rule, because the changes that CMS is finalizing in this section are, unless otherwise noted, applicable to MA organizations, Part D plan sponsors, and section 1876 cost plans, we collectively refer to these entities in this section as “plans.”

In the January 2021 final rule, entitled “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), we codified much of the communications and marketing guidance previously found in the Medicare Communications and Marketing Guidelines (MCMG). In this final rule, we are codifying additional guidance and standards from the MCMG that was not part of the January 2021 final rule related to member ID card standards, the limited access to preferred cost-sharing pharmacies disclaimer, plan website instructions on how to appoint a representative, and the website posting of enrollment instructions and forms. In addition, we are codifying several new communications and marketing requirements aimed at further safeguarding Medicare beneficiaries, including reinstating the requirement that plans include a multi-language insert with specified required materials. Finally, we are codifying requirements to address concerns associated with third-party marketing activities.

1. Required Materials and Content

Under § 422.111(i), MA plans must issue and reissue (as appropriate) member identification cards that enrollees may use to access covered services under the plan. Likewise, under 1860D–4(b)(2)(A) of the Act and § 423.120(c)(1), a Part D plan sponsor must issue a card or other type of technology that its enrollees may use to access negotiated prices for covered Part D drugs. In the proposed rule, we proposed to codify CMS's current guidance for additional ID card standards, which has historically been issued in the MCMG.

Comment: Most comments that we received on this proposal were supportive. Commenters indicated that including ID cards as required materials will ensure consistency for beneficiaries regardless of the plan in which they enroll.

Response: We acknowledge and appreciate the support for this provision as well as the awareness of the vital nature of the provision.

Comment: We received a comment that pursuant to the existing standards for required materials and context, the ID card would, as a required material, be subject to the 12-point font requirement whereas CMS guidance has previously excluded ID cards from that requirement. Such comment requested

that we continue to exclude the ID card from the 12-point font requirement to which required materials are subject.

Response: We thank the commenter and acknowledge that it would be impractical to require a 12-point font on an ID card. Furthermore, we acknowledge that we have previously (in the MCMG) excluded the ID card from the 12-point font requirement. In addition, we note that CMS has followed the guidance of the Workgroup for Electronic Data Interchange (WEDI) in crafting our required formatting for communications materials. However, as WEDI does not stipulate any requirements for font size, we will not extend our font size requirement to ID cards.

We are codifying the guidance for ID card requirements under §§ 422.2267(e)(30) and 423.2267(e)(32) as proposed, except that in response to the aforementioned comment we are including an additional clarifying at §§ 422.2267(e)(30)(vii) and 423.2267(e)(32)(vii) to exclude the ID cards from the 12-point font size requirement under §§ 422.2267(a)(1) and 423.2267(a)(1). In addition, we have renumbered the remaining required content beginning with the Federal Contracting statement, previously at §§ 422.2267(e)(30) and 423.2267(e)(32).

In the January 2021 final rule, when codifying several other required disclaimers previously provided in the MCMG, Appendix 2, at §§ 422.2267(e) and 423.2267(e), CMS inadvertently left out the disclaimer for Part D sponsors with limited access to preferred cost-sharing pharmacies. In the January 2022 proposed rule, we discussed the importance of this disclaimer and the impact of its omission on Medicare beneficiaries enrolled in Part D plans that only provide access to preferred cost-sharing through a limited number of pharmacies.

Comment: The comments we received on this proposal were supportive.

Response: We acknowledge and appreciate the support for this proposal.

For the reasons set forth in the proposed rule and in response to the supportive comments we received, we are codifying this disclaimer requirement at § 423.2267(e)(40), as proposed.

2. Website Requirements

The regulations at §§ 422.111(h)(2) and 423.128(d)(2) require plans to have an internet website and include requirements regarding posted content. In the January 2021 final rule, we codified additional requirements for plan websites at §§ 422.2265 and 423.2265 based on section 70.1.3

(Required Content) of the MCMG. In doing so, we inadvertently failed to include the requirement that plans post instructions about how to appoint a representative and include a link to a downloadable version of the CMS Appointment of Representative Form (Control Number 0938–0950), as well as enrollment instructions and forms.

Comment: We received comments supporting this proposal.

Response: We acknowledge and appreciate the support for this provision.

Comment: A commenter noted that CMS did not include the Notice of Dismissal of Appeal in part 423. Additionally, CMS has not included the Notice of Dismissal of Coverage Request in either part 422 or 423. The comment requested that CMS codify both of these notices as indicated.

Response: This comment is outside the scope of the current rule. However, CMS appreciates the observation and will consider this suggestion in future rulemaking. We note that the appeal regulations in subparts M of parts 422 and 423 (for example §§ 422.568(h) and 423.568(j)) address the content requirements for notices of dismissal.

In this final rule, after consideration of the comments received in response to this proposal and for the reasons described in the proposed rule, we are codifying these two requirements as proposed under §§ 422.2265(b)(13), 423.2265(b)(14), 422.2265(b)(14), and 423.2265(b)(15), respectively.

3. Multi-Language Insert

In the proposed rule, we explained the history of the multi-language insert (MLI) (a standardized document that informs the reader that interpreter services are available in the 15 most common non-English languages in the United States), CMS's previous requirement in the Medicare Marketing Guidelines (MMG) that plans include the MLI with certain materials, and why CMS eventually removed from this requirement for MA plans, Part D sponsors, and 1876 cost plans because it was duplicative of certain notice and tagline requirements implemented by the Office for Civil Rights (OCR) in 2016. Specifically, on May 18, 2016, the OCR published a final rule (81 FR 31375; hereinafter referenced to as the section 1557 final rule) implementing section 1557 of the Patient Protection and Affordable Care Act (ACA) (Pub. L. 111–148). Section 1557 of the ACA provides that an individual shall not be excluded from participation in, be denied the benefits of, or be subjected to discrimination on the grounds prohibited under Title VI of the Civil

Rights Act of 1964, 42 U.S.C. 2000d *et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq.* (sex (including pregnancy, sexual orientation, and gender identity)), the Age Discrimination Act of 1975, 42 U.S.C. 6101 *et seq.* (age), or section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794 (disability), under any health program or activity, any part of which is receiving Federal financial assistance; any health program or activity administered by the Department; or any program or activity administered by any entity established under Title I of the Act. Part of OCR's 2016 final rule (81 FR 27778) included the requirement that all covered entities include taglines with all "significant communications". The sample tagline provided by the Department consisted of a sentence stating "ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1-xxx-xxx-xxxx (TTY: 1-xxx-xxx-xxxx)." in the top 15 languages spoken in a state or states. Because of the inherent duplication with the MLI, CMS issued an HPMS email on August 25, 2016 removing the MLI. On June 14, 2019, OCR published a proposed rule that, among other actions, proposed to repeal the requirement that notices and taglines be provided with all significant communications (84 FR 27846). Finally, on June 19, 2020, OCR published a final rule that finalized the repeal of the notice and tagline requirements while requiring that a covered entity take reasonable steps to ensure meaningful access to its programs or activities by LEP individuals (85 FR 37160, 37210, 37245).

In a proposed rule titled "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," which appeared in the **Federal Register** on February 18, 2020 (85 FR 9002) (hereinafter referred to as the February 2020 proposed rule), CMS proposed an availability of non-English translations disclaimer. The disclaimer consisted of the statement "ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1-XXX-XXX-XXXX (TTY: 1-XXX-XXX-XXXX)." We proposed that the disclaimer be required in all non-English languages that met the five percent threshold for language

translation under §§ 422.2267(a)(2) and 423.2267(a)(2). In addition, when applicable, we proposed the disclaimer be added to all required materials under §§ 422.2267(e) and 423.2267(e). However, we did not finalize the proposed disclaimer in January 2021 final rule (86 FR 5995). In doing so, we stated that CMS believed future rulemaking regarding non-English disclaimers, if appropriate, was best addressed by OCR, as those requirements would be HHS-wide instead of limited to CMS. We also stated that CMS believed deferring to OCR's oversight and management of any requirements related to non-English disclaimers was in the best interest of the Medicare program.

It is important to note that none of CMS's actions impacting the various notifications of interpreter services changed the requirement that plans must provide these services under applicable law. Plans have long been required to provide interpreters when necessary to ensure meaningful access to limited English proficient individuals, consistent with existing civil rights laws. In fact, in the January 2021 final rule, CMS codified call center requirements under §§ 422.111(h)(1)(iii) and 423.128(d)(1)(iii) that require interpreter services be provided to non-English speaking and limited English proficient (LEP) individuals at no cost.

In the months following the publication of the January 2021 final rule, we have gained additional insight regarding the void created by the lack of any notification requirement associated with the availability of interpreter services for Medicare beneficiaries. The U.S. Census Bureau's 2019 American Community Survey (ACS) 1-year estimates show that 12.2 percent of individuals sixty-five and older speak a language other than English in the home (<https://data.census.gov/cedsci/table?q=language&tid=ACSS1Y2019.S1603>). CMS considers the materials required under §§ 422.2267(e) and 423.2267(e) to be vital to the beneficiary decision making process. Providing a notification for beneficiaries with limited English proficiency that translator services are available provides a clear path for this portion of the population to properly understand and access their benefits. We have also reviewed complaints in the Complaint Tracking Module (CTM) under the term "language" and found several reporting beneficiary confusion based on a language barrier. In retrospect, we believe that solely relying on the requirements delineated in OCR's 2020 final rule for covered entities to convey the availability of interpreter

services is insufficient for the MA, cost plan, and Part D programs, and is not in the best interest of Medicare beneficiaries who are evaluating whether to receive Medicare benefits through these plans, as well as those already enrolled. Ultimately, we believe it is counterproductive to have regulatory requirements for interpreter services without an accompanying requirement to inform beneficiaries that the service is available.

In the January 2022 proposed rule, we therefore proposed the requirement to use the MLI under §§ 422.2267(e)(31) and 423.2267(e)(33). Similar to the previously required version, the MLI must state "We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who speaks [language] can help you. This is a free service." in the 15 most common non-English languages in the United States. In addition, we proposed the requirement that plans also include the required statement in any language that meets the five percent threshold for a plan's service area, as currently required under §§ 422.2267(a)(2) and 423.2267(a)(2) for translation of required materials, when not currently on the standardized MLI. We also proposed the requirement that the MLI be included with all required materials listed in §§ 422.2267(e) and 423.2267(e). Finally, in the January 2022 proposed rule, we explained that if OCR were in the future to finalize broader or more robust requirements associated with interpreter services than what CMS requires and plans adopted those broader or more robust OCR requirements, CMS would consider plans compliant with these MLI requirements.

Comment: Most commenters supported this proposal. Many of these commenters pointed out that individuals who do not speak English are often unaware of their rights. The commenters asserted that having the MLI included with required documents was the best way to reach these individuals.

Response: We acknowledge and appreciate the support. As stated above, we have reviewed CTM cases and found reported beneficiary confusion stemming from not fully understanding materials based on a language barrier. While MA organizations, Part D sponsors, and cost plans are required to provide translator services, the requirement cannot be effective if those organizations do not also inform beneficiaries that those services are available. As we consider certain required documents to be vital to a

beneficiary's understanding of the MA, Part D, and cost plan programs, we agree that the requirement to include the MLI with those required documents is the best way to reach the target audience.

Comment: Many commenters suggested different ways to implement this provision including requiring the MLI to be sent with only specific required documents (such as the Summary of Benefits, the Evidence of Coverage, and the Annual Notice of Change), requiring the MLI as a disclaimer on certain required documents, limiting delivery of the MLI to once annually, placing the MLI on the plan's website, and sending the MLI as a small flyer with required documents.

Response: We appreciate the suggested alternate methods. However, we believe that requiring the MLI as a separate full-page document that is included or provided with all required documents is the best way for the MLI to reach the target audience. CMS required plans to provide the MLI under similar circumstances for several years before replacing it with the language assistance notice and tagline requirements adopted in OCR's 2016 final rule. OCR implemented the same dissemination method in its section 1557 final rule from July 18, 2016. Between the MLI and OCR's analogous language assistance notice and tagline requirements, CMS has used this method for over 10 years with positive feedback and few complaints. To reiterate, we are again requiring plan delivery of the MLI to address the lack of any notification requirement associated with the availability of interpreter services for Medicare beneficiaries that exists since OCR repealed the notice and tagline requirements in its June 19, 2020 final rule.

Comment: We received a comment on the MLI indicating a fear that beneficiaries will not read it as they receive a prohibitive volume of paper materials.

Response: For enrollees whose primary language is not English, we are confident, based on historical consumer testing, that they will notice a one-page document, prominently displayed with required documents, directing them how to access support in their chosen language.

After careful consideration of all the comments received, and for the reasons set forth in the January 2022 proposed rule and in our responses to the comments, we are finalizing this provision under §§ 422.2267(e)(31) and 423.2267(e)(33) as proposed.

4. Third-Party Marketing Organizations

In the proposed rule, we discussed our concerns regarding third-party marketing organizations (TPMOs) as well as the reasons for those concerns. We also explained that, while we acknowledge that TPMOs can serve a role in helping a beneficiary find a plan that best meets the beneficiary's needs, additional regulatory oversight is required to protect Medicare beneficiaries from confusing and potentially misleading activities in this space and to ensure that Medicare health and drug plans are appropriately overseeing and maintaining responsibility for the entities that conduct marketing and, potentially, enrollment activities on the plans' behalf. To this end, CMS proposed several updates to various sections of parts 422 and 423, subpart V.

First, we proposed to define TPMOs in §§ 422.2260 and 423.2260 as being organizations that are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment, that is the steps taken by a beneficiary from becoming aware of a Medicare plan or plans to making an enrollment decision. In addition, the proposed definition of TPMOs specifies that TPMOs may be first tier, downstream or related entity (FDRs), as defined under §§ 422.504(i) and 423.505(i), but TPMOs may also be other businesses which provide services to customers including an MA or Part D plan or an MA or Part D plan's FDRs. CMS specifically solicited comments from stakeholders regarding the proposed TPMO definition and whether it is sufficiently broad to capture the scope of the types of entities that may be in a position of marketing Medicare health and drug plans. Comments revealed that many of the commenters thought the definition was too broad. Those commenters indicated that they felt the definition would apply to entities to whom it shouldn't apply or would be a burden to compliant organizations instead of applying compliance actions to deter bad actors. There was comment that the definition was too narrow, and that there would be bad actors who were not captured by the definition. We decided, for the reasons discussed in our below response to these comments, that the definition, with clarifying edits described in this final rule, is sufficient for now but may choose to revisit it in future rule-making if the evolving industry landscape indicates that reevaluation is necessary.

Second, we proposed to codify, in §§ 422.2267(e)(41) and 423.2267(e)(41), the requirement that TPMOs use a

standardized disclaimer that states "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." As part of this proposal, MA organizations and Part D sponsors would need to ensure that any TPMO with which they do business, either directly or indirectly, utilizes this disclaimer where appropriate. MA organizations and Part D sponsors would also need to ensure TPMO's adherence with these requirements through contractual arrangements, review of materials or other appropriate oversight methods available to the MA organization or Part D sponsor such as complaint reviews or audits. CMS would not require the disclaimer for those TPMOs who truly offer every option in a given service area. TPMOs would be required to prominently display the disclaimer on their website and marketing materials, including all print materials and television advertising that meet the definition of marketing. We also would require that the disclaimer be provided verbally, electronically, or in writing, depending on how the TPMO is interacting with the beneficiary. In cases where the TPMO is providing information through telephonic means, the TPMO would be required to provide this disclaimer within the first minute of the call. We believe the proposed disclaimer would help to reduce the type of beneficiary confusion CMS observed when we listened to TPMO-based sales calls.

Third, we proposed to codify new TPMO oversight responsibilities in §§ 422.2274 and 423.2274, covering agent, broker, and other third-party requirements. These requirements would fall under §§ 422.2274(g) and 423.2274(g), with the heading "TPMO oversight," and would work (when applicable) in conjunction with the previously existing FDR requirements in §§ 422.504(i) and 423.505(i). As a part of their oversight responsibilities, plans that do business with a TPMO, either directly or indirectly through an FDR, would be responsible for ensuring that the TPMO adheres to any requirements that apply to the plan. An MA or Part D plan cannot purchase the services of a TPMO, and thereby evade responsibilities for compliance with Medicare marketing and communication requirements. This proposed new requirement that those instances where the TPMO does not contract either directly with the MA organization or the Part D sponsor or indirectly with a plan's FDR, but where the plan or its

FDR purchases leads or otherwise receives leads directly or indirectly from a TPMO. It is the responsibility of the MA organization or Part D sponsor to have knowledge of how and from where it (or its FDR) obtains leads or enrollments. We also proposed to require plans (and their FDRs), in their contracts, written arrangements, or agreements with TPMOs, to require TPMOs to disclose to the plan any subcontracted relationships used for marketing, lead generation, and enrollment; require sales calls with beneficiaries to be recorded in their entirety; and have TPMOs report to plans any staff disciplinary actions associated with Medicare beneficiary interaction on a monthly basis. As discussed in the proposed rule, MA organizations and Part D sponsors may not utilize TPMOs as means of evading their own compliance responsibilities, and thus these oversight requirements are intended to require plans to ensure that TPMOs adhere to any requirements that apply to the plans themselves. Based on this, we are finalizing changes to the proposed oversight requirements at §§ 422.2274(g)(2)(iii) and 423.2274(g)(2)(iii) to require that violations by TPMOs of requirements that apply to the MA organization or Part D sponsor be reported to MA organizations and Part D sponsors, in addition to disciplinary actions. These reporting requirements would ensure that plans are made aware of all TPMO-associated activities that are part of or related to the chain of enrollment.

Fourth, we proposed to codify a requirement to provide beneficiaries with certain notifications associated with TPMO lead generating activities. In the proposed rule, we discussed how beneficiaries are receiving outreach from sales agents and brokers based on previous contact and how this outreach in response to the previous contact was not prohibited as unsolicited. We explained the potential for bad actors to abuse this situation, and how beneficiaries were concerned about how the sales agent or broker had obtained the beneficiary's contact information. As part of the proposed rule, plans would be required to ensure that TPMOs conducting lead generating activities inform the beneficiary that his or her information will be provided to a licensed agent for future contact, or that the beneficiary is being transferred to a licensed agent who can enroll him or her into a new plan. This requirement would help to eliminate beneficiary confusion by making the role of lead generating TPMOs more transparent.

Overall, we believe the proposed requirements associated with TPMOs

will result in greater plan oversight of TPMOs, and in turn, will result in a more positive beneficiary experience as it relates to learning about plan choices to best meet their health care needs. We also believe the new requirements will complement and strengthen existing requirements. The finalized disclaimers and notifications will ensure that beneficiaries are more informed.

Moreover, the more robust reporting requirements and oversight we now require will create a better mechanism for plans to be made aware when beneficiary-related issues arise.

Comment: We received many comments supporting these proposals. Most of the supporting comments indicated the “severe” impact of bad actors in the TPMO industry on the Medicare beneficiary population and the MA and Part D markets. These comments also commended CMS for being accountable and taking action to curtail “predatory” activities of these entities.

Response: We acknowledge and appreciate the support of these proposals.

Comment: We received a few comments indicating that these proposed changes are not sufficient as a whole to protect Medicare beneficiaries from the actions of TPMOs. These commenters often suggested that CMS develop mechanisms, best practices, or rules to further curtail the activities of TPMOs. Other commenters suggested CMS create a reporting mechanism specifically for instances where beneficiaries have had detrimental experiences with TPMOs.

Response: We appreciate that the impact of TPMOs on Medicare beneficiaries bears further observation and analysis. As proposed, we believe that these requirements should reduce the incidence of confusing and misleading marketing activities leading to, for example, improper enrollments, by making beneficiaries more well-informed. CMS has a mechanism, through 1–800 Medicare, for reporting detrimental experiences with TPMOs. We review those complaints in our Complaint Tracking Module (CTM). CMS also engages in robust surveillance of agents associated with TPMOs, monitoring their sales and enrollment of beneficiaries. Overall, we have laid the groundwork from which we can develop additional rules addressing potentially confusing and misleading activities in this space, while acknowledging the conscientious performers who act within scope to educate and inform beneficiaries of their healthcare options. While we recognize that our authority to enforce compliance on TPMOs is

limited to MA organizations, cost plans, and Part D sponsors, there is room to develop additional parameters around TPMOs as we gain a greater awareness of their impact on the Medicare insurance landscape. We will consider the suggestions made by these commenters as we contemplate future rulemaking.

Comment: We received a comment on this provision indicating that a supporting provision further delineating the difference between educational and marketing events is necessary.

Response: We appreciate this comment. It is, however, outside the scope of this rule. We will consider this suggestion for future policymaking in §§ 422.2264(c) and 423.2264(c) as those sections provide an explanation of the difference between educational events and marketing events.

Comment: We received comments on this provision providing suggestions as to language of the disclaimer the rule requires. Some commenters suggested TPMOs be allowed to modify the disclaimer language to suit individual situations where the operational systems of the TPMO make use of the disclaimer problematic. Some commenters suggested that TPMOs be allowed to modify the disclaimer language when reaching out to individuals with whom they have a business relationship. Some commenters suggested that CMS modify the disclaimer language so that entities cannot incorrectly say that beneficiaries will receive their full Medicare benefits upon enrollment in an MA plan. Some commenters suggested that the language in the disclaimer be more direct, that the disclaimer should make it clear that not all plans and benefits are available in all service areas. Some commenters stated that CMS should require stronger disclaimer language including consideration of provider network and availability of current prescription drugs. Other commenters suggested that the disclaimer contain language referring beneficiaries to other educational tools including *Medicare.gov*, State Health Insurance Programs (SHIPs), and other educational resources.

Response: We respectfully disagree. CMS carefully considered the content and length of this disclaimer, and believes all of it contains vital beneficiary information. The potential burden imposed by reading or listening to this disclaimer is necessary to ensure that plans, and TPMOs engaged in marketing activities on their behalf, are not providing information that could mislead beneficiaries into joining plans contrary to their intention for reaching

out, or do not best meet their needs. For example, the TPMO disclaimer makes it clear that the TPMO does not offer all available plans, and that beneficiaries must call 1–800 Medicare or visit *Medicare.gov* for that information. CMS believes it provides the most pertinent information without including more content than a beneficiary can reasonably absorb and understand, especially during the limited duration of a television or radio advertisement. Requiring disclaimer language such as provider networks availability of current prescription drugs, or language referring beneficiaries to other educational resources, while good information, could cause the beneficiary to miss the most pertinent information directly related to the sales and enrollment activities of TPMOs. Furthermore, requiring a standardized notice ensures that all beneficiaries receive the same message, and assists CMS by allowing easier and more robust oversight of that message. The commenters had suggested modifications that either narrowed the scope of the disclaimer beyond what we had intended, or altered the disclaimer such that it no longer matched our intentions. While we received no specific examples of what operational limitations make compliance challenging, we will review specific requests and will consider allowing modifications accordingly. We do not believe that having an existing relationship with a beneficiary reduces the need for him or her to receive the exact information in this disclaimer. Regarding commenters who are concerned about the disclaimer not conveying that enrollees will not receive full benefits upon enrollment, please note that the requirements to not provide inaccurate or misleading information that currently apply to MAOs and Part D sponsors (§§ 422.2262(a)(1)(i), 423.2262(a)(1)(i)) also apply to TPMOs under the proposed TPMO oversight requirements. What we proposed and are finalizing does match what we intended in both definition and scope.

Comment: We received several comments on the definition of TPMOs, including comments requesting additional clarity about what types of entities would be included within this definition. Some commenters indicated that the definition of TPMOs was too broad such that the provisions would apply unfairly to different actors in the Medicare Advantage and Part D plan sales landscape including call center employees and advocates. Additionally, some commenters believed the proposed definition of TPMOs was too

narrow. Specifically, some commenters suggested that agents and brokers should be included in the definition of TPMOs. Other commenters suggested that agents and brokers should not be included in the definition of TPMOs. Some commenters suggested we limit the definition of TPMO to those entities with whom plans have a direct relationship. Some commenters suggested we limit the definition of TPMO to those entities who are able to offer only a specific plan within a service area. Some commenters suggested we limit the definition of TPMO to those entities who are able to offer only a specific plan within a service area. Some commenters suggested that the definition of TPMO be limited to only those entities who are contractually obligated to provide services to a plan.

Response: We believe that the definition is clear that TPMOs include all third-party marketers who work on behalf or provide services to plans. The definition is intentionally broad to ensure MA and Part D plans properly oversee and are accountable for any entity who profits in any manner from the enrollment of a beneficiary into an MA or Part D plan. As defined in §§ 422.2260 and 423.2260, this rule would apply to organizations, as well as agents and brokers, that are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment. TPMOs may be a first tier, downstream or related entity (FDRs), as defined under §§ 422.2 and 423.4, but may also be entities that are not FDRs but provide services to customers including an MA organization or Part D sponsor or an MA organization's or Part D sponsor's FDR. We have carefully considered the wording of this provision as to the type of entities it encompasses. As described in the proposed rule, our intent is to cover entities that are conducting marketing and/or enrollment activities that result in a beneficiary's enrollment in a Medicare plan, and the definition of TPMO is deliberately broad to accomplish that. With respect to the comments regarding the inclusion of individual agents and brokers in the definition of TPMO, we note that the proposed definition of TPMO included FDRs, which CMS has historically interpreted to mean individual agents and brokers, as well as organizational entities (72 FR 68704). However, because our intention to include individuals including independent agents and brokers was not sufficiently clear, we are finalizing the definition of TPMO at §§ 422.2260 and 423.2260 with

an update to clarify that the definition includes such individuals as well as organizations. In addition, we note that definition of TPMOs in the proposed rule included incorrect citations when referencing the regulatory definitions of first tier, downstream, or related entities. These incorrect citations at §§ 422.504(i) and 423.505(i) have been corrected in this final rule to correctly refer to §§ 422.2 and 423.4. We will explore the definition in future rulemaking if we feel that the landscape of the industry evolves such that the definition we are finalizing requires reevaluation.

After careful consideration of all the comments received, and for the reasons set forth in the January 2022 proposed rule and in our responses to the comments, we are finalizing the proposed changes to amend part 422 subpart V and part 423 subpart V with the following modifications. We are updating the TPMO oversight requirements at §§ 422.2274(g)(2)(iii) and 423.2274(g)(2)(iii) to make clear that violations by TPMOs of requirements that apply to the MA organization or Part D sponsor must be reported to MA organizations and Part D sponsors, in addition to disciplinary actions. We are updating the definition of TPMOs at §§ 422.2260 and 423.2260 to include individuals such as independent agents and brokers. We are making a technical correction to the definition of TPMO at §§ 422.2260 and 423.2260 to include correct citations to the definitions of FDRs at §§ 422.2 and 423.4. Finally, we are adding a technical correction that clarifies that ID cards as required documents are exempt from the requirement to have all text in 12-point font. We are finalizing all the other provisions in this section as proposed.

To reiterate and summarize, the new and revised regulatory sections and their content are as follows:

- Sections 422.2260 and 423.2260 are revised to add a definition for Third-Party Marketing Organization (TPMO).
- Sections 422.2265(b)(13), 423.2265(b)(14), 422.2265(b)(14), and 423.2265(b)(15) are revised to add instructions on how to appoint a representative and to add enrollment instructions and forms.
- Sections 422.2267(e)(30) and 423.2267(e)(32) are revised to add the Member ID card and requirements for the card as a model document.
- Sections 422.2267(e)(31) and 423.2267(e)(33) are revised to add the Multi-Language Insert.
- Sections 422.2267(e)(41) and 423.2267(e)(41) are revised to add the Third-Party Marketing disclaimer.

- Section 423.2267(e)(40) is revised to add the Limited Access to Preferred Cost-Sharing disclaimer.

- Sections 422.2274 and 423.2274 are revised to apply MA and Part D oversight to TPMOs.

G. Regulatory Changes to Medicare Medical Loss Ratio Reporting Requirements and Release of Part C Medical Loss Ratio Data (§§ 422.2460, 422.2490, and 423.2460)

1. Background

Section 1103 of Title I, Subpart B of the Health Care and Education Reconciliation Act (Pub. L. 111–152) amended section 1857(e) of the Act to add a medical loss ratio (MLR) requirement to Medicare Part C (MA program). An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. Because section 1860D–12(b)(3)(D) of the Act adopts by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Medicare Part D program. In the May 23, 2013 **Federal Register**, we published a final rule titled “Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs” (78 FR 31284) (hereinafter referred to as the May 2013 Medicare MLR final rule), we codified the MLR requirements for MA organizations and Part D prescription drug plan sponsors (Part D sponsors) (including organizations offering cost plans that offer the Part D benefit) in the regulations at 42 CFR part 422, subpart X, and part 423, subpart X.

Generally, the MLR for an MA or Part D contract reflects the ratio of costs (numerator) to revenues (denominator) for all enrollees under the contract. For an MA contract, the MLR reflects the percentage of revenue received under the contract spent on incurred claims for all enrollees, prescription drug costs for enrollees in MA plans under the contract offering the Part D benefit, quality initiatives that meet the requirements at § 422.2430, and amounts used to reduce Part B premiums. The MLR for a Part D contract reflects the percentage of revenue received under the contract spent on incurred claims for all enrollees for Part D prescription drugs, and on quality initiatives that meet the requirements at § 423.2430. The percentage of revenue that is used for other items such as administration, marketing, and profit is excluded from the numerator of the MLR (see

§§ 422.2401 and 423.2401; 422.2420(b)(4) and 423.2420(b)(4); 422.2430(b) and 423.2430(b).

For contracts for 2014 and later, MA organizations and Part D sponsors are required to report their MLRs and are subject to financial and other sanctions for failure to meet the statutory requirement that they have an MLR of at least 85 percent (see §§ 422.2410 and 423.2410). The statute imposes several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds, a prohibition on enrolling new members, and ultimately, contract termination. The minimum MLR requirement creates incentives for MA organizations and Part D sponsors to reduce administrative costs, such as marketing costs, profits, and other uses of the revenue received by plan sponsors, and helps to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health and drug plans.

Section 1001(5) of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10101(f) of the Health Care and Education Reconciliation Act (Pub. L. 111–152), also established a new MLR requirement under section 2718 of the Public Health Service Act that applies to issuers of employer group and individual market private insurance. We will refer to the MLR requirements that apply to issuers of private insurance as the “commercial MLR rules.” Regulations implementing the commercial MLR rules are published at 45 CFR part 158.

We proposed modifications to the MLR reporting requirements in the Medicare Part C and Part D programs and to the regulation that governs the release of Part C MLR data.

2. Reinstate Detailed MLR Reporting Requirements (§§ 422.2460 and 423.2460)

Each year, MA organizations and Part D sponsors submit to CMS data necessary for the Secretary to determine whether each MA or Part D contract has satisfied the minimum MLR requirement under sections 1857(e)(4) and 1860D–12(b)(3)(D) of the Act. In the May 2013 Medicare MLR final rule (78 FR 31284) that established the Medicare MLR regulations, CMS codified at §§ 422.2460 and 423.2460 that, for each contract year, each MA organization and Part D sponsor must submit an MLR Report to CMS that included the data needed by the MA organization or Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract such as the amount of incurred claims, expenditures on

quality improving activities, non-claims costs, taxes, licensing and regulatory fees, total revenue, and any remittance owed to CMS under § 422.2410 or § 423.2410.

To facilitate the submission of MLR data, CMS developed a standardized MLR Report template that MA organizations and Part D sponsors were required to populate with their data and upload to the Health Plan Management System (HPMS), starting with contract year (CY) 2014 MLR reporting, which occurred in December 2015. Based on the data entered by the MA organization or Part D sponsor for each component of the MLR numerator and denominator, the MLR reporting software would calculate an unadjusted MLR for each contract. The MLR reporting software would also calculate and apply the credibility adjustment provided for in §§ 422.2440 and 423.2440, based on the number of member months entered into the MLR Report, in order to calculate the contract’s adjusted MLR and remittance amount (if any). In addition to the numerical fields used to calculate the MLR and remittance amount, the MLR Report template included narrative fields in which MA organizations and Part D sponsors provided detailed descriptions of the methods used to allocate expenses, including how each specific expense met the criteria for the expense category to which it was assigned.

The proposed rule discussed how CMS originally modeled the Medicare MLR reporting format on the tools used to report commercial MLR data, in keeping with our general policy of attempting to align the Medicare MLR requirements with the commercial MLR requirements to limit the burden on organizations that participate in both markets, and to make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes. The proposed rule also explained how, as part of an initiative to reduce the regulatory burden on private industry, we later amended the reporting requirements by scaling back the amount of MLR data that MA organizations and Part D sponsors submit to CMS on an annual basis, starting with CY 2018. Under current §§ 422.2460 and 423.2460, for CY 2018 and subsequent contract years, MA organizations and Part D sponsors are only required to report each contract’s MLR and the amount of any remittance owed to CMS; they are no longer required to submit the underlying data needed to calculate and verify reported MLR and remittance amount, if any. In the final rule titled “Medicare Program; Contract Year 2019 Policy and

Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program” (83 FR 16440, 16675), which appeared in the April 16, 2018 **Federal Register** (hereinafter referred to as the April 2018 final rule) and finalized the current MLR reporting requirements, we expressed our belief that we would still be able to effectively oversee MA organizations’ and Part D sponsors’ compliance with the MLR requirements by relying solely on audits, as authorized under §§ 422.2480 and 423.2480.

As discussed in greater detail in the proposed rule at 87 FR 1903 through 1904, in light of subsequent experience overseeing the administration of the Medicare MLR program while the simplified MLR reporting requirements have been in effect, and after further consideration of the potential impacts on beneficiaries and costs to the government and taxpayers when CMS has limited access to detailed MLR data, we have reconsidered the changes to the MLR reporting requirements that were finalized in the April 2018 final rule. We have come to recognize the limitations of our current approach to MLR compliance oversight, in which we do not collect the information needed to verify that a contract’s MLR has been calculated accurately, except in the small number of cases that we can feasibly audit each year. As noted in the proposed rule at 87 FR 1905, we believe we would need to greatly expand the number of audits we conduct if we were to rely on them as our sole means of validating the accuracy of MLR reporting, and we anticipate that the increased cost to the government and the aggregate burden across all of the additional MA organizations and Part D sponsors selected for audits would negate the savings that the April 2018 final rule estimated would result from the changes to the MLR reporting requirements.⁸⁷ For these reasons, we proposed to reinstate the detailed MLR reporting requirements that were in effect for CYs 2014 through 2017. In addition, we proposed to collect additional data on certain categories of expenditures, and to make conforming changes to our data collection tools, which is discussed in section II.G.3. later in this final rule.

⁸⁷ The April 2018 final rule (83 FR 16715) estimated that the change in the MLR reporting requirements that CMS finalized for CYs 2018 and subsequent contract years would result in annual savings of \$1,446,417 per year (\$490,000 to the government and \$904,884 to MA organizations and Part D sponsors).

Comment: Many commenters agreed with our proposed reinstatement of the MLR reporting requirements and believe reinstating these requirements will provide transparency to beneficiaries and the public.

Response: We appreciate the support.

Comment: Some commenters expressed opposition to the proposed reinstatement of the Medical Loss Ratio reporting requirement that was previously in effect for contract years 2014–2017. These commenters state that this proposal will add administrative burden. Several commenters expressed concern that more detailed MLR reporting for supplemental benefits will add burden and administrative costs for MA organizations and Part D sponsors. Commenters suggested that CMS require a single consolidated report for supplemental benefits costs rather than a separate report for each benefit. A majority of these commenters suggested that CMS maintain the current simplified MLR reporting requirements that have been in effect since 2018.

Response: We appreciate the feedback. We proposed to reinstate the collection of detailed MLR reporting requirements that were in effect for CYs 2014 through 2017 to improve transparency and oversight concerning the use of Medicare Trust Fund dollars. This requires reporting of the underlying data used to calculate and verify the MLR and any remittance amount, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, and regulatory fees. We address the collection of more detailed data about categories of supplemental benefits in section II.G.3. of this final rule.

In light of subsequent experience overseeing the administration of the Medicare MLR program while the simplified MLR reporting requirements have been in effect, and after further consideration of the potential impacts on beneficiaries and costs the government and taxpayers when CMS has limited access to detailed MLR data, we have reconsidered the changes to the MLR reporting requirements that were finalized in the April 2018 final rule. We have come to recognize the limitations of our current approach to MLR compliance oversight, in which we do not collect the information needed to verify that a contract's MLR has been calculated accurately, except in the small number of cases that we can feasibly audit each year.

In developing the MLR reporting format, CMS modeled the data collection on tools used to report commercial MLR data. This was in

keeping with a general policy of modeling the data collection on tools used to report commercial MLR data, with modifications for Medicare-specific needs in order to limit the burden on organizations that participate in both markets, and to make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes.

Additionally, given the minimal data we currently receive from MA organizations and Part D sponsors, we believe that we would need to greatly expand the number of audits we conduct if we were to rely on them as our sole means of validating the accuracy of MLR reporting. We would need to conduct comparatively resource heavy audits in order to identify potentially costly errors in the calculation of the MLR and remittance amount, including errors that would have been flagged systematically during the desk review process. We believe that the increased cost to the government and the aggregate burden across all of the additional MA organizations and Part D sponsors selected for audits (\$13.8 million per year) would negate the savings that the April 2018 final rule estimated would result from the changes to the MLR reporting requirements (\$1.5 million per year). Additional information on the projected cost and burden estimates of auditing MLR reports can be found in the Regulatory Impact Analysis (RIA) pages.

Given that MA organizations and Part D sponsors are already tracking expenses by line of business and contract in order to comply with our current regulations and account for supplemental benefit expenditures for both internal accounting and bid development purposes, we estimate that the additional start-up and ongoing costs and time burden for submitting detailed data will be moderate. We estimate that MA organizations and Part D sponsors will incur minimal one-time start-up costs associated with developing processes for capturing the necessary data and will incur ongoing annual costs relating to data collection, populating the MLR reporting form, conducting an internal review, submitting the MLR reports to the Secretary, and conducting internal audits. Please see additional discussion of these costs in the Collection of Information Requirements section of this rule.

We are finalizing this provision without modification.

3. Changes to Medicare MLR Reporting Regulations, Data Collection Instrument, and Regulations Authorizing Release of Part C MLR Data (§§ 422.2460, 422.2490, and 423.2460)

As noted throughout this section of this final rule, we proposed to amend our regulations to reinstate the MLR reporting requirements that were in effect for CYs 2014 through 2017, with some modifications. Under our proposed amendments, paragraph (a) of § 422.2460 would state that, except as provided in paragraph (b), for each contract year, each MA organization must submit to CMS, in a timeframe and manner that we specify, a report that includes the data needed to calculate and verify the MLR and remittance amount, if any, for each contract, including the amount of incurred claims for Medicare-covered benefits, supplemental benefits, and prescription drugs; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; total revenue; and any remittance owed to CMS under § 422.2410.

We proposed similar amendments to paragraph (a) of § 423.2460, except § 423.2460(a) as proposed would refer to “incurred claims for covered drugs,” would omit any mention of “covered services (both Medicare-covered benefits and supplemental benefits),” and would refer to the remittance owed to CMS under § 423.2410. In addition, we proposed to revise paragraph (b) of both §§ 422.2460 and 423.2460 to specify that the limited MLR data collection requirements under that paragraph only apply to MLR reporting for CYs 2018 through 2022.

The proposed rule noted that, in connection with our proposal to reinstate the detailed MLR reporting requirements, starting with MLR reporting for CY 2023, we intend to require MA organizations and Part D sponsors to submit their MLR data to CMS using the MLR Reporting Tool that was used to report MLR data for CYs 2014 through 2017, with certain changes. The proposed rule, at 87 FR 1907, discussed the three types of changes that we intend to make to the MLR Reporting Tool:

- First, we will revise the MLR Reporting Tool's formulas to incorporate changes to the MLR calculation that have been finalized since CMS stopped developing the MLR Reporting Tool after CY 2017 MLR Reports were submitted. For example, we will add categories for fraud reduction expenses and medication therapy management programs in the section for Activities that Improve Healthcare Quality,

consistent with changes in the April 2018 final rule that redefined these categories of expenditures as quality improvement activities (83 FR 16670 through 16673). Similarly, we will design the MLR Reporting Tool to automatically calculate and insert the medical savings account (MSA) deductible factor, added to § 422.2440 in a June 2020 final rule (85 FR 33908).

- Second, we will separate out certain items that are currently consolidated into or otherwise accounted for in existing lines of the MLR Reporting Tool. For example, we will separate out low-income cost-sharing subsidy amounts, which were previously subtracted from the MLR numerator and excluded from the denominator, into an information-only line in the MLR Reporting Tool's numerator section.

- Third, we will separate out the single line in the MLR Report for claims incurred during the contract year covered by the MLR Report into separate lines for benefits covered by Medicare Parts A and B, certain additional supplemental benefits (that is, benefits not covered by Part A, B, or D and meeting the criteria in § 422.100(c)(2), but excluding supplemental benefits that extend or reduce the cost-sharing for items and services covered under Parts A and B), and Part D prescription drug benefits.

The proposed rule noted our intention to require MA organizations to report all expenditures for Medicare-covered benefits, including extended A/B coverage (by which we mean, for example, coverage of additional days during an inpatient stay) and cost-sharing reductions (by which we mean the value of the difference between the cost-sharing under Medicare FFS and the plan's cost-sharing), on the same line of the MLR Reporting Tool, based on our assumption that it would be exceedingly difficult for MA organizations to separately identify and track spending on extended coverage of original Medicare benefits and cost-sharing reductions. We solicited comment on whether this is a reasonable assumption and whether the MLR Reporting Tool should instead mirror how MA bids are submitted under § 422.254(b).

The proposed rule discussed our intention to have MA organizations report expenditures for additional supplemental benefits (supplemental benefits meeting the criteria in § 422.100(c)(2) but excluding supplemental benefits that extend or reduce the cost-sharing for items and services covered under Parts A and B) on multiple lines of the MLR Reporting Tool, which will represent different

types or categories of supplemental benefits. We explained that requiring MA organizations to account for their supplemental benefit expenditures by benefit type or benefit category will provide more transparency into how the MLR is being calculated, and it will assist CMS in verifying the accuracy of the MLR calculation, particularly with respect to expenditures related to categories of supplemental benefits that MA organizations must already separately report to CMS for purposes of bid development. The proposed rule also stated that the public release of information on supplemental benefit spending by benefit type or category may be helpful to beneficiaries who wish to make their enrollment decisions based on a comparison of the relative value of the supplemental benefits actually provided by different MA organizations. We did not propose to require separate reporting of Part D supplemental benefit expenditures (that is, they would continue to be reported combined with other Part D expenditures).

The proposed rule explained that we intend to expand the MLR reporting requirements beyond what was required under the detailed MLR reporting requirements that were in effect for CYs 2014 through 2017, to include expenditures related to supplemental benefits. As part of reinstating more detailed MLR reporting, the proposed rule described collecting data on claims incurred for certain supplemental benefits (that is, benefits not covered by Part A, B, or D and meeting the criteria in § 422.100(c)(2), but excluding supplemental benefits that extend or reduce the cost-sharing for items and services covered under Parts A and B). Based on these considerations, we intend to expand the MLR reporting requirements beyond what was required under the detailed MLR reporting requirements that were in effect for CYs 2014 through 2017, to include expenditures related to the following categories of supplemental benefits:

- Dental
- Vision
- Hearing
- Transportation
- Fitness Benefit
- Worldwide Coverage/Visitor Travel
- Over the Counter (OTC) Items
- Remote Access Technologies
- Meals
- Routine Foot Care
- Out-of-network Services
- Acupuncture Treatments
- Chiropractic Care
- Personal Emergency Response System (PRS)

- Health Education
- Smoking and Tobacco Cessation Counseling
- All Other Primarily Health Related Supplemental Benefits
- Non-Primarily Health Related Items and Services that are Special Supplemental Benefits for the Chronically Ill (SSBCI) (as defined in § 422.102(f))

In the proposed rule at 87 FR 1907 through 1908, we discussed the factors that we took into consideration in compiling the list of supplemental benefit types and categories in the proposed rule. We solicited comment on whether the list of supplemental benefit types and categories would be appropriate breakouts for separating out supplemental benefit expenditures in the MLR Reporting Tool. We noted that we were interested in feedback that addressed whether we should increase or decrease the number of types or categories of supplemental benefits, as well as suggestions for alternative categories or for consolidating the previously listed benefit types or categories into larger categories.

We received some comments requesting that requesting that CMS either collapse or expand the proposed supplemental benefit categories. As discussed in our response to these comments, we believe it is more appropriate for CMS to retain flexibility to modify the scope of data fields and the specific list of supplemental benefit categories required to be reported on the MLR Reporting Template. Maintaining this flexibility will allow CMS to collect data that is sufficiently detailed to enable us to understand benefit expenditures and verify and increase accountability for the accuracy of MLR calculation. We are finalizing the amendments to §§ 422.2460(a) and 423.2460(a) to provide us with the flexibility to modify the scope of data fields and categories required for supplemental benefit expenditures. The intent of this rule is not to create a more detailed but static MLR report; rather this rule is intended to enable reporting requirements that support the program needs, such as supporting MLR calculation, verifying data reporting accuracy, gaining insight into supplemental benefit policies, and providing transparency into program expenditure allocation.

In considering the scope of data fields and list of supplemental benefit categories for reporting we will take into account the following four factors, which were previously included in the proposed rule in setting forth our rationale for the list of supplemental

benefit categories. First, data elements and categories should enable a thorough reporting of data elements in categories that support MLR calculation, reduce errors in reporting, and increase our ability to verify data reporting accuracy. Second, data elements and categories for supplemental benefits should be selected to provide transparency into how MA program payments are allocated and may focus on specific benefits, such as the non-primarily health related supplemental benefits offered to the SSBCI population, for the purposes of providing CMS with information on the impact of a specific benefit change. Third, we will take into consideration the percentage of MA plans that offer each type of supplemental benefit in the most recent year for which data on plan benefit packages is available (that is, looking at CY 2022 for developing the CY 2023 Reporting Tool), so that the lines we add to the MLR Reporting Tool are more likely to allow for comparison of MA organizations' expenditures on types of supplemental benefits that are widely offered. In addition, in deciding whether to require separate reporting of the expenditures for a particular supplemental benefit type, we considered the percentage of contracts that currently offer that supplemental benefit under just one plan, as we believe expenditures associated with benefits offered under only one plan under a contract would constitute plan-level data, which CMS proposed to exclude from public release of MLR data consistent with the exclusions for MLR data reported at the plan level and information submitted for contracts consisting of a single plan (see § 422.2490(b)(2)). Fourth in establishing the scope of data fields and categories for supplemental benefits, we acknowledge the trade-offs between the additional information gained from changing requirements and the additional burden placed on MA organizations and Part D sponsors brought about by changing requirements. We will take the balance between the increased value of additional information and the increased reporting burden into account in developing requirements on the scope of data fields and specific list of supplemental benefit categories.

Modifications to the MLR data requirements for supplemental benefits expenditures will be set forth in a revision to the MLR Paperwork Reduction Act package (CMS-10476, OMB 0938-1232) and made available to the public for review and comment under the standard PRA process which

includes the publication of 60- and 30-day **Federal Register** notices and the posting of the collection of information documents on our PRA website.

The list of supplemental benefits included in the proposed rule should be viewed as an example of categories of supplemental benefits CMS is interested in collecting and is based on the standards described above. We will set forth data reporting requirements in a revised package as required by the PRA. This package will be published in the **Federal Register** and be available for public comment.

In addition, the proposed rule discussed how we intend to use our authority under §§ 422.2490 and 423.2490 to release to the public the Part C and Part D MLR data we proposed to collect, including the additional data we proposed to collect on supplemental benefit expenditures, to the same extent that we released the information we formerly collected under the MLR reporting requirements in effect for CYs 2014 through 2017. The proposed rule noted that, consistent with §§ 422.2490(c) and 423.2490(c), the release of the MLR data we proposed to collect for a contract year would occur no sooner than 18 months after the end of the applicable contract year, and would be subject to the exclusions in §§ 422.2490(b) and 423.2490(b). We proposed to amend § 422.2490(b)(2) by adding new paragraph (b)(2)(ii), which will exclude from release data on amounts that are reported as expenditures for a specific type of supplemental benefit, where the entire amount that is reported represents costs incurred by the only plan under the contract that offers that benefit. For example, if only one plan under a contract offers Dental X-rays as a supplemental benefit, and expenditures for that benefit are the only amounts reported on that line of the MLR Reporting Tool, we will exclude the entire amount reported on that line from our public data release. However, if only one plan under a contract covers Dental X-rays, and another plan under that same contract is the only plan under the contract that covers Extractions, expenditures for both benefits will be reported in the Dental line in the MLR Reporting Tool, and that combined amount (assuming both plans had expenditures in the Dental category) will not be excluded from our public data release. As stated in the proposed rule, we believe data regarding supplemental benefit expenditures is only sensitive to the extent that the data reveals plan-level expenditures for a specific benefit offered under a single plan, and that these concerns do not

exist when expenditures for multiple types of supplemental benefits or from multiple plans are included in the same line of the MLR Reporting Tool.

We solicited comment on this proposed exclusion, including any suggestions for how we would implement this exclusion (for example, by adding check boxes next to the applicable lines in the MLR Reporting Tool, where users would add a check mark if their expenditures for the supplemental benefit type or category in the line by the checkbox represented expenditures for a single plan and single benefit type), and whether additional exclusions should be added to our MLR data release regulations. We also solicited comment on whether there is additional sensitivity around expenditures for supplemental benefits generally or for any types of supplemental benefits in particular, such that public release of data concerning those expenditures would be harmful.

Comment: A number of commenters supported CMS' efforts to provide additional transparency as part of the proposal to reinstate the detailed MLR reporting previously in effect for contract years 2014–2017. They believed more detailed reporting will demonstrate the value of services being offered to beneficiaries, as included in plan bids, and provide transparency around how rebate dollars are being put to use by plans.

Response: We appreciate the support.

Comment: Some commenters were opposed to the public release of MLR data related to amounts paid for incurred expenditures for supplemental benefits. These commenters do not believe information on expenditures on supplemental services will help beneficiaries effectively distinguish the value offered by different plans.

Response: In the final rule titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements," which appeared in the **Federal Register** on November 15, 2016 (81 FR 80170) (hereinafter referred to as the CY 2017 PFS final rule), we adopted §§ 422.2490 and 423.2490 to authorize the release of MLR reports along with a regulation authorizing release of MA bid data. In that rule, we explained the rationale for releasing MA and Part D MLR reports,

which included increasing transparency and access to Federal data sets, alignment with the public release of MLR data of commercial issuer, facilitating the public evaluation of the evaluation of the MA and Part D programs by providing insight into the efficiency of health insurers' operations, providing beneficiaries with information that can be used to assess the relative value of Medicare health and drug plans, and enhancing the competitive nature of the MA and Part D programs. We further stated that the release of this data would promote accountability in the MA and Part D programs, by making MLR information publicly available for use by beneficiaries who are making enrollment choices and by allowing the public to see whether and how privately-operated MA and Part D plans administer Medicare—and supplemental—benefits in an effective and efficient manner. The January 2022 proposed rule acknowledged that this existing regulation for disclosure of MLR reports would include disclosure of the more detailed reports we intended to require beginning with CY 2023. We discussed in that prior rulemaking how we believe that protecting against disclosures of individual beneficiary information and information at the plan level would be sufficient to protect against disclosure of proprietary or confidential commercial information. Disclosure of the additional details about MA supplemental benefits is consistent with the rationale and purpose of §§ 422.2490 and 423.2490. Public access to information on supplemental benefit spending by benefit type or category may be a valuable tool for consumers (to make their enrollment decisions based on a comparison of the relative value of the supplemental benefits actually provided by different MA organization), researchers (to potentially use this data to provide insight on trends in supplemental benefit coverage in the MA programs or to better understand how managed care in Medicare differs from managed care for non-Medicare populations), and the public (to have information at an aggregate level about expenditures and benefits in the Medicare program).

In the proposed rule titled “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare

Diabetes Prevention Program Model” (81 FR 46162), which appeared in the **Federal Register** on July 15, 2016 (hereinafter referred to as the CY 2017 PFS proposed rule) we enumerated the benefits CMS associated with the release of Part C and Part D MLR data to the public. In that proposed rule, we stated that the release of Part C and Part D MLR data could lead to research into how managed care in the Medicare population differs from and is similar to managed care in other populations (such as the individual and group markets) where MLR data is also released publicly, and could inform future administration of these programs (81 FR 46396). We further stated that the release of this data would promote accountability in the MA and Part D programs, by making MLR information publicly available for use by beneficiaries who are making enrollment choices and by allowing the public to see whether and how privately-operated MA and Part D plans administer Medicare—and supplemental—benefits in an effective and efficient manner (81 FR 46397). Notably, in the CY 2017 PFS final rule, in response to comments that requested that CMS release only the MLR percentage for a contract, CMS expressly rejected that approach because releasing only the minimum amount of MLR data for MA and Part D contracts would not align with CMS' release of the detailed MLR data submitted by commercial plans (see 81 FR 80439). However, when we amended §§ 422.2460 and 423.2460 to scale back the MLR reporting requirements starting with CY 2018 MLR reporting, we did not indicate that we had subsequently concluded that MLR data would not provide this value to the public, nor did we acknowledge that a direct consequence of CMS ending the detailed MLR reporting requirements, was that our release of Medicare MLR data would no longer align with the release of commercial MLR data, as we would only be releasing the MLR percentage and remittance amount (if any) for MA and Part D contracts, starting with MLR data submitted for CY 2018.

We believe it is appropriate that we reaffirm our position that the public release of Part C and Part D MLR data provides value to the public both by increasing market transparency and improving beneficiary choice. We believe that the value in CMS releasing to the public detailed MLR data in accordance with §§ 422.2490 and 423.2490, and of alignment with the disclosure of commercial MLR data, provides further support for our

proposal to require MA organizations and Part D sponsors to submit such detailed data to us on an annual basis, starting with MLR reporting for CY 2023. Further, while not every beneficiary will use the MLR data as part of making enrollment decisions, we believe providing access to more detailed information about expenditures on supplemental benefits, as reported in the MLR Reporting Tool, will provide a means for beneficiaries to determine the value provided by MA plans.

Overall, we believe that the release of incurred expenditures for supplemental benefits is consistent with the rationale explained in the release of MLR reporting in the 2016 final rule. We do not believe it is necessary or appropriate to create exceptions from this existing regulation to exclude disclosure of the data that will be released for incurred expenditures for supplemental benefits, especially when that data will be provided at an aggregate level without risk of disclosing specific plan-level costs that might be used to put a particular MA plan at a competitive disadvantage.

Comment: A commenter cited that reverting to the requirement to submit more detailed expenditure data on the MLR and the newly added requirement to submit expenditure data on supplemental benefits, in particular, is duplicative of data in the bid pricing tool (BPT).

Response: In our view, the data collected during the bid process and the detailed data collected through the MLR report are not fully comparable. The data collected on the BPT is at the plan benefit package (PBP) level while MLR data is reported at the contract level. MA organizations and Part D sponsors submit bids at the plan level and typically use historical spending and utilization as the basis to for their bid projections for the applicable year. For example, MAOs this June will use 2021 spending and utilization as the basis for trending forwarding their bids to the 2023 plan year. If a plan is new or the MA organization or Part D sponsor expects a significant change in the plan's 2023 enrollment or risk profile, the MA organization or Part D sponsor can use historical 2021 experience from another plan or group of plans that the MA organization or Part D sponsor expects to have had a similar enrollment/risk profile. For this reason, there is not always a one-to-one relationship between the historical plan experience used for bidding for a specific plan and the plan's expenditures in the payment year. For MLR reporting, MAOs submit historical information for a specific contract and

specific contract year, not at the PBP level, so the detailed MLR data is not duplicative of the bid data. In addition, we intend to structure the MLR reporting so that data on supplemental benefits in the detailed MLR report are more granular than the broad supplemental benefit categories used in the BPT. The more detailed categories of reporting for supplemental benefits will provide increased transparency regarding the expenditures on supplemental benefits and enable us to assess the impact of specific policies, such as the provision of non-primarily health related supplemental services to the SSBCI population. Moreover, because the time lag between submission and release of public use files for the MLR data is significantly shorter than the time lag between submission and release of public use files of bid data, users have access to more recent data with the MLR.

The MLR data is typically released for more recent contract years than the BPT data. Under § 422.272(b), MA bid pricing data is released for a contract year that is at least 5 years prior to the upcoming calendar year. In comparison, according to § 422.2490, MLR data cannot be released earlier than 18 months after the end of the applicable contract year. CMS anticipates that for future years, MLR data will be released for more recent years than MA bid pricing data due to these timing requirements.

Comment: Commenters stated that the release of expenditure information on supplemental benefits could risk revealing proprietary cost information and may threaten current MA market competition since supplemental benefits vary between plans, which helps drive competition. Commenters note that given the flexibility around the types of supplemental benefits MAOs may offer and the variety of benefit and payment structures used to offer these benefits, the cost information provided is not “apples to apples” across contracts and is not useful for comparison by beneficiaries. As an example, a commenter noted that if only two or three plans in a given area offered a particular benefit category and that information were made publicly available, each plan could readily assess the other’s costs and could result in core business strategy and other highly proprietary cost information being revealed.

Response: Currently, §§ 422.2490(b)(2) and 423.2490(b)(2) prohibit release of information that is reported in the MLR reports at the plan level. Our proposal, which we are finalizing, amends that provision to also

protect amounts that are reported as expenditures for a specific type of supplemental benefit where the entire reported amount represents costs incurred by the only plan under the contract that offers that benefit. The data will be aggregated at the contract level, rather than at the PBP level, which we believe will prevent releases of proprietary cost information.

Additionally, line items in the detailed MLR reporting will include aggregation at the provider type or service level (for example, different types of dental benefits would be reported together as a single line item) in the general supplemental benefit categories. Many MA and Part D contracts cover large or multiple geographic regions or areas and are made up by several plans, avoiding the risk of releasing plan-specific data. As commenters note, the flexibility commenters describe around the types of supplemental benefits MAOs may offer and the variety of benefit and payment structures used to offer supplemental benefits limits the comparability of the data across contracts and therefore, mitigates the risk of revealing proprietary cost information through the release of the supplemental benefit expenditures data. Moreover, as noted in the proposed rule, in deciding whether to require separate reporting of the expenditures for a particular supplemental benefit type, we considered the percentage of contracts that currently offer that supplemental benefit under just one plan, as we believe expenditures associated with benefits offered under only one plan under a contract would constitute plan-level data. In creating a list of potential categories of supplemental benefits for the more detailed MLR reporting, we did not include supplemental benefit types or categories offered by less than 10 percent of all MA plans in 2021, with the exception of SSBCI that are not primarily health related, in order to protect individual plan information. Because of the potential variation in coverage of different items and services, such as the non-primarily health related services provided to the SSBCI population, which can range from indoor air quality equipment to transportation to services supporting self-direction depending on the needs of an individual enrollee whose overall function or health is reasonably expected to be improved by the item or service, we do not believe that the aggregate data available in the MLR reports about expenditures in this category could reveal confidential business strategies or cost information of an MA organization. We will also

review the expenditure information on supplemental benefits to gain a better understanding of the data and analyze the number of contracts that include a given supplemental service and take this into consideration in creating files for public use.

Additionally, according to §§ 422.2490(b)(1) and 423.2490(b)(1), narrative descriptions that MA organizations submit to support the information reported to CMS pursuant to the reporting requirements at § 422.2460, such as descriptions of expense allocation methods, are excluded from MLR data released to the public.

Finally, consistent with §§ 422.2490(c) and 423.2490(c), the release of the MLR data we propose to collect for a contract year will occur no sooner than 18 months after the end of the applicable contract year, and will be subject to the exclusions in §§ 422.2490(b) and 423.2490(b). For example, CMS does not release the narrative for the specifics around spending for any aspect of the MLR, including supplemental benefits per §§ 422.2490(b)(1) and 423.2490(b)(1). Finally, we believe the time lag between submission of data for a given contract year and public release of the data mitigates the potential threat to MA market competition on the basis of supplemental benefits.

Comment: Several commenters cited the challenges of reporting more detailed information on supplemental benefits, and requested CMS delay implementation.

Response: We do not believe that there are sufficient challenges for MA organizations with regard to reporting the more detailed MLR information to delay implementation beyond the MLR report due for CY 2023. Requiring MA organizations to account for their supplemental benefit expenditures by benefit type or benefit category will provide more transparency into how the MLR is being calculated, and it will assist CMS in verifying the accuracy of the MLR calculation, particularly with respect to expenditures related to categories of supplemental benefits that MA organizations must already separately report to CMS for purposes of bid development. In order to ensure accurate MLR reporting, for bid development purposes, and for internal accounting and planning purposes, MA plans presumably already collect detailed information on supplemental benefit expenditures. Given that plans will submit the detailed MLR reports at end of 2024 for contract year 2023, we believe plans will have adequate time to prepare for reporting additional

requirements in the MLR; therefore, a delay in implementation is not warranted.

Comment: A few commenters raised concerns regarding quality improving activities (QIA) and requested that CMS ensure that QIA expenses represent actual value provided for consumers' premium dollars and that plans do not abuse the removal of the "fraud reduction expenses" cap.

Response: We appreciate the commenters concerns and remind commenters that the regulations at §§ 422.2430(a)(3) and 423.2430(a)(3) require QIA to be grounded in evidence-based practice that can be objectively measured. Under the current MLR reporting requirements, CMS is unable to determine the extent to which QIA expenses are actually spent on quality improving activities. The more detailed reporting reinstates requirements that plans submit narratives that explain their QIA methodology (for example, there is a line on reporting dedicated to spending on fraud reduction specifically). We believe these reinstated measures will prevent plans from misusing the removal of the fraud reduction cap.

Comment: A few commenters supporting CMS' efforts to reinstate the detailed MLR reporting urged CMS to clarify how health plans should capture and report such information and believed that the claims-based reporting framework may not be appropriate for all supplemental benefits. Commenters stated that using a per member per month (PMPM) reporting system would better illustrate what financial support a plan is providing for such benefits.

Response: We appreciate the feedback. A per member per month (PMPM) reporting of expenditures is not consistent with the general calculation of the medical loss ratio or the method of reporting expenditure information. For the purposes of the MLR, MA organizations and Part D sponsors submit data on incurred claims for each contract, regardless of the type of payment arrangement with providers. The medical loss ratio is calculated by dividing total expenditures (as defined by the MLR instructions and reported to CMS) by total revenues (as defined by the MLR instructions and reported to CMS) for a given contract for a given contract year. A per member per month (PMPM) reporting for selected service categories, such as supplemental services, as suggested by the commenter, would not be suitable for the purpose of the MLR report. We are finalizing the detailed MLR reporting, including flexibility for CMS to change the specific line items and supplemental

benefit categories that are reported by MA organizations.

Comment: A few commenters recommended expanding reporting for the "Non-Primarily Health Related Items that are Special Supplemental Benefits for the Chronically Ill (SSBCI)" category, and suggested adding sub-categories such as food, transportation, and housing, which align with the broader areas of focus for CMS and health plans.

Another commenter recommended that CMS consolidate the "Wellness" and "Fitness Benefit" categories, thus establishing a "Fitness and Wellness Benefit" category, which would incorporate the programs that use a more holistic approach to the health and wellbeing.

A commenter requested CMS provide clarification on how the "Fitness Benefit" should be classified in the MLR reporting, given that currently "memory fitness" supplemental benefits are filed as a specific category under the "Fitness Benefit" category, as are physical fitness supplemental benefits and wearable device supplemental benefits. They proposed CMS require plans to break out their MLR data across the three categories of fitness benefit, to provide data that evaluate how these very distinct types of fitness benefit are being implemented.

Response: We appreciate the feedback related to expanding and collapsing supplemental benefit categories and line items. As noted above, maintaining flexibility to modify the scope of data fields and categories for MA supplemental benefits will allow CMS to collect data that is sufficiently detailed to enable us to understand benefit expenditures, verify and increase accountability for the accuracy of MLR calculation and accommodate evolving policy and program needs. We describe four standards we will use to determine supplemental benefit data reporting requirements above. One of those standards is the percentage of MA plans that offer each type of supplemental benefit.

With regard to the requests for more detailed reporting for the "Fitness" and "Non-Primarily Health Related Items that are Special Supplemental Benefits for the Chronically Ill (SSBCI)" categories, as noted in the proposed rule, we proposed to limit separate reporting of expenditures for supplemental benefit types or categories if these services were offered by less than 10 percent of all MA plans in 2021. The exception was the category of services for the SSBCI population that are not primarily health related; we included this category in the proposed

rule because we believe this information will help us assess the impact of our 2021 rule change that allows all amounts paid for covered services to be included in the MLR numerator as incurred claims (prior to this rule change, only amounts paid "to providers"—which is defined in § 422.2 in terms of the provision of healthcare items and services—for covered services could be included in incurred claims, which would have excluded, for example, pest control). We will continue to take the concentration of each type of supplemental benefit category offered into consideration in proposing the list of supplemental benefit categories in the PRA package.

Similarly, with regard to request to combine the "Wellness" and "Fitness" benefit categories, we will also consider the standard previously described related to the percentage of MA plans offering these specific categories of supplemental benefits.

Generally, as noted previously in this section II.G.3. of the final rule, we will consider the other standards related to administrative burden, data transparency, and data accuracy in developing the proposed reporting requirements in the PRA package.

CMS will propose the MLR data requirements in a PRA package that will be published in the **Federal Register** for public comment. The comment period is 60 days, during which plans and the public may comment on the MLR data reporting requirements. CMS will take these comments into consideration in developing final MLR data reporting requirements, which will be published in final PRA package.

After consideration of the comments and for the reasons outlined in the proposed and final rules and our responses to comments, we are finalizing the proposed amendments to §§ 422.2460(a) and (b) and 423.2460(a) and (b) without modification. We do note for readers that the MLR report will be subject to PRA processes and encourage the submission of comments related to reporting requirements and the structure of MLR reporting once the PRA package is posted for public comment.

In addition, we are finalizing the requirement for MA organizations to separately report expenditures for supplemental benefits (supplemental benefits meeting the criteria in § 422.100(c)(2) but excluding supplemental benefits that extend or reduce the cost-sharing for items and services covered under Parts A and B) on multiple lines of the MLR Reporting Tool, which will represent different types or categories of supplemental

benefits. Requiring MA organizations to account for their supplemental benefit expenditures by benefit type or benefit category will serve program purposes, such as providing more transparency into how the MLR is being calculated, and assisting CMS in verifying the accuracy of the MLR calculation, particularly with respect to expenditures related to categories of supplemental benefits that MA organizations must already separately report to CMS for purposes of bid development. We did not propose a separate reporting of Part D supplemental benefits expenditures and continue to believe that a separate reporting of Part D supplemental benefits expenditures is not needed at this time. We will set forth detailed reporting requirements through the PRA process as noted previously.

4. Technical Change to MLR Reporting Regulations (§§ 422.2460 and 423.2460)

In addition to our proposal to reinstate the detailed MLR reporting requirements that were in effect for CYs 2014 through 2017, with some modifications, and to add new data fields to our MLR Reporting Tool as described in the previous section of this preamble, we proposed to make a clarifying amendment to our MLR reporting regulations.

Currently, §§ 422.2460(d) and 423.2460(d) state that the MLR is reported once, and is not reopened as a result of any payment reconciliation process. We proposed to amend this paragraph to note that it is subject to an exception in new paragraph (e), which as proposed will provide that, with respect to an MA organization (in the case of proposed § 422.2460(e)) or Part D sponsor (in the case of proposed § 423.2460(e)) that has already submitted to CMS the MLR report or MLR data submission for a contract for a contract year, paragraph (d) does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. Proposed paragraph (e) will also provide that such resubmission must be authorized or directed by CMS, and upon receipt and acceptance by CMS, will be regarded as the contract's MLR report or data submission for the contract year for purposes of part 422, subpart X, and part 423, subpart X.

As explained in more detail in the proposed rule at 87 FR 1908 through 1909, we characterized this as a clarifying amendment because we believe it is clear from the discussion in the May 2013 Medicare MLR final rule that the provision stating that the MLR will be reported once, and will not be

reopened as a result of any payment reconciliation process, was intended to codify the policy decision that the MLR for a contract year is based on the contract year revenue figure available at the time of reporting, and is not subject to change if the contract year revenues increase or decrease through adjustments that take place in a future year. The proposed rule at 87 FR 1909 discussed this requirement at §§ 422.2460(d) and 423.2460(d) in the context of other provisions in our MLR regulations. We believe this discussion provides additional support for our position that we did not intend to prohibit ourselves from collecting or considering additional or corrected MLR data submitted to address deficiencies or inaccuracies in the original annual MLR submission required under §§ 422.2460 and 423.2460. Specifically, if, based on the data available at the time of the original MLR submission, or on the data that should have been available at the time of the original MLR submission, the MAO or Part D sponsor submits an MLR report or data submission that contains errors or omissions, the MA organization or Part D sponsor must notify CMS of the incorrect report submission. CMS will review and may require a resubmission.

The proposed rule also noted at 87 FR 1909 that a prohibition on any and all corrections or resubmissions would be contrary to our longstanding practice, which dates back to when CMS first began collecting Part C and Part D MLR data (for CY 2014) in December 2015, of allowing MA organizations and Part D sponsors to resubmit their MLR Data Forms for a contract year in order to correct errors and omissions in the original MLR filing without treating that resubmission as a reporting of the MLR for purposes of §§ 422.2460(d) and 423.2460(d).

Comment: A commenter requested additional clarification on CMS' technical changes and proposal for submitting corrections on MLR data. The commenter requested CMS clarify what changes and payment reconciliations would result in requiring an organization to resubmit MLR information and the types of MLR changes that CMS expects plans to report. Further, the commenter requested clarification on any proposed timeline or timing limitations for making changes and how that may correspond with potential audits. The commenter requested further clarification on the materiality thresholds that would trigger the need for a refiling, and examples of what criteria would necessitate a refiling to improve plan compliance. Another

commenter expressed concern that requiring MLR corrections as a result of ongoing adjustments, such as direct and indirect remuneration (DIR) adjustments that can be made for years after the initial DIR submission, could require refiling of MLR information for several years. This commenter also asked about the process by which an MA organization or Part D sponsor would resubmit an MLR report.

Response: The general concept underlying the resubmission of an MLR report remains unchanged from our original intent in the May 2013 Medicare MLR final rule. In the proposed rule, we stated that with respect to an MA organization (in the case of proposed § 422.2460(e)) or Part D sponsor (in the case of proposed § 423.2460(e)) that has already submitted to CMS the MLR report or MLR data submission for a contract for a contract year, paragraph (d) does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. We also stated in the proposed rule that our remarks in the 2013 Medicare MLR proposed and final rules made it clear that we never intended to prohibit ourselves from collecting, or taking into account, additional or corrected MLR data that is submitted to address deficiencies or inaccuracies in the annual MLR submission required under §§ 422.2460 and 423.2460. We believe that the remittances owed based on a failure to meet the MLR standard should be based on the revenue and expenditure figures at the time of the report, and should not be subject to change if this revenue or expenditure figure is decreased or increased in a future year. If the revenue or expenditure figures increase or decrease as the result of an omission or other error committed by the MA organization or Part D sponsor, then the entity must notify CMS and may be required to resubmit the MLR report. We understand the commenter's concerns regarding ongoing regularly occurring processes that affect payments, such as the reopenings of Part D payment reconciliation; however, this requirement for notifying CMS of errors in the MLR report does not extend to such adjustments that occur after the MLR report is submitted and finalized. Furthermore, payment reconciliations applicable for a contract year that occur after the contract year MLR report is submitted and finalized would not trigger the resubmission of that MLR report. Based on our prior experience, we do not anticipate that the identification and reporting to CMS

of issues in an MLR report will be commonplace. If we see that organizations are re-stating or correcting MLR submissions that are related to MLR reports that were submitted a number of years ago, then we will revisit this issue. We decline to set a materiality threshold at this time and as we state previously, CMS will review on a case-by-case basis instances in which an MLR report may need to be resubmitted. If CMS decides that an MLR report should be resubmitted, we will provide entities with instructions on how to resubmit at that time.

We assume the commenter who asked about audits is referring to our standard desk review of the MLR reports described at § 422.2460. The resubmission of MLR reports described herein is separate from reporting issues detected through the standard desk reviews of MLR reports. If an error is detected during a desk review, the MLR report is not considered final until it has been corrected and resubmitted and passes the desk review.

Comment: A commenter requested that CMS confirm whether resubmission of an MLR report and/or data may be initiated by CMS only or if resubmission may be initiated by a MA organization or Part D sponsor.

Response: CMS confirms that MLR resubmissions may be initiated by a MA organization, Part D sponsor, or CMS. The regulations we are finalizing at §§ 422.2460(e) and 423.2460(e) specify that CMS can either require or allow an MLR resubmission. We note that upon notification by an MA organization or Part D sponsor of an error in reporting, CMS will work with the reporting entity to gather additional information as necessary and determine whether a resubmission of the MLR report is required.

Comment: A commenter stated that if a plan were at or around the 85 percent threshold when it filed its report, it would be disincentivized from identifying and collecting any erroneous payments after the data submission deadline for fear of subsequently revising its claims estimates, falling below 85 percent, having to refile, and potentially receiving an enrollment penalty.

Response: It is incumbent upon the MA organization or Part D sponsor to submit data that is complete, accurate, and truthful.

MA organizations and Part D sponsors that inaccurately report revenues or expenditures in an MLR filing, taking into account payment policy that was in effect during the contract year and payment amounts that the plan received for that contract year prior to the submission of the MLR report, may be required, as determined by CMS, to resubmit the MLR data for the given contract year. For example, if MA organizations and Part D sponsors identify errors (such as double counting, math errors, or misclassification of a type of revenue or expenditure that is discovered after submission of an MLR report), the organization should contact CMS and may be required to refile as determined by CMS. Additionally, if an MA organization or Part D sponsor develops estimates of revenues or expenditures in preparing the MLR report that are inconsistent with payment policy or MLR guidance in place at the time of submission of the report, the MA organization or Part D sponsor must notify CMS.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing amendments at §§ 422.2460(d) and (e) and 423.2460(d) and (e), as proposed.

H. Pharmacy Price Concessions in the Negotiated Price (§ 423.100)

1. Introduction

Under Medicare Part D, Medicare makes partially capitated payments to private insurers, also known as Part D sponsors, for covering prescription drug benefits for Medicare beneficiaries. Often, the Part D sponsor or its pharmacy benefit manager (PBM) receives compensation after the point of sale that serves to lower the final amount paid by the sponsor to the pharmacy for the drug. Under Medicare Part D, this post-point-of-sale compensation is called Direct and Indirect Remuneration (DIR) and is factored into CMS's calculation of final Medicare payments to Part D plans. DIR

includes rebates from manufacturers, administrative fees above fair market value, price concessions for administrative services, legal settlements affecting Part D drug costs, pharmacy price concessions, drug costs related to risk-sharing settlements, or other price concessions or similar benefits offered to some or all purchasers from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred under the Part D plan (see § 423.308).

Total DIR reported by Part D sponsors has been growing significantly in recent years. The data Part D sponsors submit to CMS as part of the annual reporting of DIR⁸⁸ show that pharmacy price concessions (generally referring to all forms of discounts, direct or indirect subsidies, or rebates that a pharmacy pays to a Part D sponsor to reduce the costs incurred by Part D sponsors), net of all pharmacy incentive payments, have grown faster than any other category of DIR⁸⁹ received by sponsors and their contracted PBMs. This means that pharmacy price concessions now account for a larger share than ever before of reported DIR and a larger share of total gross drug costs in the Part D program. In 2020, pharmacy price concessions accounted for about 4.8 percent of total Part D gross drug costs (\$9.5 billion), up from 0.01 percent (\$8.9 million) in 2010. As shown in Table 2, the growth in pharmacy price concessions from 2010 to 2020 has been a continuous upward trend with the exception of 2011.

⁸⁸ CMS collects DIR data under collection approved under OMB control number 0938-0964 (CMS-10174) ("Collection of Prescription Drug Event Data from Contracted Part D Providers for Payment"). CMS does not release publicly the DIR data that we collect. The one exception was a highly summarized release of certain 2014 DIR data related to manufacturer rebates: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/PartD_Rebates.

⁸⁹ Sponsors report all DIR to CMS annually by category at the plan level. DIR categories include: Manufacturer rebates, administrative fees above fair market value, price concessions for administrative services, legal settlements affecting Part D drug costs, pharmacy price concessions, drug costs related risk-sharing settlements, etc.

TABLE 2: PHARMACY PRICE CONCESSIONS BY YEAR (2010–2020)

Contract Year	Total Pharmacy Price Concessions	% Change
2010	\$ 8,869,347	–
2011	\$8,582,354	-3.2%
2012	\$68,086,163	693.3%
2013	\$228,573,206	235.7%
2014	\$538,421,239	135.6%
2015	\$1,719,179,214	219.3%
2016	\$2,125,460,000	23.6%
2017	\$ 4,001,741,355	88.3%
2018	\$6,339,517,817	58.4%
2019	\$8,130,024,785	28.2%
2020	\$9,535,197,775	17.3%

Source: Summary Direct and Indirect Remuneration Report Data, 2010–2020.

The data show that pharmacy price concessions, net of all pharmacy incentive payments, grew more than 107,400 percent between 2010 and 2020. The data also show that much of this growth occurred after 2012, when the use by Part D sponsors of performance-based payment arrangements with pharmacies became increasingly prevalent. Part D sponsors and their contracted PBMs have been increasingly successful in recent years in negotiating price concessions from network pharmacies. Such price concessions are negotiated between pharmacies and sponsors or their PBMs, independent of CMS, and are often tied to the pharmacy's performance on various measures defined by the sponsor or its PBM. Performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased, on average, nearly 170 percent per year between 2012 and 2020 and now comprise the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates.

The negotiated price is the primary basis by which the Part D benefit is adjudicated, as it is used to determine plan, beneficiary, manufacturer (in the coverage gap), and government cost obligations during the course of the payment year, subject to final reconciliation following the end of the coverage year. Under the current definition of “negotiated prices” at § 423.100, negotiated prices must include all price concessions from network pharmacies except those that cannot reasonably be determined at the point of sale. However, because performance adjustments typically occur after the point of sale, they are not included in the price of a drug at the point of sale.

As discussed in the proposed rule, based on stakeholder feedback and

sponsor-reported DIR data, we understand that the share of pharmacies' reimbursement that is contingent upon their performance under such arrangements has grown steadily each year. When pharmacy price concessions received by Part D sponsors are not reflected in lower drug prices at the point of sale and are instead used to reduce plan liability, beneficiaries generally see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing. Thus, beneficiaries who utilize drugs end up paying a larger share of the actual cost of a drug. Moreover, when the point-of-sale price of a drug that a Part D sponsor reports on a prescription drug event (PDE) record as the negotiated price does not include such discounts, the negotiated price of each individual prescription is rendered less transparent and less representative of the actual cost of the drug for the sponsor.

President Biden's Executive Order (E.O.) 14036, “Promoting Competition in the American Economy” (86 FR 36987), section 5 (“Further Agency Responsibilities”), called for agencies to consider how regulations could be used to improve and promote competition throughout the prescription drug industry. Because variation in the treatment of pharmacy price concessions by Part D sponsors may have a negative effect on the competitive balance under the Medicare Part D program, and given the programmatic impacts laid out above and the charge from the E.O., CMS proposed changes that would standardize how Part D sponsors apply pharmacy price concessions to negotiated prices at the point of sale.

As discussed in the proposed rule, at the time the Part D program was established, we believed, as discussed in the January 2005 final rule (70 FR

4244), that market competition would encourage Part D sponsors to pass through to beneficiaries at the point of sale a high percentage of the price concessions they received. However, in recent years, less than 2 percent of sponsors have passed through any price concessions to beneficiaries at the point of sale. We now understand that sponsors may face market incentives not to apply price concessions at the point of sale because of the advantages that accrue to sponsors in terms of lower premiums (also an advantage for beneficiaries). Pharmacy price concessions reduce plan costs, and having the concessions not be applied at the point of sale reduces plan costs and plan premiums at the expense of the beneficiary having lower cost-sharing at the point of sale, thus shifting some of the net costs to the beneficiary via higher cost-sharing. We believe that Part D sponsors are incentivized to have lower premiums versus lower cost-sharing because anecdotal evidence suggests beneficiaries focus more on premiums instead of cost-sharing when choosing plans.

For this reason, as part of a November 2017 proposed rule titled “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program” (82 FR 56419 through 56428), which appeared in the **Federal Register** on November 28, 2017, we published a “Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale.” In the Request for Information, we solicited comment on whether CMS should require that the negotiated price at the point of sale for a covered Part D drug must include all price concessions that the Part D

sponsor could potentially collect from a network pharmacy for any individual claim for that drug. Of the many comments received, the majority were from pharmacies, pharmacy associations, and beneficiary advocacy groups that supported the adoption of such a requirement claiming that it would: (1) Lower beneficiary out-of-pocket drug costs (especially critical for beneficiaries who utilize high cost drugs); (2) stabilize the operating environment for pharmacies (by creating greater transparency and allegedly making the minimum reimbursement on a per-claim level more predictable); and (3) standardize the way in which plan sponsors and their PBMs treat pharmacy price concessions. Some commenters—mostly Part D sponsors and PBMs—were against such a policy, claiming that it would limit their ability to incentivize quality improvement from pharmacies. In the proposed rule titled “Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses” (83 FR 62174 through 62180), which appeared in the **Federal Register** on November 30, 2018 (hereinafter referred to as the November 2018 proposed rule), we solicited comment on a potential policy approach under which all pharmacy price concessions received by a plan sponsor for a covered Part D drug, including contingent price concessions paid after the point of sale, would be included in the negotiated price (83 FR 62177). Specifically, we considered adopting a new definition for the term “negotiated price” at § 423.100, which would mean the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor’s intermediary. In the final rule titled “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,” which appeared in the **Federal Register** on May 23, 2019 (84 FR 23867), we noted that we received over 4,000 comments on this potential policy approach, indicated that we would continue studying the issue, and left the existing definition of “negotiated prices” in place.

To address concerns about the lack of transparency in the performance measures used to evaluate pharmacy performance, in the February 2020 proposed rule, we proposed to amend the regulatory language at § 423.514(a) to establish a requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network

pharmacy agreements. We explained in the proposed rule that, once collected, we would publish the list of pharmacy performance measures in order to increase public transparency. In the final rule titled “Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,” which appeared in the **Federal Register** on January 19, 2021 (86 FR 5684), we finalized the proposed amendment to § 423.514(a), such that, starting January 1, 2022, Part D sponsors are required to disclose their pharmacy performance measures to CMS.

After considering the comments received on the November 2018 and January 2022 proposed rules, and in light of recent data indicating that pharmacy price concessions have continued to grow at a faster rate than any other category of DIR,⁹⁰ applicable beginning with contract year 2024, we are finalizing the policy proposed in the January 2022 proposed rule to amend § 423.100 to define the term “negotiated price” to ensure that the prices available to Part D enrollees at the point of sale are inclusive of all possible pharmacy price concessions. Effective January 1, 2024, we will delete the current definition of “negotiated prices” (in the plural) and we will add a definition of “negotiated price” (in the singular), applicable January 1, 2024, to make clear that a negotiated price can be set for each covered Part D drug. We believe this approach accommodates the different approaches to applying price concessions under sponsor and PBM payment arrangements with pharmacies, which may provide for price concessions to be applied uniformly as a percentage adjustment to the price for all Part D drugs dispensed by a pharmacy or have price concessions differ on a drug-by-drug basis. In addition, defining “negotiated price” in the singular is consistent with the regulations for the coverage gap discount program, which define the term “negotiated price” at § 423.2305, and it is compatible with our existing regulations, which at times refer to the “negotiated price” for a specific drug rather than “negotiated prices” for multiple drugs. Second, we will define “negotiated price” as the lowest possible reimbursement a network pharmacy will receive, in total, for a

particular drug, taking into account pharmacy price concessions. For the reasons described below, we are finalizing these proposals.

2. Background

Section 1860D–2(d)(1) of the Act requires that a Part D sponsor provide beneficiaries with access to negotiated prices for covered Part D drugs. Under the definition of “negotiated prices” at § 423.100, the negotiated price is the price paid to the network pharmacy or other network dispensing provider for a covered Part D drug dispensed to a plan enrollee that is reported to CMS at the point of sale by the Part D sponsor. This point-of-sale price is used to calculate beneficiary cost-sharing. More broadly, the negotiated price is the primary basis by which the Part D benefit is adjudicated, as it is used to determine plan, beneficiary, manufacturer (in the coverage gap), and government liability during the course of the payment year, subject to final reconciliation following the end of the coverage year.

Under current law, Part D sponsors can, for the most part, choose whether to reflect in the negotiated price the various price concessions they or their intermediaries receive from all sources, not just pharmacies. Specifically, section 1860D–2(d)(1)(B) of the Act requires that negotiated prices “shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . .” Part D sponsors are allowed, but generally not required, to apply rebates and other price concessions at the point of sale to lower the price upon which beneficiary cost-sharing is calculated. Under the existing definition of negotiated prices at § 423.100, however, negotiated prices must include all price concessions from network pharmacies that can reasonably be determined at the point of sale.

To date, very few price concessions have been included in the negotiated price at the point of sale. All pharmacy and other price concessions that are not included in the negotiated price must be reported to CMS as DIR at the end of the coverage year using the form required by CMS for reporting Summary and Detailed DIR (OMB control number 0938–0964). These data on price concessions are used in our calculation of final plan payments, which, under section 1860D–2(d)(1)(B) of the Act, are required to be based on costs actually incurred by Part D sponsors, net of all applicable DIR. Reinsurance payments under section 1860D–15(b) of the Act, and risk sharing payments and adjustments under section 1860D–

⁹⁰From 2018 to 2020, pharmacy price concessions increased by 50.4 percent while all other DIR increased by 23.5 percent.

15(e)(2) of the Act are also required to be based on costs actually incurred by Part D sponsors. In addition, pursuant to section 1860D–2(d)(2) of the Act, Part D sponsors are required to disclose the aggregate negotiated price concessions made available to the sponsor by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers.

When price concessions are applied to reduce the negotiated price at the point of sale, some of the concession amount is apportioned to reduce beneficiary cost-sharing. In contrast, when price concessions are applied after the point of sale, as DIR, the majority of the concession amount accrues to the plan, and the remainder accrues to the government. For further discussion on this matter, please see the CMS Fact Sheet from January 19, 2017 “Medicare Part D Direct and Indirect Remuneration,” found on the CMS website at <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>. The January 2022 proposed rule explained in detail how pharmacy price concessions applied as DIR can: (1) Lower plan premiums and increase plan revenues; (2) result in cost-shifting to certain beneficiaries (in the form of higher cost-sharing) and the government (through higher reinsurance and low-income cost-sharing subsidies); and (3) obscure the true costs of prescription drugs for consumers and the government.

3. Changes to the Definition of Negotiated Price (§ 423.100)

As discussed in the proposed rule, in the May 2014 final rule (79 FR 29844), we amended the definition of “negotiated prices” at § 423.100 to require Part D sponsors to include in the negotiated price at the point of sale all pharmacy price concessions and incentive payments to pharmacies—with an exception, intended to be narrow, that allowed the exclusion of contingent pharmacy payment adjustments that cannot reasonably be determined at the point of sale (the reasonably determined exception). At that time, we did not anticipate the growth of performance-based pharmacy payment arrangements that we have observed in subsequent years.

The proposed rule discussed how, based on feedback from stakeholders as well as information submitted by plan sponsors in their annual DIR reports, we have come to understand that the reasonably determined exception has been applied more broadly than we had

initially envisioned, due to the shift by Part D sponsors and their PBMs towards contingent pharmacy payment arrangements. In short, because performance-based pharmacy payment adjustments are contingent upon performance over a period of time that extends beyond the point of sale, the stakeholders asserted that by definition, the amount of these adjustments cannot “reasonably be determined” at the point of sale as they cannot be known in full at the point of sale. As a result, the reasonably determined exception prevents the current policy from having the intended effect on price transparency, consistency (by reducing differential reporting of pharmacy payment adjustments by sponsors), and beneficiary costs.

Given the predominance of plan sponsors’ use of performance-contingent pharmacy payment arrangements, we do not believe that the existing requirement that pharmacy price concessions be included in the negotiated price can be implemented in a manner that achieves the goals previously discussed: Meaningful price transparency, consistent application of all pharmacy payment concessions by all Part D sponsors, and preventing cost-shifting to beneficiaries and taxpayers. Therefore, to establish a requirement that accomplishes these goals while better reflecting current pharmacy payment arrangements, we proposed to delete the existing definition of the term “negotiated prices” at § 423.100 and add a definition of the term “negotiated price” at § 423.100 to mean the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D sponsor or the sponsor’s intermediary (that is, the amount the pharmacy would receive net of the maximum possible reduction that could result from any contingent pharmacy payment arrangement). Specifically, as noted previously, we proposed to delete the current definition of “negotiated prices” (in the plural) and to add a new definition of “negotiated price” (in the singular) in order to make clear that a negotiated price can be set for each covered Part D drug, and the amount of pharmacy price concessions may differ on a drug-by-drug basis. Our proposed definition of negotiated price would specify that the negotiated price for a covered Part D drug must include all pharmacy price concessions and any dispensing fees, and exclude additional contingent amounts (such as incentive fees) if these amounts increase prices. Under our proposal, we would not change Part D sponsors’ ability to pass

through other, non-pharmacy price concessions and other direct or indirect remuneration amounts (for example, legal settlement amounts and risk-sharing adjustments) to enrollees at the point of sale. These proposed provisions are discussed in the following sections.

a. All Pharmacy Price Concessions

In the proposed rule, we proposed to adopt a new definition of “negotiated price” at § 423.100 that would include all pharmacy price concessions received by the plan sponsor for a covered Part D drug. The proposed definition would omit the reasonably determined exception, meaning that all price concessions from network pharmacies, negotiated by Part D sponsors and their contracted PBMs, would have to be reflected in the negotiated price that is made available at the point of sale and reported to CMS on a PDE record, even when such price concessions are contingent upon performance by the pharmacy.

Section 1860D–2(d)(1)(B) of the Act requires that negotiated prices “shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . .” We have previously interpreted this language to mean that some, but not all, price concessions must be applied to the negotiated price (see, for example, 70 FR 4244 and 74 FR 1511). Although we continue to believe that the prior interpretation of “take into account” was permissible, we believe that our initial interpretation may have been overly definitive with respect to the intended meaning of “take into account.” We believe that a proper reading of the statute supports requiring that all pharmacy price concessions be applied at the point of sale. As proposed, requiring that all pharmacy price concessions be applied at the point of sale would ensure that negotiated prices “take into account” at least some price concessions and, therefore, would be consistent with and permitted by the plain language of section 1860D–2(d)(1)(B) of the Act.

The proposed rule noted that the regulatory change we proposed would change the reporting requirements for Part D sponsors, but it does not affect what sponsors may arrange in their contracts with network pharmacies regarding payment adjustments after the point of sale. Contracts between sponsors or their PBMs and pharmacies can continue to provide for performance-based payment adjustments. The requirement that pharmacy price concessions be passed through to the point-of-sale price only

directly impacts the price that is used to determine beneficiary cost-sharing and the information that is populated and reported on the PDE record, but it does not dictate the amount that is ultimately paid to the pharmacy or the timing of payments and adjustments.

Comment: Most of the comments we received supported the adoption of a requirement that pharmacy price concessions be applied to the negotiated price at the point of sale. Many of the commenters who supported the proposal agreed that Part D sponsors or the sponsor's intermediaries apply the "reasonably determined" exception in the current definition of "negotiated prices" to nearly all performance-based pharmacy payment adjustments and that the exclusion of these adjustments from the negotiated price has resulted in cost-shifting to beneficiaries and the government. A majority of the commenters agreed with our assessment that the requirement to include all pharmacy price concessions in the negotiated price at the point of sale would lead to lower overall beneficiary spending for prescription drugs, even after accounting for possible increases in beneficiary premiums.

Many commenters explained that they supported the proposal because they believed it would increase price transparency for beneficiaries, the government, and other stakeholders. Several commenters agreed with our observation in the proposed rule that there is currently wide variation in reporting of DIR to CMS, with some, albeit few, plan sponsors including certain pharmacy price concessions in negotiated price, while others continue to report them as DIR. Some commenters suggested that this inconsistency in reporting makes it difficult for beneficiaries to accurately compare plans with respect to the true costs of their medications. These commenters suggested that requiring all pharmacy price concessions to be accounted for in negotiated price would enhance the quality of information available to beneficiaries and provide them with a better understanding of how they will progress through the phases of the Part D benefit based on their current medications. Several commenters believed that increased price transparency would also create a more level playing field among plans by providing more consistency in how Part D sponsors report these price concessions. Many commenters suggested that pharmacies would also benefit from the increased price transparency because it would provide information necessary for more accurate

budgeting and improved ability to evaluate proposed PBM contracts.

Response: We thank these commenters for their support and agree that changing the definition of "negotiated price" will provide greater transparency and lower out-of-pocket costs for beneficiaries.

Comment: Some commenters stated that the policy would harm competition among pharmacies, leading to higher program costs. These commenters explained that under a revised definition of "negotiated price," sponsors would no longer be able to apply pharmacy price concessions as DIR to reduce plan premiums. Several commenters stated that plan sponsors have demonstrated that the use of preferred networks has put a downward pressure on net prices and noted that pharmacies aggressively compete for preferred status in low premium plans. Knowing that beneficiaries prefer these plans, pharmacies (and, in particular, large retail-based pharmacies) are willing to offer substantial concessions to ensure that they have access to a large and fast-growing membership base. These commenters suggested that beneficiaries are not as sensitive to—or aware of—point-of-sale negotiated prices in comparison to premiums, and if sponsors are no longer able to reduce premiums by applying pharmacy price concessions as DIR, the result will be less effective competition between pharmacies for network placement. These commenters concluded that the use of post-point-of-sale pharmacy price concessions can give sponsors further leverage with pharmacies to negotiate prices, which decreases costs for the entire program.

A few commenters were concerned that including pharmacy price concessions in the negotiated price would give pharmacies the power to impact future discount levels and pharmacies' increased negotiating power would dramatically impact costs for patients, taxpayers, and plans. A few commenters suggested that pharmacies would not agree to economically equivalent discounts and would use the "any willing provider" provisions to mandate that they must be allowed to participate in the network even at less of a discount.

Response: The comments contending that sponsors' inability to apply pharmacy price concessions as DIR to reduce premiums will lead to less effective competition among pharmacies for network placement assume that post-point-of-sale recoupments are a more effective incentive than post-point-of-sale bonus payments. Commenters did not cite evidence to support this

assumption; therefore, we believe pharmacies would continue to have incentives to compete for placement in networks. In addition, the aggressive competition among pharmacies for placement in low premium plan networks would be a continuing incentive for plan sponsors to keep premiums as low as possible regardless of the change in how the negotiated price is reported to CMS. To the extent that this policy results in increased transparency and information symmetry it would encourage market competition and improve competition among pharmacies.

As noted above, several commenters stated that plan sponsors have demonstrated that the use of preferred networks has put a downward pressure on net prices, and we see no reason why this would change under the new policy. In spite of the statutory requirement at section 1860D-4(b)(1)(A) of the Act that Part D sponsors permit the network participation of any pharmacy willing to accept their standard terms and conditions, Part D sponsors and pharmacies remain free to negotiate terms of preferred network participation. The commenters provided no evidence to support the assertion that post-point-of-sale incentive payments (if used) would provide any less effective an incentive for pharmacies to continue to compete for preferred network status. We believe the policy would improve transparency and not necessarily affect any party's leverage.

Comment: We received some comments that opposed the adoption of a requirement that all pharmacy price concessions be included in the negotiated price at the point of sale because it would lead to higher premiums and increased government costs. Several commenters stated that the financial and budgetary impact of revising the definition of negotiated price to include all pharmacy price concessions does not address the Administration's objectives to reduce overall drug prices. A few commenters noted that the CMS impact analysis estimates that drug manufacturers would have a financial gain due to less liability during the coverage gap. These commenters stated that this is particularly concerning as it financially rewards the very industry responsible for high drug prices. A few commenters posited that any savings from the policy would not be distributed evenly among beneficiaries. The commenters noted that although a subset of beneficiaries would pay less for discounted drugs, other beneficiaries would only experience higher premiums. The

commenters also pointed out that some of the cost would be shifted to the Federal Government and would ultimately be borne by taxpayers. A few commenters were concerned this rule would disproportionately increase the financial burden for vulnerable beneficiaries with limited resources that are especially cost-conscious. They stated that premium increases due to the rule may potentially hinder progress in health equity for vulnerable populations and asked CMS to consider the potential to detract from the Agency's overall goal of improving health equity and access.

Response: While reducing overall prices is one of the Administration's objectives, the new definition of "negotiated price" set forth in this rule was not intended to meet that objective. The new definition will lead to savings for some beneficiaries by lowering the prices they pay for prescription drugs at the point of sale. As explained in the proposed rule, when pharmacy price concessions and other price concessions are not reflected in the negotiated price (that is, are applied instead as DIR at the end of the coverage year), beneficiary cost-sharing increases. For many Part D beneficiaries who utilize drugs and thus incur cost-sharing expenses, this means, on average, higher overall out-of-pocket costs, even after accounting for the premium savings tied to higher DIR. A principal purpose of any health insurance is to help reduce the financial burden borne by enrollees who need to utilize covered benefits.⁹¹ We believe it is appropriate that savings from price concessions go toward defraying the out-of-pocket costs of the beneficiaries who purchase prescription drugs.

We disagree that this rule would increase the financial burden for vulnerable beneficiaries, hinder progress in health equity for vulnerable populations, or detract from the Agency's overall goal of improving health equity and access. In fact, the lower cost-sharing for prescription drugs will help beneficiaries with serious health conditions, who bear a disproportionate burden of health care costs. These beneficiaries have reported difficulties paying for prescription drugs as a common problem.⁹² As stated earlier in the preamble, the application of all pharmacy price concessions to the negotiated price will lower cost-sharing for beneficiaries with the most serious health conditions. In addition, lower

beneficiary cost-sharing can lead to increased medication adherence, which could result in a potential decrease in overall medical costs.⁹³ Finally, this policy does not change how much LIS-eligible beneficiaries pay in cost-sharing or premiums, and therefore the low-income subsidy will continue to protect the most vulnerable populations.

Comment: A few commenters stated that, although including all pharmacy price concessions in the price at the point of sale could lead to lower cost-sharing for beneficiaries, it does not solve the complexities of drug pricing. For example, these commenters noted that the policy would not help beneficiaries who take expensive drugs with no post-point-of-sale rebates or discounts.

Response: We appreciate the comment. Although we believe adopting this new definition of "negotiated price" is an important first step toward improving the affordability of drugs for the majority of beneficiaries who do not receive the low-income subsidy (LIS), and improving price transparency, we acknowledge that this change does not, nor is it intended to, address the full range of complexities of drug pricing, and may not directly reduce out-of-pocket costs for all beneficiaries. However, as discussed in further detail in section IV of this final rule, we project that the new definition of "negotiated price" (modified to be applied across all phases of the Part D benefit, including the coverage gap phase (see comments, response and discussion below)) will save beneficiaries \$26.5 billion between 2024 and 2032.

Comment: Some commenters opposed the policy on the ground that the new definition of "negotiated price" would violate the statutory definition of negotiated price at section 1860D–2(d)(1)(B) of the Act. Some commenters suggested that CMS would be exceeding its delegated authority if it finalized a requirement that all pharmacy price concessions be included in the point-of-sale price. Commenters also stated that Congress's intent was to provide Part D sponsors with the flexibility in administering the Part D prescription drug benefit as a private market model and that the pharmacy price concession rule breaks with this fundamental trust in private markets instilled in the statute by Congress. In addition, some commenters noted that CMS has on

multiple previous occasions recognized that the term "negotiated price," as defined by Congress, grants Part D plans discretion in how they treat pharmacy price concessions and, as a result of this flexibility, Part D plans have been drivers of innovation in benefit design. Some commenters contended that CMS cannot now purport to interpret the statute in a way that eliminates post-point-of-sale pharmacy price concessions, given that the agency previously found that the plain language of the statute permitted such price concessions. Further, commenters stated that an agency may not reverse a longstanding and reasoned policy without an adequate and thoughtful explanation for such a decision. Because the rule is unaligned with the intent of Congress, commenters argued, a reviewing court may find such policy changes to be substantively invalid because they would not be based on a permissible construction of the statute.

A few commenters writing in support of revising the definition stated that the statutory definition of negotiated price gives CMS the authority to require Part D plan sponsors to include all price concessions in the negotiated price. These commenters explained that section 1860D–2(d)(1)(B) of the Act specifies that the negotiated price "shall" take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs. These commenters stated that the statute's use of the word "shall" means that the negotiated price is required to reflect these price concessions. These commenters reasoned that, because the statute does not specify what percentage of these price concessions must be used to lower negotiated prices and thus passed through to patients at the point of sale or otherwise provide details about implementing the pass-through requirement, CMS has the authority to fill in those details. These commenters noted that plan sponsors and PBMs have exploited the ability to exclude price concessions that "cannot reasonably be determined at the point of sale" under the current definition of negotiated price. These commenters stated that plan sponsors and PBMs have applied this exception broadly and not passed the vast majority of pharmacy price concessions through to the point of sale, and that by doing so, plan sponsors and PBMs are violating CMS's intent in allowing this exception (see 2014 final rule titled "Contract Year 2015 Policy and Technical Changes to

⁹¹ Keisler-Starkey, K.B., & Bunch, L.N. (2021). Health Insurance Coverage in the United States: 2020. *United States Census Bureau*.

⁹² Kyle, M.A., Blendon, R.J., Benson, J.M., Abrams, M.K., & Schneider, E.C. (2019). Financial hardships of Medicare beneficiaries with serious illness. *Health Affairs*, 38(11), 1801–1806.

⁹³ Cong, M., Chaisson, J., Cantrell, D., Mohundro, B.L., Carby, M., Ford, M., . . . & Nigam, S.C. (2021). Association of co-pay elimination with medication adherence and total cost. *The American Journal of Managed Care*, 27(6), 249–254. <https://doi.org/10.37765/ajmc.2021.88664>.

the Medicare Advantage and the Medicare Prescription Drug Benefit Programs” (79 FR 29878), which appeared in the **Federal Register** on May 23, 2014).

Response: As we stated in the proposed rule, section 1860D–2(d)(1)(B) of the Act requires that negotiated prices “shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs” The statutory language does not prescribe the extent to which the negotiated prices shall take into account negotiated price concessions, and therefore, provides CMS with the authority to decide whether plan sponsors should be required to include all price concessions in the negotiated price. We have previously interpreted this language to mean that some, but not all, price concessions must be applied to the negotiated price (see, for example, 70 FR 4244 and 74 FR 1511). Although we continue to believe that the prior interpretation of “take into account” was permissible, we believe that our initial interpretation may have been overly definitive with respect to the intended meaning of “take into account.” Requiring that all pharmacy price concessions be applied at the point-of-sale would ensure that negotiated prices “take into account” at least some price concessions and, therefore, would be consistent with and permitted by the plain language of section 1860D–2(d)(1)(B) of the Act. In this way, the negotiated price is required to “take into account” these price concessions. This policy we are finalizing is thus consistent with the statutory definition of negotiated price. In addition, the policy we are adopting is consistent with CMS’s delegated authority to interpret the statute and administer the Medicare program. Moreover, the statutory definition of negotiated price should be viewed in the broader context of administration of the Part D program and support better functioning of the Part D benefit overall. The policy we are adopting does so by addressing market incentives for plans to keep premiums low, by reducing point-of-sale costs for beneficiaries and by bringing the balance of cost-sharing among the government, plans, and beneficiaries into better alignment. We disagree with commenters who contend that CMS cannot change its interpretation of the statute. As noted above, the statutory language at section 1860D–2(d)(1)(B) of the Act does not prescribe the extent to which the negotiated prices shall take into account negotiated price concessions, and

therefore, provides CMS with the authority to decide whether plan sponsors should be required to include all pharmacy price concessions in the negotiated price. We believe that it is a permissible interpretation of the statute to require that all pharmacy price concessions be applied at the point of sale. The policy decision to treat pharmacy price concessions in this way is supported by evidence indicating that very few pharmacy price concessions are being passed on to beneficiaries in the form of lower cost-sharing at the point of sale and the significant growth in such concessions. As noted by some commenters, CMS originally believed that Part D plans would apply price concessions to the negotiated price due to pharmacy and beneficiary market competition; however, this has not been occurring as expected. As discussed in the proposed rule preamble, the sponsor reported data and stakeholder comments (83 FR 62174 through 62180) indicate that most price concessions are being applied after the point-of-sale. We reconsidered our interpretation of section 1860D–2(d)(1)(B) given that the initial interpretation does not accomplish the goals of meaningful price transparency, consistent application of pharmacy payment concessions, and preventing cost shifting to beneficiaries and taxpayers. We also disagree with commenters who claim that CMS is reversing its longstanding policy without an adequate explanation. CMS has carefully and thoroughly considered this issue over several years. Indeed, since 2014, CMS has addressed this topic multiple times, including soliciting comment through a formal process three times and holding numerous listening sessions.

We disagree with commenters who contend that the policy we are adopting in this rule is inconsistent with trust in private markets or would hinder innovation in benefit design. As noted in the proposed rule, this policy changes the reporting requirements for Part D sponsors; it does not govern payment arrangements or eliminate post-point-of-sale price concessions, but rather only requires that all pharmacy price concessions be included in the negotiated price. Therefore, Part D sponsors remain free to negotiate innovative arrangements with network pharmacies. In addition, to the extent our policy increases transparency and information symmetry, as noted previously, it would improve competition in private markets. Regarding comments about Congressional intent for Part D sponsor

flexibility, we do not believe this policy fundamentally changes Part D sponsor flexibility in administering the Part D benefit. Sponsors continue to exercise extensive flexibility over plan design and payment.

CMS appreciates commenters support for the revision of the regulatory definition and statutory interpretation. As discussed in the preamble and mentioned by commenters that support revising the definition, this policy requiring that all pharmacy price concessions be applied to the negotiated price would ensure that negotiated prices “take into account” at least some price concessions and would be passed on to beneficiaries in the form of lower cost-sharing at the point of sale.

Comment: A few commenters stated that a requirement that the negotiated price reflect the lowest possible reimbursement to the pharmacy at the point of sale would violate the statutory prohibition under section 1860D–11(i) of the Act on CMS “institut[ing] a price structure for the reimbursement of covered part D drugs.” Commenters stated that requiring pharmacy price concessions to be passed through at the point of sale would effectively create a price structure for pharmacy payment whereby sponsors would have to negotiate only on the lowest possible price/rates with each and every pharmacy with which they contract. Commenters argued that this “single variable negotiating system” would result in standard rates across all pharmacy lines of business.

Response: CMS did not propose, and is not adopting, a price structure for the reimbursement of covered Part D drugs; rather, the requirement that the negotiated price reflect the lowest possible reimbursement the pharmacy will receive for a particular drug regulates only the reporting of data on the PDE record. The examples provided in this rule under section 3c. Lowest Possible Reimbursement Example clearly illustrate how the requirement that the negotiated price reflect the lowest possible reimbursement would be reflected on the PDE, under different payment arrangements. The policy we are adopting in this final rule has no bearing on how a pharmacy’s payment is calculated or what price structure sponsors use. Sponsors still have the option of negotiating with pharmacies on factors related to the payment rate ultimately received by the pharmacy, which may be higher than the negotiated price. While sponsors must comply with the prompt payment requirements at § 423.530, they continue to have discretion over the timeframes

for settling payment incentives and penalties.

Comment: Most commenters, including beneficiary advocates and beneficiaries, applauded CMS' effort to provide cost-sharing relief to beneficiaries.

Some commenters stated that, if finalized, the requirement that all pharmacy price concessions be included in the negotiated price would increase beneficiary confusion and frustration over health care costs. These commenters suggested that beneficiaries do not have an awareness of the impact of pharmacy price concessions on their overall pharmacy drug and premium costs, and beneficiaries will not understand that their increased premium costs will be due to Part D sponsors no longer reporting pharmacy price concessions as DIR.

Response: We thank commenters for their support of the application of all pharmacy price concessions to the negotiated price, which will lower beneficiary cost-sharing. Moreover, establishing consistency in how sponsors report pharmacy price concessions will allow for more meaningful price comparisons (for both premium and cost-sharing) and more well-informed choices by consumers. While beneficiaries may not immediately understand the factors underlying premiums increases and cost-sharing decreases, they will be better positioned to compare plans, because the standardized reporting of negotiated price required by this rule will create a more consistent basis for comparing plans based on premiums and cost-sharing.

Comment: Several commenters who opposed adopting a new definition of "negotiated price" stated that a requirement that all pharmacy price concessions be passed through at the point of sale, as opposed to being reported as DIR, would violate the statutory "non-interference clause," at section 1860D-11(i) of the Act, which specifies that "the Secretary . . . may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors." A few commenters charged that the new definition would be designed to directly affect the contracting processes between plans and pharmacies by mandating changes to point-of-sale prices. Several commenters indicated that the policy would take away Part D sponsors' and PBMs' ability to negotiate downside incentives with pharmacies tied to performance or quality targets, and that it would impair their ability to negotiate rates with pharmacies. A few commenters suggested that the new

definition would limit the tools available to Part D sponsors to establish varied and innovative incentive arrangements with contracted pharmacies intended to achieve important goals, such as increasing generic dispensing rates, and to focus on priorities, such as reducing the use of high-risk medications and improving medication adherence. Several commenters asserted that pharmacy price concessions are used to develop a preferred pharmacy network while also keeping Part D premiums low and expressed concern that adopting the new definition of "negotiated price" would limit the ability of plan sponsors to negotiate effective, high-value contracts with pharmacies, resulting in an increase in both beneficiary premiums and government spending, as well as a decrease in preferred pharmacy networks.

A commenter noted that this policy would adversely affect the reductions in cost-sharing for beneficiaries that have been realized under the Part D Senior Savings Model. The commenter stated that Part D plans that participate in this Center for Medicare & Medicaid Innovation (CMMI) model are relying on their preferred pharmacy networks to stock and dispense specific products. The commenter noted that additional contract terms help plans achieve goals under models and that pharmacy interactions can increase adherence to prescribed medications and foster therapeutic substitution that can save beneficiaries and plans money in the long run. The commenter stated this policy will put the benefits achieved through this model at risk by interfering with the relationships that have been formed between PBMs and pharmacies.

Some commenters stated that the new definition of "negotiated price" would not violate the "non-interference clause." Several commenters asserted that CMS would not be inserting itself into negotiations between plan sponsors, PBMs, and pharmacies by defining the negotiated price and altering the manner in which to account for pharmacy price concessions. Rather, some commenters stated, CMS is authorized to promulgate regulations in accordance with the Medicare statute's any willing provider and prompt payment requirements, and such regulations would not run afoul of Medicare's non-interference clause. Commenters also noted that CMS retains authority to promulgate such regulations in the interest of protecting market competition, which is consistent with the plain meaning of the text of the non-interference clause. Some commenters noted that plan sponsors

and their PBMs and pharmacies are still free to negotiate any reimbursement, concessions, or pay structure they like.

Response: We agree with commenters that this rule does not violate the non-interference clause. This rule does not implicate or impose requirements on plan-pharmacy interactions, such as contracting, negotiations, payments rates, incentive arrangements, quality goals or targets, performance-based payments or performance-based contracting. Sponsors and pharmacies remain free to negotiate any such arrangements they wish—this rule requires only that the negotiated price reflect the price that the parties have negotiated as the lowest possible reimbursement that the pharmacy could receive for a particular drug, inclusive of all pharmacy price concessions. As noted above, the requirement that the negotiated price reflect the lowest possible reimbursement that a pharmacy receives for a drug is directly related to the reporting of data on the PDE record and determination of beneficiary cost-sharing and to promoting price transparency to the beneficiary. The connection that commenters make between this policy and adverse effects on the Part D Senior Savings model and Part D sponsors and pharmacy relationships is unclear. To the extent that our policy has an effect on the calculation of cost-sharing under the model, we would anticipate that the model could be adapted, to accommodate new requirements and policies. As we have stated previously, this policy does not impose requirements on contracts between sponsors or their PBMs and pharmacies; therefore, we do not see how this policy affects performance-based payment adjustments that exist in the Senior Savings Model. We agree that pharmacy interactions can increase adherence to prescribed medications and foster therapeutic substitution that can save beneficiaries and plans money in the long run.

Comment: A commenter noted that beneficiary costs are based on a combination of premiums and cost-sharing, both of which are already fully disclosed to the beneficiary through plan materials and other tools like Medicare Plan Finder (MPF). This commenter stated that beneficiaries use tools like MPF to choose plans based on factors including cost-sharing, premiums, formulary coverage, pharmacy network, Star Ratings, and integration or non-integration with MA plans. This commenter maintained that tools like MPF already allow for a real, meaningful, and actionable comparison of plan prices and efficiencies and

therefore, promoting transparency through this policy is unnecessary.

Commenters believed that the pharmacy price concession rule will undo the effectiveness of MPF and create less transparency by causing confusion with the introduction of the new definition of negotiated price. Commenters were also concerned that if CMS allows plans the flexibility to determine how much of the pharmacy price concessions to pass through at the point of service (POS) for applicable drugs in the coverage gap (while using the negotiated price determined using the lowest possible reimbursement to the pharmacy in the non-coverage gap phases), then MPF will need to be updated to account for the differences, which could add to beneficiary confusion.

Commenters recommend that CMS use the MPF tool to examine which factors most impact beneficiaries when making a plan choice before CMS makes drastic changes to the program through the pharmacy price concession rule. They suggested that CMS use underlying MPF data to perform analysis to determine how important premiums are in the total calculus of plan choice as compared to overall out-of-pocket (OOP) costs.

Commenters also stated that the proposal would require development of processes to ensure accurate information is posted on MPF and that there would be considerable challenges with loading accurate pharmacy network data into MPF in a timely fashion, as there is likely to be increased network volatility as contracts are renegotiated.

Response: We agree with commenters that MPF is a valuable tool that beneficiaries use to make informed decisions. We note that the cost-sharing and premium data for Part D reflected in the MPF is and will continue to give beneficiaries an accurate assessment of their expected costs for a given plan. This policy does not affect the accuracy of the data in MPF as the new definition of negotiated price does not change how the out-of-pocket costs are displayed to the beneficiary. As discussed elsewhere in this rule, CMS is finalizing a policy to require that pharmacy price concessions be applied to the negotiated price across all phases of the Part D benefit, including the coverage gap phase. Therefore, MPF will not need to account for the difference in how pharmacy price concessions are applied in the gap versus non-coverage gap phases. Thus, we do not see how commenters' claims that the new definition will cause confusion due the

new definition of negotiated price are substantiated.

In addition, CMS's MPF tool utilizes drug prices net of rebates and other price concessions that are applied at the point of sale, so MPF's current design already supports the collection and display of drug prices as contemplated under this rule. Therefore, CMS does not anticipate implementing changes to the MPF tool or the methodology currently in place. Plans should refer back to the Part D drug pricing submission guidance published annually by CMS. This guidance provides technical instructions on how to submit drug prices that account for rebates and other price concessions that are applied at the point of sale. The applicability date of January 1, 2024, for the new definition of negotiated price provides time for sponsors to prepare data for submission to MPF.

We understand that beneficiaries consider many factors in selecting a plan and that the relative importance of premium costs as opposed to out-of-pocket costs can vary depending upon a beneficiary's particular circumstances. Moreover, even for beneficiaries who prioritize premium costs over other factors, this rule will result in premiums that better reflect the relative efficiency of plan designs for prescription drug coverage, and therefore, this policy will contribute to more informed choices by beneficiaries.

Comment: A few commenters expressed concern that the impact of the rule would likely be more profound on prescription drug plans (PDPs) than Medicare Advantage prescription drug (MA-PDs) plans, as many PDPs would be unable to avoid a significant increase in premiums, and could potentially be priced out of the market. Commenters explained that PDPs lack the additional financial cushion available to MA organizations (MAOs) as a result of their offering an integrated benefit. Also, PDPs lack the financial incentives of Star Ratings bonus payments for which MAOs are eligible. Commenters were concerned that as beneficiaries lose access to PDPs, many would be forced to enroll in MA-PDs, and be driven from original Medicare, which may be a source of comfort and stability to many, especially older beneficiaries, into managed care plans.

Response: CMS appreciates the comments and concerns about potential differential impacts on PDPs versus MA-PDs. One outcome of this rule is that beneficiary cost-sharing may be reduced, regardless of the plan type in which they are enrolled. The statement that beneficiaries may be driven from original Medicare to Medicare

Advantage assumes that Part D benefits are the sole factor behind individuals' decisions in choosing between original Medicare and Medicare Advantage. We note that many factors, such as geographic location, Medicare Advantage plan options, and preferences related to provider choices, are also important considerations for many beneficiaries in choosing between original Medicare and Medicare Advantage. We also note that beneficiaries selecting original Medicare (for other reasons) will be comparing PDP premiums against one another and not comparing PDP premiums against MA-PD premiums. Medicare Advantage plans that use Part C rebates to offset Part D premium increases may need to forgo offering other benefits that would have been provided with those funds.

Comment: Some commenters stated that it would be extremely challenging, if not impossible, to implement changes to bid assumptions, renegotiate pharmacy contracts, and make the necessary revisions to pharmacy adjudication systems prior to January 1, 2023, and recommended that the implementation of the rule be postponed until 2024 or later. Commenters noted that if the rule is applicable for contract year 2023, there could be disruptions in member benefits because of the contracting and systems changes that would have to happen in time for the Fall 2022 Open Enrollment. As a result of the compressed timeline, they are concerned that focus will be taken away from member benefits.

A commenter noted that Part D plan sponsors would need to renegotiate their contracts with PBMs. This commenter stated that not only would it be necessary to renegotiate fee arrangements, but also, given the rule, Part D plan sponsors may want to discuss new business strategies and underwriting scenarios with their PBMs. The commenter explained that this is a lengthy, resource-intensive process that precedes pharmacy contracting because it is the plan that sets the target for pharmacy contracts that the PBM negotiates. This commenter stated that CMS' proposed timeline would cause the Part D sponsor/PBM negotiations to occur at the same time as PBMs are trying to renegotiate pharmacy contracts.

Commenters also explained that changes to pharmacy contracts would not be mere technical changes, but would include how, when, and the amount pharmacies would receive in reimbursement. Commenters stated that most pharmacies are likely to see a significant reduction in reimbursement, which could result in some pharmacies

refusing to participate in the Part D network at the new reimbursement rate. Commenters explained that issues with participation could impact preferred pharmacy arrangements and network access, which could result in additional time needed for additional contracting to ensure that pharmacy network access requirements are satisfied.

However, other commenters indicated that plans/PBMs customarily impose new terms without any consultation or negotiation. Some commenters stated that most fees charged to pharmacies are placed in the provider manual, which is included by reference into the contract terms. A commenter stated that all or substantially all PBMs have contractual terms in place with pharmacies to enable payment term modifications for any change in DIR, such as requiring immediate renegotiation of rates or setting a fixed reimbursement rate in the event of policy change. This commenter believed that any additional delay in providing this rule would improperly place Part D plan sponsor and PBM profits above beneficiary well-being and believe CMS' current proposed timeline is appropriate.

Response: We find commenters' concerns regarding the ability to effectuate contract negotiations and make potential systems changes in time for 2023 implementation to be compelling. To give all parties sufficient time to implement this policy, including making the systems changes that will be needed to ensure that cost-sharing is correctly adjudicated for beneficiaries at the point of sale, we are modifying our proposal and finalizing an applicability date of January 1, 2024. This will give the Part D sponsors over a year to contract and prepare bids for the 2024 contract year. In addition, based upon our experience implementing changes in the Part D program that require Part D sponsor and PBM system changes, we believe that this additional time is sufficient to operationalize the new definition of negotiated price. We are making corresponding changes to the regulation at 42 CFR 423.100 to retain the current regulatory definition of "negotiated prices" for 2023 and adopt the new regulatory definition of "negotiated price" for 2024 and thereafter.

Comment: A significant volume of letters were submitted as the result of a letter writing campaign and encouraged CMS to move forward as swiftly as possible in adopting the new definition of negotiated price.

Response: We thank the commenters for their feedback. While we appreciate the need to pass meaningful out of pocket cost savings to and increase drug

price transparency for beneficiaries as soon as possible, concerns related to contracting and operational timelines that could disrupt successful implementation are sufficiently compelling to warrant making this policy applicable beginning on January 1, 2024.

After consideration of comments received, CMS is finalizing the new definition of negotiated price at § 423.100 effective January 1, 2024. Under this definition, the negotiated price must be the lowest possible reimbursement a network entity will receive, in total, for a particular drug and include all pharmacy price concessions. To implement this policy, we will also remove the existing definition of negotiated prices at § 423.100, effective January 1, 2024.

b. Lowest Possible Reimbursement

To effectively capture all pharmacy price concessions at the point-of-sale consistently across sponsors, we proposed to require that the negotiated price reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug. Under this approach, the price reported at the point of sale would need to include all price concessions that could potentially flow from network pharmacies, as well as any dispensing fees, but exclude any additional contingent amounts that could flow to network pharmacies and thus increase prices over the lowest possible reimbursement level, such as incentive fees. That is, if a performance-based payment arrangement exists between a sponsor and a network pharmacy, the point-of-sale price of a drug reported to CMS would need to equal the final reimbursement that the network pharmacy would receive for that drug under the arrangement if the pharmacy's performance score were the lowest possible. If a pharmacy is ultimately paid an amount above the lowest possible reimbursement (such as in situations where a pharmacy's performance under a performance-based arrangement triggers a bonus payment or a smaller penalty than that assessed for the lowest level of performance), the difference between the negotiated price reported to CMS on the PDE record and the final payment to the pharmacy would need to be reported as negative DIR as part of the annual report on DIR following the end of the year. For an illustration of how negotiated prices would be reported under such an approach, see the lowest cost reimbursement example provided later in this rule.

By requiring that sponsors assume the lowest possible pharmacy performance when reporting the negotiated price, we would be prescribing a standardized way for Part D sponsors to treat the unknown (final pharmacy performance) at the point of sale under a performance-based payment arrangement, which many Part D sponsors and PBMs have identified as the most substantial operational barrier to including such concessions at the point of sale. The proposed rule discussed our bases for believing that requiring that the negotiated price reflect the lowest possible reimbursement a network pharmacy could receive for a Part D drug is the best approach to achieve our goals, as noted previously, of (1) consistency (standardized reporting of negotiated prices and DIR); (2) preventing cost-shifting to beneficiaries; and (3) price transparency for beneficiaries, the government, and other stakeholders.

Consistent with this approach, we proposed that all contingent incentive payments (that is, an amount that is paid to the pharmacy instead of a price concession from the pharmacy) be excluded from the negotiated price. As explained in the proposed rule, including the amount of any contingent incentive payments to pharmacies in the negotiated price would make drug prices appear higher at a "high performing" pharmacy, which receives an incentive payment, than at a "poor performing" pharmacy, which is assessed a penalty, and would also reduce price transparency. This pricing differential could create a perverse incentive for beneficiaries to choose a "lower performing" pharmacy for the advantage of a lower price. Additionally, Part D sponsors and their intermediaries previously asserted in public comments on the 2017 and 2018 rules that network pharmacies lose motivation to improve performance when all performance-based adjustments are required to be reported up-front. Revising the negotiated price definition as proposed would mitigate this concern by allowing sponsors and their intermediaries to continue to motivate network pharmacies to improve their performance with the promise of future incentive payments that would increase pharmacy reimbursement from the level of the lowest possible reimbursement per claim. Further, we emphasized that the proposed changes would not require pharmacies to be paid in a certain way; rather we would be requiring standardized reporting to CMS of drug prices at the point of sale.

c. Lowest Possible Reimbursement Example

To illustrate how Part D sponsors and their intermediaries would report costs under our proposal, we provided the following example. Suppose that under a performance-based payment arrangement between a Part D sponsor and its network pharmacy, the sponsor will implement one of three scenarios: (1) Recoup 5 percent of its total Part D-related payments to the pharmacy at the end of the contract year for the pharmacy's failure to meet performance standards; (2) recoup no payments for average performance; or (3) provide a bonus equal to 1 percent of total payments to the pharmacy for high performance. For a drug that the sponsor has agreed to pay the pharmacy \$100 at the point-of-sale, the pharmacy's final reimbursement under this arrangement would be: (1) \$95 for poor performance; (2) \$100 for average performance; or (3) \$101 for high performance. Under the current definition of negotiated prices, the reported negotiated price is likely to be \$100, given the reasonably determined exception for contingent pharmacy payment adjustments. However, under the proposed definition, for all three performance scenarios, the negotiated price reported to CMS on the PDE record at the point of sale for this drug would be \$95, or the lowest reimbursement possible under the arrangement. Thus, if a plan enrollee were required to pay 25 percent coinsurance for this drug, then the enrollee's costs under all scenarios would be 25 percent of \$95, or \$23.75, which is less than the \$25 the enrollee would pay today (when the negotiated price is likely to be reported as \$100). Finally, any difference between the reported negotiated price and the pharmacy's final reimbursement for this drug would be reported as DIR at the end of the coverage year. Under this requirement, the sponsor would report \$0 as DIR under the poor performance scenario (\$95 minus \$95), -\$5 as DIR under the average performance scenario (\$95 minus \$100), and -\$6 as DIR under the high-performance scenario (\$95 minus \$101), for every covered claim for this drug purchased at this pharmacy.

Comment: Many commenters encouraged CMS to address the proposed rule's potential impact on pharmacy cash flow during the first quarter of 2023 assuming the rule is implemented in January 2023. Many commenters expressed concern that a pharmacy's payments for CY 2022 DIR fees to Part D sponsors and/or their

PBMs will be due concurrently with the time pharmacies expect to receive lower reimbursements at the point of sale. Many of these commenters urged CMS to implement this proposal on January 1, 2023; however, due to the potential impact of the retroactive fees and implementation of the rule, these commenters urged CMS to require sponsors and/or their PBMs to establish payment plans with pharmacies that need them during the transition period. Commenters noted that when Medicare Part D was established, hundreds of pharmacies closed because of cash flow issues, necessitating Congressional action to establish prompt pay rules. These commenters urged that CMS emphasize that prompt payment requirements will continue to be enforced.

Response: CMS understands these concerns but does not have the authority to mandate payment plans between plans sponsors and pharmacies. We acknowledge the possibility that changes in cash flow may cause some already struggling pharmacies to decrease services or medication availability, and/or be unable to remain in business, which may impact pharmacy networks. Note that CMS will be particularly attuned to plan compliance with pharmacy access standards under § 423.120 to ensure that all Medicare Part D beneficiaries have convenient access to pharmacies and medications. Therefore, we encourage Part D sponsors to consider options, such as payment plans or alternate payment arrangements, to minimize impacts to vulnerable pharmacies and the patients they serve. We also note that the prompt payment requirements for Part D, as described in § 423.520, will continue to apply and that Part D sponsors must pay clean claims in accordance with the prompt pay regulation. As noted elsewhere, we are finalizing an applicability date of January 1, 2024, instead of January 1, 2023. Nonetheless, we would expect these same concerns that commenters raised for January 1, 2023 to be similarly applicable to January 1, 2024. With this extra implementation time, we believe Part D sponsors and pharmacies will now have adequate time to implement payment plans or make other arrangements to address these cash flow concerns at the beginning of 2024.

Comment: Many commenters wrote in support of a requirement that the negotiated price reflect the lowest possible reimbursement to the pharmacy because they believed this approach would make it possible for pharmacies to better predict the

minimum reimbursement they could receive on a per-claim level.

Response: We thank these commenters for their support of this policy. We agree that defining negotiated price to mean the lowest possible reimbursement received by the pharmacy will provide greater transparency and may improve predictability of per-claim revenue.

Comment: Several commenters opposed the policy, suggesting that a requirement that the price paid to a pharmacy for a covered Part D drug be net of all possible downward adjustments would effectively eliminate the ability of Part D plans to employ performance-based negative pharmacy payment adjustments. A few commenters suggested that the elimination or restriction of performance-based pharmacy payment arrangements is out of line with current CMS initiatives to expand and incentivize value-based arrangements, such as the recently announced agenda to expand value-based care in Medicare by CY 2023. Commenters stated that restricting or eliminating payment arrangements that incentivize pharmacy performance is counterintuitive to these ongoing efforts to bring increased value to the Part D program as well as the rest of Medicare. A few commenters stated that this rule will make it harder to achieve the bold quality agenda set forth by CMS (cited in *Health Affairs* written by CMS officials). These commenters stated that pharmacy DIR is generated by two-sided, value-based contracts—similar to contracts entered into by health plans and other providers as the optimal path to transform health care delivery and payment. These commenters also noted that these pharmacy DIR contracts often focus on driving Stars performance and increasing generic dispensing to the benefit of the Medicare program and its beneficiaries. Some commenters stated that applying all pharmacy price concessions at the point of sale would negatively impact Star Ratings and performance-based models such as MIPS and APMs. Commenters argued that if sponsors adopt a “bonus only model” when paying pharmacies for performance, there will not be an adequate financial incentive for pharmacies to help plans improve pharmacy measures. A few commenters noted that performance on adherence measures has been trending up as has the generic dispensing rate and MTM completion. These commenters stated that this proposal would interfere with the DIR contracting that has yielded these impressive results.

A commenter noted that recent research has shown that pharmacy performance measures that address social determinants of health (SDOH) help promote equitable and high-quality care. The commenter stated that Medicare beneficiaries are best served when their providers are focused on addressing community-level SDOH barriers, and in pharmacy care, a number of programs are funded and incentivized through Part D plan price concessions that CMS would effectively eliminate.

Response: We did not propose to eliminate or restrict the use of any performance-based pharmacy payment arrangements, and we do not agree that a policy of requiring the negotiated price to reflect the lowest possible reimbursement to the pharmacy for a Part D drug eliminates or restricts Part D sponsors' ability to institute performance-based pharmacy payment arrangements. The new definition of negotiated price that we are adopting in this final rule does not mandate how sponsors contract with, incentivize, or pay pharmacies in their network. The new definition of negotiated price applies only to how the PDE data is populated and reported and thus the price of the drug on which beneficiary cost-sharing is determined. We also disagree with the implication that performance-based contingent incentive payments provide pharmacies with insufficient motivation to engage in activities that impact sponsors' Star Ratings and other performance-based models. Rather, sponsors remain free to motivate pharmacies by offering performance-based payment arrangements to pharmacies. Applying all pharmacy price concessions to the negotiated price will provide pharmacies with more information on the reimbursement they will receive if they fail to meet performance metrics. While we are not specifying payment arrangements between plan sponsors and pharmacies, we encourage fair and equitable value-based arrangements, including those focused on social determinants of health (SDOH), that improve beneficiaries' quality of care and reduce health care costs.

Comment: Many commenters urged CMS to collect pharmacy performance measure information from Part D sponsors as finalized in the January 2021 final rule (86 FR 5864) to assess concerns raised by pharmacies about performance measures. Several commenters noted that PBMs often apply one-size-fits-all metrics that are not relevant to a pharmacy's population or specialty. Commenters explained that they are penalized for not having a large

enough population for a credible sample that PBMs use to assess performance. A few commenters noted they were penalized for not meeting generic dispensing rates because the pharmacies are specialty pharmacies serving a population whose medical conditions do not have available generic drugs for treatment. A commenter recommended that plan sponsors not be able to apply the pharmacy price concessions to all pharmacies within a particular chain of pharmacies, such as local chains or supermarket pharmacies, based on the performance of the lowest performing pharmacy in the chain. This commenter stated that the ability of pharmacies to meet performance standards set forth by PBMs and plan sponsors is hindered by the fact that no consideration is given to inherent handicaps, such as socio-economic disparities between pharmacy geographic locations or as noted above differences in dispensing practices between retail and specialty drugs. Many commenters noted that penalties from one measure and one medication are applied to all medications, setting thresholds pharmacies cannot meet.

Response: We appreciate the comments regarding the nature of and differing application of pharmacy performance metrics to assess pharmacy performance; however, we did not propose to address pharmacy performance metrics in the proposed rule. We addressed reporting of pharmacy performance measures to CMS in the January 2021 final rule (86 FR 5864). In the January 2021 final rule, we finalized a proposal to give CMS the authority to establish a Part D reporting requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreements. This authority to establish a reporting requirement is effective January 2022; however, the actual data elements must be proposed through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process in a future package. We encourage the industry to continue to work together on developing a set of pharmacy performance measures through a consensus process and Part D sponsors to adopt such measures to ensure standardization, transparency and fairness. We are aware that the Pharmacy Quality Alliance (PQA), a measure developer, is working to build consensus on pharmacy-level measures across pharmacies, plans, PBMs, and other stakeholders.

Comment: Some commenters stated that CMS did not articulate any rational basis for giving "preferable" treatment

for pharmacy incentive payments over pharmacy price concessions. A few commenters asserted that giving special treatment to higher payments to pharmacies underscores the arbitrary and capricious nature of CMS's effort to redefine negotiated price. A few commenters supported a requirement that all contingent incentive payments be excluded from the negotiated price. The commenters noted that this approach supports PBMs' ability to measure and monitor pharmacy performance on Stars Ratings-related measures and incentivize pharmacies for their performance without negatively impacting the beneficiaries' cost-sharing.

Response: We disagree that the proposal gives preferential treatment or higher payments to pharmacies. The proposed rule does not impose requirements on the actual payments made to pharmacies. This rule sets forth requirements that standardize how and when pharmacy price concessions are reported to CMS. In the proposed rule, we described the information gathered through the Request for Information in the November 2017 proposed rule regarding pharmacy price concessions (payments from network pharmacies to sponsors or their intermediaries for "poor performance") and incentive payments (payments made to pharmacies by plan sponsors or their intermediaries for "high performance"). The primary concern with including incentive payments in the negotiated price is that including these types of payments in the negotiated price would make drug prices appear higher at a "high performing" pharmacy, which receives an incentive payment, than at a "poor performing" pharmacy, which is assessed a penalty. This pricing differential could create a perverse incentive for beneficiaries to choose a "lower performing" pharmacy for the advantage of a lower price. Additionally, Part D sponsors and their intermediaries previously asserted in public comments on the 2017 and 2018 rules that network pharmacies lose motivation to improve performance when all performance-based adjustments are required to be reported up-front. Revising the negotiated price definition to include pharmacy price concessions and not incentive payments would mitigate this concern by allowing sponsors and their intermediaries to motivate network pharmacies to improve their performance with the promise of future incentive payments that would increase pharmacy reimbursement from the level of the lowest possible reimbursement per

claim. We thank the commenters for the support on excluding incentive payments from the negotiated price and agree that not including contingent incentive payments in the negotiated price best aligns beneficiary, plan, and pharmacy incentives.

Comment: Many commenters requested that CMS establish safeguards to guarantee that pharmacies participating in Medicare Part D receive a reasonable rate of reimbursement. These commenters urged the administration to ensure that the negotiated price at a minimum cover the pharmacy's costs of purchasing and dispensing covered items and providing covered services. A few commenters requested that CMS establish a flat dispensing fee or an alternative model such as a pharmacy reimbursement model based on a public drug pricing benchmark such as national average drug acquisition costs (NADAC) plus a fair dispensing fee in line with those in state Medicaid fee-for-service program.

Response: Thank you for these suggestions. CMS will consider these suggestions for future rulemaking.

Comment: Some commenters suggested that, as an alternative to requiring that all pharmacy price concessions be included in the negotiated price, CMS could achieve the policy goals of controlling and reducing drug prices and improving transparency by making changes to the treatment of pharmacy DIR in Part D sponsors' bids. Some commenters recommended that plan sponsors be required to reflect some or all of the expected pharmacy DIR in cost-sharing amounts when they submit their Part D bids. A few commenters encouraged CMS to consider imposing a penalty for systematically underestimating DIR within plan bids.

Some commenters offered alternatives to the implementation of the new definition of negotiated price. One suggestion was to offer Part D sponsors the flexibility to launch an additional new plan beyond what is currently allowable, for example, three PDP products per contract. This new plan could be structured to test CMS' negotiated price proposal, while the other existing Part D plans remain using the current approach. A similar suggestion was for CMS to perform a case-control study to test the implementation of the new definition of negotiated price. A third suggestion was for CMS to require additional options for treatment of pharmacy price concessions. These options could for example, include no pharmacy price concession arrangements or explicitly limit the amount of pharmacy price

concession payment arrangements relative to point-of-sale payments. Under this approach, pharmacies could choose one of the options and not be excluded from network participation. Commenters noted that these approaches would allow CMS to gather data before finalizing the requirements set forth in this rule.

A few commenters recommended that CMS focus on creating pricing transparency through the widespread use of provider and beneficiary-level real-time benefit tools (RTBT). One of these commenters explained that prescriber RTBT allows for real-time decision-making to guide beneficiaries, advise them of their options with a focus on clinically needed drugs and the prices of those drugs. According to the commenter, although many plans use RTBT, the tools are proprietary and can lead to highly variant experiences. Congress has mandated broader adoption of RTBT by 2023 and mandated provider use of these tools. The commenter noted that National Council for Prescription Drug Programs (NCPDP) has developed a standard for a real-time prescription benefit request and response for use by providers and asked that CMS name the specific telecommunications standard for use by Part D program participants. This commenter believes that RTBT, rather than changing point-of-sale pricing, creates a way to get pricing information into the hands of beneficiaries, without the need for computers or smart phones, which promotes efficient and socially sensitive SDOH-focused care delivery.

Response: We thank commenters for their suggestions regarding alternative approaches to implementing the new definition of negotiated price, but we decline to adopt these approaches. We do not believe that a policy that requires sponsors to include all pharmacy price concessions in the negotiated price and some of the alternatives suggested by commenters are mutually exclusive or that the availability of alternatives should prevent us from adopting the revised definition of "negotiated price."

With regard to use of the RTBT to promote price transparency, CMS is committed to the use of tools that promote efficient and socially sensitive social determinants of health focused care delivery. Regulations at § 423.160(b)(7) require Part D plans to implement one or more electronic RTBT capable of integrating with at least one prescriber's e-Prescribing (eRx) system or electronic health record (EHR). CMS will continue to evaluate available electronic standards for RTBT to determine if they are appropriate for the Part D program and propose updated

standards, if appropriate. In the meantime, this rule will promote lower beneficiary cost-sharing, which also will help beneficiaries to overcome financial barriers to the medications they need.

Comment: A few commenters recommended that if CMS instructs plans to bid with existing law and regulations in effect currently for the 2023 bid deadline and then finalizes this policy as proposed, then CMS consider conducting the proposed 2019 voluntary two-year demonstration that would consist of a modification to the Part D risk corridors in order to better manage a transition to new requirements.

Response: Thank you for the suggestions. However, we decline to adopt them at this time, as we have changed the applicability of this rule to January 1, 2024, which, as noted previously, provides sufficient transition time.

After considering the comments received, we are adopting a requirement as proposed that the negotiated price reflect the lowest possible reimbursement that the network entity will receive, in total, for a particular covered Part D drug, including all price concessions and any dispensing fees, but excluding additional contingent amounts that increase prices.

d. Additional Considerations

In order to implement the proposed change, we indicated we would leverage existing reporting mechanisms to confirm that sponsors are appropriately applying pharmacy price concessions at the point of sale. Specifically, we indicated we would likely use the estimated rebates at point-of-sale field on the PDE record to also collect the amount of point-of-sale pharmacy price concessions. We also indicated that we would likely use fields on the Summary and Detailed DIR Reports to collect final pharmacy price concession data at the plan and national drug code (NDC) levels. Differences between the amounts applied at the point of sale and amounts actually received, therefore, would become apparent when comparing the data collected through those means at the end of the coverage year.

Comment: Several commenters questioned how data ensuring the lowest possible reimbursement will be transmitted to the pharmacy via the required HIPAA-standard transactions and how data will map to the PDE and to the pharmacy remittance. Both plan/PBMs and pharmacies raised these questions, as all stakeholders are currently required to use the National Program for Prescription Drug Plans (NCPDP) Telecommunications standard

version D.0 (D.0) for claims adjudication, and the Health Care Claim Payment/Advice Transaction Set (X12 835) to support the claims payment process. A few commenters stated that D.0 would need to be replaced by an updated standard, as the current standard cannot support another cost field to convey post-point-of-sale remuneration to downstream entities. A commenter posited that such capability would not be available until 2027 or beyond.

Response: We disagree with commenters that there is no mechanism under the current NCPDP data format for Part D sponsors to provide information on a drug's negotiated price to pharmacies. PCMS does not dictate or provide guidance regarding plans' billing arrangements, and has identified the two following approaches that could accomplish the goal of transmitting a drug's negotiated price data between plan sponsors and pharmacies using the data format available today.

The following example reflects a payment arrangement where the pharmacy point-of-sale payment reflects the negotiated price.

Example 1: Pharmacy is paid Negotiated Price of \$90 at the Point of Sale.

Pharmacy Point-of-Sale Transactions:

- Ingredient Cost Paid + Dispense Fee Paid = \$90 (this is the total amount that will be paid to the pharmacy by all parties)
- Patient Pay (beneficiary cost share in deductible is 100%) = \$90
- Total Amount Paid (Plan paid) = \$0

Because the Negotiated Price of \$90 is the lowest possible reimbursement there is no need for an informational field to indicate future deductions from the pharmacy.

The second example reflects a payment arrangement in which a plan/PBM pays the pharmacy more than the negotiated price at the point of sale. The Total Gross Payment (negotiated price plus post-POS pharmacy price concession) could be populated in the Total Amount Paid Field on the claim response, and the post-POS pharmacy could be included in an informational structured text field. Under this scenario the pharmacy could compute the negotiated price by reducing the Total Gross Payment by the amount noted in the informational field on the pharmacy claim response. The PBM would calculate the beneficiary cost share at the point of sale using the negotiated price and not the total gross payment.

The following example reflects this payment arrangement where the price paid to the pharmacy at the point of sale

does not reflect the negotiated price and so the amount that needs to be adjusted has to be separately conveyed in the informational field within D.0. The PBM computes beneficiary and plan cost-sharing based on the negotiated price; however, the pharmacy will have to subtract the amount reported by the PBM in the informational field to determine the negotiated price.

Example 2: Pharmacy is paid \$100 at the Point of Sale, Negotiated Price is \$90.

Pharmacy Point-of-Sale Transactions:

- Ingredient Cost Paid + Dispense Fee Paid = \$100 (this is the total amount that will be paid to the pharmacy by all parties)
- Patient Pay (Beneficiary cost share in deductible is 100% of negotiated price) = \$90
- Total Amount Paid (plan paid) = \$10 (this plan paid amount is necessary to have pricing fields balance on a claim)
- Additional Message

Information – (informational structured claim response indicates the amount that could be taken back post point of sale) = Negative \$10

Both of these arrangements can be reflected within the current standard, and indeed historically this is how coordination of benefits occurred prior to availability of specific pricing fields. Additionally, any amount paid by the pharmacy to the plan post-point-of-sale could be reported at the claim level (CLP) on the 835 and will be reported in the Estimated Rebate at the Point of Sale field 40 on the PDE as some plans are doing today. This would allow the information to be transparent from the point-of-sale transaction to the PDE.

We agree with commenters who pointed out that the pharmacy price concessions cannot be conveyed to downstream supplemental payers unless price concession values are conveyed in a dedicated cost field, which is not available under D.0. Because these price concession amounts could only be conveyed in an informational field, the current NCPDP standard does not support providing this information to a supplemental payer on a COB claim. So, if the PBM uses the method illustrated in Example 2, the pharmacy would be unable to provide transparency around any amounts that will be taken back post point of sale on the COB claim that will be sent to a supplemental payer.

However, we are including Example 2 for PBMs to use when implementing the new rule because it will still benefit those supplemental payers who provide coverage based on beneficiary cost-

sharing, and will retain the status quo for supplemental payers who pay based on plan-paid amounts.

Comment: A few commenters explained that Part D bidding and payment policies in the Advance Notice would be impacted by these provisions that are not mentioned in the AN. For example, the risk adjustment model for CY 2023 is proposed to be calibrated on 2018 claims and encounter data, plus expenditure data from 2019 PDE records that do not reflect pharmacy DIR being applied at POS. Commenters noted that the risk adjustment is not the only issue impacted by pharmacy DIR at POS but also the underlying trends used to make the annual adjustments to Medicare Part D benefit parameters would also be impacted.

Response: Given that we are finalizing an applicability date of January 1, 2024, the policy we are adopting will not affect Part D payment in 2023. We will consider commenters' feedback as we prepare the Part D payment policies for the 2024 Advance Notice.

Comment: A few commenters urged CMS' Office of the Actuary to provide plan sponsors with bid guidance as soon as possible to ensure accuracy of the bids. Commenters noted that the pharmacy DIR impacts if the rule were final, were not referenced in the draft Bid Pricing Tool (BPT) or the Advance Notice. Commenters noted that Part D sponsors will have to choose whether to prepare their bids under current regulations where they assume that (a) the definition of negotiated price remains the same, or (b) the new definition of negotiated price is finalized. A few commenters indicated that if the industry is not aligned on assumptions, there will be significant disruption for beneficiaries due to the erratic bidding in the market. Also, commenters noted that the uncertainty of the proposed rule adds additional actuarial risk, which may result in plans adopting more conservative (that is, higher) plan pricing, in order to mitigate the impacts of the uncertainty during the bidding period.

Response: As noted above, we are finalizing this rule with an applicability date of January 1, 2024. CMS will communicate bid guidance to support the bid development process with sufficient lead time for the 2024 bid cycle.

Comment: A commenter noted that the Out-of-Pocket Cost (OOPC) Models are under development and targeted for release in April 2022, possibly prior to the publication of the final rule. The commenter was concerned as the values produced from these models are used in CMS's bid review and while the

baselines were released on January 21, 2022, the average price for each RxCUI in the model could be influenced by adoption of the proposal to require the negotiated price to include pharmacy price concessions. The commenter stated that CMS would have to decide whether adjustments for potential changes in the average price for each RxCUI in the model would be appropriate. The same commenter noted that in relation to pricing changes, the Health Plan Management System (HPMS) Formulary Submission and Part D Pricing File Submission (PDPFS) Modules are expected to be released on May 16, 2022, and that the formulary submission module may be directly impacted by this proposal, while plan sponsor and PBM formulary strategy most certainly will. The commenter noted that the Part D pricing file module would likely either have to be delayed or re-released to appropriately reflect this final rule.

Response: Given the applicability date of January 1, 2024, changes to the OOPC model tool for 2023 are not needed. We will consider whether updates will be appropriate for the OOPC model for 2024.

Comment: A commenter requested that CMS ensure that Part D sponsors and their PBMs load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems that interface with contracted pharmacies. The commenter noted that this information goes hand-in-hand with a real-time prescription benefit model in providing at the point of prescribing and even at the point of dispensing an accurate accounting of the beneficiary's out-of-pocket cost for their prescription.

Response: We appreciate the suggestion. We will monitor the situation to determine whether it is necessary that we take any additional steps to ensure that Part D sponsors and their PBMs have made the appropriate changes to their claims processing systems.

After consideration of the comments, we will finalize our proposal to use existing reporting mechanisms to confirm that sponsors are appropriately applying pharmacy price concessions to the negotiated price.

e. Negotiated Prices of Applicable Drugs in the Coverage Gap

The negotiated price of an applicable drug is also the basis by which manufacturer liability for discounts in the coverage gap is determined. Section 1860D–14A(g)(6) of the Act provides that, for purposes of the coverage gap discount program, the term “negotiated

price” has the meaning it was given in § 423.100 as in effect as of the enactment of section 3301 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (PPACA), as amended by section 1101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), except that it excludes any dispensing fee for the applicable drug. Under that definition, which is codified in the coverage gap discount program regulations at § 423.2305, the negotiated price is the amount the Part D sponsor (or its intermediary) and the network dispensing pharmacy (or other network dispensing provider) have negotiated as the amount such a network entity will receive, in total, for a covered Part D drug, reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale, and net of any dispensing fee or vaccine administration fee for the applicable drug.

In the November 2018 proposed rule (83 FR 62179), we solicited comment on whether to require sponsors to include pharmacy price concessions in the negotiated price in the coverage gap. Under such an approach, the negotiated price of the applicable drug for purposes of determining manufacturer coverage gap discounts, would include all pharmacy price concessions as in all other phases of the Part D benefit under the proposed revision to the definition of negotiated price at § 423.100. Because the statutory definition of negotiated price for purposes of the coverage gap discount program references price concessions that the Part D sponsor has elected to pass through at the point-of-sale, we explained that we did not believe it would be appropriate to require sponsors to include all price concessions in the negotiated price for purposes of the coverage gap discount program. However, we indicated our belief that there would be authority under the statute to require sponsors to include all *pharmacy* price concessions in the negotiated price for purposes of the coverage gap discount program because such concessions necessarily affect the amount that the pharmacy receives in total for a particular applicable drug. We also noted that pharmacy price concessions account for only a share of all price concessions a sponsor might receive. Thus, even if a plan sponsor were required to include all pharmacy price concessions in the negotiated price of an applicable drug at the point of sale, the plan sponsor must

still make an election as to how much of the overall price concessions (including non-pharmacy price concessions) it receives will be passed through at the point of sale.

In the November 2018 proposed rule, we also sought comment on an alternative approach under which Part D sponsors would determine how much of pharmacy price concessions to pass through at the point-of-sale for applicable drugs in the coverage gap, and beneficiary, plan, and manufacturer liability would be calculated using this alternate definition of negotiated price.

The majority of the comments on the November 2018 proposed rule that addressed the possible inclusion of pharmacy price concessions in the negotiated price of applicable drugs in the coverage gap expressed support for applying the same definition of negotiated price in all phases of the Part D benefit, as they believed maintaining the same definition for all phases of the benefit would provide more transparency and consistency at the point of sale, minimize beneficiary confusion, and avoid the operational challenges of having two different rules for applying pharmacy price concessions to applicable drugs in the coverage gap versus other phases of the Part D benefit. Some commenters disagreed with our assessment that CMS has the legal authority to require that all pharmacy price concessions be included in the negotiated price of applicable drugs in the coverage gap, as they felt this was at odds with the reference to “price concessions that the Part D sponsor had elected to pass-through to Part D enrollees at the point-of-sale” in the regulatory definition of “negotiated price” at § 423.100 as in effect when the PPACA was enacted. Commenters noted that if CMS were to adopt the alternative approach under which sponsors would be required to include pharmacy price concessions in the negotiated price for applicable drugs in all phases of the Part D benefit other than the coverage gap, it would be necessary for CMS to issue very specific guidance explaining how to operationalize different definitions of “negotiated price” for the coverage gap versus the non-coverage gap phases of the Part D benefit.

In the proposed rule, we noted that we continue to believe that section 1860D–14A(g)(6) of the Act would not preclude us from revising the definition of negotiated price at § 423.2305 to require Part D sponsors to apply all pharmacy price concessions for applicable drugs at the point of sale. However, we did not propose to adopt such a mandate and noted that allowing plans flexibility with respect to the

treatment of pharmacy price concessions for applicable drugs in the coverage gap would moderate increases to beneficiary premiums and government costs.

In summary, under our proposed approach, for non-applicable drugs in the coverage gap, and during the non-coverage gap phases of the Part D benefit for applicable drugs, claims would be adjudicated using the negotiated price determined using the lowest possible reimbursement to the pharmacy. In contrast, for applicable drugs during the coverage gap, plans would have the flexibility to determine how much of the pharmacy price concessions to pass through at the point of sale, and beneficiary, plan, and manufacturer liability in the coverage gap would be calculated using this alternate negotiated price.

Based on comments we received on the November 2018 proposed rule, we anticipate that if we were to adopt the proposed approach, we would need to provide technical or operational guidance to Part D sponsors regarding the calculation of the gap discount, PDE reporting, and straddle claim processing. We solicited comment on whether there are other topics CMS would need to address in new guidance if we finalized the proposed approach. We also requested that commenters with concerns about the feasibility of sponsors having two different rules for applying pharmacy price concessions to applicable drugs in the coverage gap versus other phases of the Part D benefit provide detailed explanations of their concerns, with specificity and examples.

In addition, we solicited comment on whether, as an alternative to our proposed approach, we should require that Part D sponsors apply pharmacy price concessions to the negotiated price of applicable drugs in the coverage gap. As noted above, we believe that such a requirement would also be consistent with section 1860D-14A(g)(6) of the Act.

Comment: The majority of commenters indicated that pharmacy price concessions should be included in the negotiated price for applicable drugs in the coverage gap. Commenters stated that applying pharmacy price concessions at the point of sale, regardless of the benefit phase, is the least confusing option for beneficiaries and provides consistency and transparency at the point of sale. Some noted that predictability in out-of-pocket costs is critically important for seniors and people with disabilities. Some commenters believed that applying the same rules regarding the

reporting of pharmacy price concessions in the coverage gap would reduce beneficiary out-of-pocket costs and improve patient access and affordability. Several commenters stated that having two different sets of rules would be hard to explain to beneficiaries and create beneficiary confusion. A few commenters raised concerns about how two definitions could be effectively communicated in Medicare Plan Finder files, with greater potential for errors in the information and confusion among enrollees.

Many commenters stated that it would be operationally challenging to have different rules for applying pharmacy price concessions in the coverage gap versus other phases of the Part D benefit. Commenters noted that it was unclear how Part D plans, PBMs, and pharmacies could operationalize two different rules for negotiated prices. Others noted that having two different approaches would increase administrative costs for pharmacies, plan sponsors, PBMs, and other stakeholders, and that claims systems would need to be reprogrammed. Commenters stated that if there were two different approaches, Part D sponsors would need specific guidance regarding the calculation of the gap discount, PDE reporting, and straddle claim processing. In addition, commenters were concerned that having different rules for the negotiated price would result in significant complexity during the bid process and CMS oversight. Some commenters noted the potential for confusion and errors and administrative costs associated with implementation.

Response: We appreciate the thoughtful feedback on maintaining two separate rules for determining the negotiated price and the concerns about the potential for beneficiary confusion, added administrative burden and cost, and implementation challenges that would result from applying one approach to the negotiated price for applicable drugs in the coverage gap phase and another for non-applicable drugs in the gap, as well as for drugs in all other phases of the Part D benefit.

As noted in the preamble of the proposed rule, in the November 2018 proposed rule (83 FR 62179), we solicited comment on whether to require sponsors to include pharmacy price concessions in the negotiated price of applicable drugs in the coverage gap. Because the statutory definition of negotiated price for purposes of the coverage gap discount program references price concessions that the Part D sponsor has *elected* to pass through at the point-of-sale, we

explained that we did not believe it would be appropriate to require sponsors to include all price concessions in the negotiated price for purposes of the coverage gap discount program. However, we indicated our belief that there would be authority under the statute to require sponsors to include all *pharmacy* price concessions in the negotiated price for purposes of the coverage gap discount program because such concessions necessarily affect the amount that the pharmacy receives in total for a particular applicable drug. We also noted that pharmacy price concessions account for only a share of all price concessions a sponsor might receive. Thus, even if a plan sponsor were required to include all pharmacy price concessions in the negotiated price of an applicable drug, the plan sponsor must still make an election as to how much of the overall price concessions (including non-pharmacy price concessions) it receives will be passed through to beneficiaries at the point-of-sale.

Given our authority under the statute to require plans to include all *pharmacy* price concessions to the negotiated price for all phases of the Part D benefit and the beneficiary confusion, additional administrative burden and costs, and implementation challenges posed by maintaining two approaches for purposes of the two definitions of negotiated price, we are finalizing our proposal with modification to use the negotiated price determined using the lowest possible reimbursement to the pharmacy across all phases of the Part D benefit, including for applicable drugs in the coverage gap phase. Accordingly, we are revising the definition of negotiated price at § 423.2305 to clarify that the negotiated price must be inclusive of all pharmacy price concessions in the coverage gap phase of the Part D benefit but that sponsors continue to have the flexibility to elect which non-pharmacy price concessions are to be passed through at the point of sale. After consideration of the comments, we are finalizing our proposal with modification to use the negotiated price determined using the lowest possible reimbursement to the pharmacy across all phases of the Part D benefit, including the coverage gap phase.

4. Pharmacy Administrative Service Fees

As noted in the proposed rule, we are aware that some sponsors and their intermediaries believe certain fees charged to network pharmacies—such as “network access fees,” “administrative fees,” “technical fees,”

and “service fees”—represent valid administrative costs and, thus, do not believe such fees should be treated as price concessions. However, pharmacies and pharmacy organizations report that they do not receive anything of value for such administrative service fees other than the ability to participate in the Part D plan’s pharmacy network.

Thus, we restate the conclusion we provided in the May 2014 final rule (79 FR 29877): When pharmacy administrative service fees take the form of deductions from payments to pharmacies for Part D drugs dispensed to Part D beneficiaries, they clearly represent charges that offset the sponsor’s or its intermediary’s operating costs under Part D. We believe that if the sponsor or its intermediary contracting organization wishes to be compensated for these services and have those costs treated as administrative costs, such costs should be accounted for in the administrative costs of the Part D bid. If instead these costs are deducted from payments made to pharmacies for purchases of Part D drugs, such costs are price concessions and must be treated as such in Part D cost reporting. This is the case regardless of whether the deductions are calculated on a per-claim basis.

The regulations governing the Part D program require that price concessions be fully disclosed. If not reported at all, these amounts would result in another form of so-called PBM spread in which inflated prices contain a portion of costs that should be treated as administrative costs. That is, even if these amounts did represent costs for services rendered by an intermediary organization for the sponsor, then these costs would be administrative service costs, not drug costs, and should be treated as such. Failure to report these costs as administrative costs in the bid would allow a sponsor to misrepresent the actual costs necessary to provide the benefit and thus to submit a lower bid than necessary to reflect its revenue requirements (as required at section 1860D–11(e)(2)(C) of the Act and at § 423.272(b)(1) of the regulations) relative to another sponsor that accurately reports administrative costs consistent with CMS instructions.

Comment: Some commenters expressed support for the requirement that legitimate administrative service fees be recorded as administrative costs in the bid and not as a pharmacy price concession. The commenters explained these fees typically provide no additional value to the pharmacy or the beneficiary beyond the ability to participate in the Medicare Part D plan’s pharmacy network and instead mainly

offset the sponsor’s or its intermediary’s costs of operating the Part D plan, which the commenters contended should not be the responsibility of a network pharmacy. A few commenters requested that CMS provide further clarification on the definition of pharmacy administrative service fees and what should be considered under such definition.

Response: CMS appreciates the commenters’ support. As discussed in the May 2014 final rule (79 FR 29877), pharmacy price concessions characterized as “network access fees,” “administrative fees,” “technical fees,” or “service fees” and are taken as deductions from payments to pharmacies for drugs dispensed, represent charges that offset sponsor or PBM operating costs. If a sponsor or its intermediary contracting organization wishes to be compensated for these services then such administrative costs should be accounted for as such in the Part D bid. However, when such fees take the form of deductions from payments to pharmacies for dispensed Part D drugs, such costs are price concessions and must be reflected in the negotiated price. This is the case regardless of whether the deductions are calculated on a per-claim basis. CMS declines at this time to further define what should be considered pharmacy administrative service fees, but we may consider providing further clarification in future rulemaking.

Comment: A commenter requested that CMS clarify how it intends to ensure that administrative service fees are being properly recognized and reported. This commenter recommended that CMS utilize Medicare Part D Reporting Requirements to ensure fees charged to pharmacies are properly reported as either administrative costs or price concessions. Another commenter requested that CMS require a Part D sponsor (and its PBM) attest that any administrative service fees charged by the Part D sponsor (or its PBM) are utilized for administrative services and that such services are relevant and applicable to the pharmacy against which the fees are applied.

Response: We appreciate the concerns raised by commenters and will consider what steps might be necessary in the future to ensure that administrative service fees are properly reported to CMS.

Comment: A number of commenters expressed concerns that the Part D sponsors could use the classifications of price concessions and pharmacy administrative service fees to manipulate the Part D bidding and MLR

processes in order to retain additional profit. A commenter was concerned that Part D sponsors had incentives to bid in ways that allowed the sponsors to retain pharmacy price concessions and not apply them to the negotiated price, diminishing the value available to enrollees at the point of sale. This commenter stated that plans overbid by underestimating DIR in order to retain additional profit during the plan’s reconciliation process. The commenter is concerned that the terms of the MLR requirements may permit Part D sponsors to inflate their actual expenditures, or “incurred claims,” by classifying their arbitrary charges to pharmacies as “administrative fees” or “administrative service fees.” By doing so, a Part D sponsor inflates their reported incurred claims so that they can retain such fees while simultaneously reducing the sponsor’s probability of paying remittances under the MLR. This commenter noted that if such fees were instead reported as post-point-of-sale price concessions, then they would increase the plan’s probability of paying a remittance under the MLR. This commenter stated that the MLR requirement was created to encourage plans to: (1) Provide value to beneficiaries, (2) be transparent and accountable for expenditures, and (3) reduce health care costs.

A commenter rejected the notion that Part D plans have an incentive to deliberately underestimate DIR in Part D bids in order to increase plan profits. This commenter stated that there are multiple mechanisms in place to prevent abuse of the system. The commenter cited the bid review process, Part D risk corridors, and the MLR requirement as examples of programmatic features that limit Part D plan sponsors’ gaming of bids and profits. The commenter asserts that the Office of the Actuary would refuse to approve bids if a sponsor were “consistently off” in projections. They contended that the current plan payment structure applies appropriate incentives and allows for appropriate oversight to ensure that private market innovation delivers competitive and meaningful choices to beneficiaries and financial savings to taxpayers.

Response: While the bid review process, Part D risk corridors and the MLR requirement limit Part D plan sponsors’ ability to game bids and profits to an extent, we do not agree with the commenters’ implication that these are CMS. The commenters do not address the analysis of Part D plan payment and cost data we discussed in the proposed rule, which show that in recent years, DIR amounts that Part D

sponsors and their PBMs actually received have consistently exceeded bid-projected amounts, by an average of 0.6 percent and as much as 3 percent as a share of gross drug costs from 2010 to 2020. The commenter merely asserts that the Office of the Actuary would have refused to approve bids if a sponsor were “consistently off” in projections. They fail to elaborate under which conditions the Office of the Actuary would reject a bid from a Part D sponsor because the Part D sponsor has been historically off in their bids, but could provide an argument that their current bid is actuarially sound. We do not believe the MLR requirement nor the Part D risk corridors function to solve or disincentivize the trend of underbidding DIR. The MLR requirement mandates that sponsors remit funds if less than 85 percent of all revenues are spent on prescription drugs or quality improvement activities. When Part D sponsors share extra profits through the Part D risk corridor with the Federal Government due to the sponsor underestimating DIR, sponsors typically keep a significant majority of the extra profits. For example, when a Part D sponsor’s target amount or revenue exceeds their allowable risk corridor costs by 10%, the sponsor would retain 75% of the extra profits while the Federal Government would recoup 25%. Also, a Part D sponsor could underestimate DIR relative to its bid and receive additional profits up to the maximum amount permitted by the Part D risk corridors without necessarily failing to meet the 85 percent MLR requirement.

CMS appreciates the commenter’s concerns that Part D sponsors could manipulate the treatment of payments from pharmacies in different Part D processes in order to retain additional profits. However, we believe the requirements for both MLR and under this final rule are clear that a Part D sponsor could not treat a fee as an administrative cost for one purpose, but a drug cost for the other. While Part D sponsors have had an incentive to bid using an assumption that pharmacy price concessions would not be applied at the point of sale to achieve advantageous premiums, Part D sponsors must submit Part D bids that comply with the Part D statute, regulations, and rules applicable for the contract year as the basis for their actuarial assumptions, and in relation to the issuance of this final rule Part D sponsors will be required to reflect the new definition of negotiated price in all phases of the Part D benefit in their Part D bids. The definition of “price

concession” and the requirements of the MLR would not allow Part D sponsors to inflate the “incurred claims” in their MLR by reclassifying amounts that are deducted from payments made to pharmacies for purchases of Part D drugs as administrative fees. “Incurred claims” in the MLR numerator include direct drug costs that are actually paid (§ 423.2420(b)(2)(i)) and excludes administrative fees (§ 423.2420(b)(4)). The definition of “price concession” mirrors “actually paid” as defined in § 423.308. A “price concession” is defined as any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Similarly, “actually paid” are costs that must be actually incurred by the Part D sponsor and must be net of DIR from a source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Therefore, any amount that would be considered a price concession in the application of this rule would also be netted from the incurred claims amount in the MLR numerator, which is why we believe the requirements for both MLR and this final rule are clear that a Part D sponsor could not treat a fee as an administrative cost for one purpose, but a drug cost for the other.

5. Defining Price Concession (§ 423.100)

Section 1860D–2(d)(1)(B) of the Act stipulates that the negotiated price shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered Part D drugs. Section 1860D–2(d)(2) of the Act further requires that Part D sponsors disclose to CMS the aggregate negotiated price concessions by manufacturers that are passed through in the form of lower subsidies, lower monthly beneficiary premiums, and lower prices through pharmacies and other dispensers. While “price concession” is a term important to the adjudication of the Part D program, it has not yet been defined in the Part D statute or in Part D regulations and sub-regulatory guidance. Therefore, to avoid confusion among Part D sponsors and other stakeholders of the Part D program resulting from inconsistent terminology, we proposed to add a regulatory definition for the term “price concession” at § 423.100 that is consistent with how that term is used in subsections (d)(1)(B) and (d)(2) of section 1860D–2 of the Act.

We proposed to define price concession to include any form of

discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. The proposed definition would note that price concessions include but are not limited to discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.

The proposed rule noted that adopting the proposed definition of price concession would not affect the way in which price concessions must be accounted for by Part D sponsors in calculating costs under a Part D plan, and it would not require the renegotiation of any contractual arrangements between a sponsor and its contracted entities. Therefore, the proposed definition of price concession has no impact under the Federal requirements for Regulatory Impact Analyses.

Comment: Many commenters expressed concern that PBMs will restructure pharmacy fees to sources other than claim-level fees to circumvent CMS’s intent in the proposal and provided recommendations on what CMS should include or consider. Some commenters wanted CMS to clarify that pharmacies would not be held accountable for “non-pharmacy” price concessions (for example, manufacturer rebates).

Many commenters asked CMS to confirm that any fee related to or assessed because of a Part D prescription drug claim is considered a price concession. Commenters expressed that this should be true whether the fee represents an administrative fee, a transaction fee, or the value of a contingent amount, such as a performance-based penalty. Many commenters explained that the fees and price concessions that PBMs utilize in contracts and pharmacy manuals have different names, but were primarily deductions from their reimbursements. Commenters felt these deductions must be treated as a price concession and fully disclosed to them on individual adjudicated claim responses and remittance advices within the prompt pay rules of 14 calendar days.

Response: We believe that the definition of “price concession” that we discussed in the proposed rule is broad enough to include all forms of discounts, direct or indirect subsidies, or rebates that serve to reduce the costs incurred under Part D plans by Part D sponsors, so that Part D sponsors and their intermediaries are limited in

circumventing CMS' intent without fundamentally changing. When pharmacy administrative service fees take the form of deductions from payments to pharmacies, they represent charges that offset the sponsor's or its intermediary's operating costs under Part D. If the sponsor or its intermediary contracting organization wishes to be compensated for these services and have those costs treated as administrative costs, such costs should have been accounted for in the administrative costs of the Part D bid. However, if the sponsor or its intermediary deducts these same costs from payments to pharmacies, such costs are price concessions and must be reflected in the negotiated price. For pharmacy price concessions that are not at the claim level, Part D sponsors would have to determine a methodology to attribute such concessions to the claim level to remain in compliance with the definition of negotiated price.

We are confirming that under the definition of negotiated price we are adopting in this final rule, the negotiated price must include pharmacy price concessions, and does not require inclusion of non-pharmacy price concessions, such as manufacturer rebates. To the extent a non-pharmacy price concession is applied to the negotiated price, it would reduce the negotiated price, but not reduce the amount that is the lowest possible reimbursement the pharmacy could receive as reimbursement for a covered Part D drug under the contract between the pharmacy and the Part D sponsor or the sponsor's intermediary.

Comment: Some commenters recommended changes to our proposed definition of "price concession." These commenters recommended that the definition consider administrative service fees. A commenter recommended that in our proposed definition after the phrase "received by the Part D sponsor or its intermediary contracting organization" that we add "for a particular claim at any time during the contract year." This commenter also recommended that after the phrase "from any source" that we add "including a network dispensing pharmacy." Finally, in the list of examples of price concessions, the commenter recommended that we include "fees or other charges to network dispensing pharmacy." Another commenter recommended that we modify the definition of "price concession" by adding, after the phrase "that serves to decrease the costs incurred under the Part D plan by the Part D sponsor," "or its intermediary contracting organization under the Part

D plan." This commenter also recommends that the examples be expanded to include "any type of fee or other amount that a Part D sponsor or its intermediary contracting organization retains from payments made to such pharmacies or providers for their provision of Part D drugs or requires such pharmacies or providers to pay in connection with its provision of Part D drugs under a Part D network, including but not limited to transaction fees, network participation fees and administrative fees." Commenters also requested that CMS define "administrative service fees."

Response: For the reasons stated previously, we believe the definition we are adopting in this final rule is sufficient to identify price concessions. CMS will take commenters' suggestions for changes to the definition of price concession, as well as for a new definition of "administrative service fees," into consideration for future rulemaking.

We are finalizing our proposal without modification to define "Price concession" to include any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor at § 423.100.

III. Requests for Information

A. Request for Information: Prior Authorization for Hospital Transfers to Post-Acute Care Settings During a Public Health Emergency

We are committed to ensuring that hospitals, post-acute care facilities (including long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), and skilled nursing facilities (SNFs)), physicians, and MA organizations have the tools necessary to provide access to appropriate care to patients without unnecessary delay during a public health emergency (PHE). Throughout 2020 during the Coronavirus Disease 2019 Public Health Emergency (COVID-19 PHE), we consistently issued guidance to address permissible flexibilities for MA organizations as part of an ongoing effort to help MA enrollees, and the health care systems that serve them, avoid delays and disruptions in care. We recognize that any delays or disruptions in care that might transpire within the MA program could have a ripple effect and also negatively impact the timely provision of appropriate care to patients covered under payer systems external to MA (for example, employer-

sponsored insurance). Additionally, we recognize the positive impact that payers in general can have through the adoption of flexibilities that support hospitals' ability to effectively manage resources when a hospital experiences a substantial uptick in hospitalizations.

As a result of the guidance and clarification that we issued throughout 2020, a large proportion of MA organizations opted to relax or completely waive their prior authorization requirements with respect to patient transfers between hospitals and post-acute care facilities during plan year 2020, consistent with our guidance encouraging flexibility to ensure access to care. However, as the PHE continued into 2021, many MA organizations reinstated prior authorization requirements, which some stakeholders reported contributed to capacity issues and delays in care within hospital acute care settings. For example, one stakeholder reported that only 5 percent of intensive care unit (ICU) beds were open in their state during the month of August 2021, and stated that the scarcity of available beds could be mitigated if more MA organizations reinstated waivers on prior authorization requirements for patient transfers. Another stakeholder reported that it was not uncommon for a hospital to wait up to 3 business days to receive a decision from an MA organization for a request for a patient transfer—a delay which prevented the hospital from moving patients to the next appropriate care setting in a timely manner and forced the unnecessary use of acute-care beds. The same stakeholder reported that a high rate of initial denials from MA organizations also contributed to delays in patient transfer. We acknowledge our responsibility to ensure that our programs' policies do not hinder access to care, especially during a public health emergency. Therefore, in response to these reports and the uptick in COVID-19 hospitalizations across the country, we sought information from stakeholders in order to assess the impact of MA organizations' use of prior authorization or other utilization management criteria during certain PHEs. Through this request for information (RFI), CMS sought additional information from all affected stakeholders, especially MA organizations, hospitals, post-acute care facilities, professional associations, states, and patient advocacy groups regarding the effects of both the relaxation of and reinstatement of prior authorizations on patient transfers during a PHE.

We noted that we remain mindful of the impact the MA program's policies have on the health care system as a whole, and strongly encouraged MA organizations to continuously re-assess the need for flexibilities in their utilization management practices. We noted that with regard to prior authorization and other utilization management practices, we permit MA organizations the choice to uniformly waive or relax plan prior authorization requirements at any time in order to facilitate access to care, even in the absence of a disaster, declaration of a state of emergency, or PHE. Generally, MA organizations are required to ensure that enrollees are notified of changes in plan rules of this type in accordance with § 422.111(d); however, when the provisions under § 422.100(m)(1) go into effect during a disaster or emergency, as they did during the COVID-19 PHE, MA organizations are permitted to immediately implement plan changes that benefit enrollees, including a waiver of prior authorization requirements, without the 30-day notification requirement at § 422.111(d)(3).

We invited the public to submit comments for consideration as CMS assesses the impact of MA organizations' prior authorization requirements for patient transfer on a hospital's ability to effectively manage resources and provide appropriate and timely care during a PHE. We indicated that the primary objective of this RFI was for us to glean information from stakeholders about the effects of MA organizations' prior authorization requirements for patient transfers on a hospital's ability to furnish the appropriate care to patients in a timely manner in the context of a PHE. This was a general RFI related to prior authorizations on patient transfers during any PHE. While many commenters may have chosen to provide information in the context of the COVID-19 PHE, we welcomed and encouraged commenters to provide information in the context of any PHE.

B. Request for Information: Building Behavioral Health Specialties Within MA Networks

CMS is dedicated to ensuring that MA beneficiaries have access to provider networks sufficient to provide covered services in accordance with the standards described in section 1852(d)(1) of the Act and in §§ 422.112(a) and 422.114(a)(1). Accordingly, CMS strengthened network adequacy rules for MA plans by codifying our network adequacy

standards at § 422.116 in the June 2020 final rule.

Currently, we require MA organizations to submit data for behavioral health providers, specifically psychiatry (provider-specialty type) and inpatient psychiatric facility services (facility-specialty type), using the Health Service Delivery (HSD) tables. The HSD tables are submitted to CMS during an MA organization's formal network review and are utilized to demonstrate compliance with network adequacy standards. The HSD tables must list every provider and facility with a fully executed contract in the MA organization's network, and are uploaded to the Health Plan Management System (HPMS) for an automated review. MA plans must have sufficient providers within a certain time and distance of 85 or 90 percent of beneficiaries residing the plan's service area, depending on the type of counties in the service area, under § 422.116. We also encouraged plans to provide more choices for enrollees to access care using telehealth for certain specialties, including psychiatry, through our policy under § 422.116(d)(5), while maintaining enrollees' right to access in person care for these specialty types. To encourage and account for telehealth providers in contracted networks, § 422.116(d)(5) provides MA plans a 10-percentage point credit towards the percentage of beneficiaries that reside within published time and distance standards when the plan's network includes telehealth providers for certain specialties and the plan covers additional telehealth benefits, as defined in § 422.135. However, as noted in the proposed rule, even with the availability of the additional 10-percentage point credit for the use of telehealth providers, it is our understanding that MA organizations may experience difficulties meeting network adequacy standards with respect to behavioral health providers.

In order to increase our understanding of issues related to MA enrollees' access to behavioral health specialties, CMS sought input from industry stakeholders on the challenges MA organizations face when building an adequate network of behavioral health providers for MA plans. More specifically, we issued an RFI that solicited comment on issues including, but not limited to, the following:

- Challenges related to a lack of behavioral health provider supply in certain geographic regions for beneficiaries, health plans, and other stakeholders;
- Challenges related to accessing behavioral health providers for enrollees

in MA plans, including wait times for appointments;

- The extent to which a behavioral health network affects a beneficiary's decision to enroll in an MA plan;
- Challenges for behavioral health providers to establish contracts with MA plans;
- Providers' inability or unwillingness to contract with MA plans, including issues related to provider reimbursement;
- Opportunities to expand services for the treatment of opioid addiction and substance use disorders;
- The overall impact of potential CMS policy changes as it relates to network adequacy and behavioral health in MA plans, including in rural areas that may have provider shortages; and
- Suggestions from industry stakeholders on how to address issues with building adequate behavioral health networks within MA plans.

We acknowledge and appreciate all comments submitted in response to this RFI. While we will not be responding to those comments in this final rule, we will take the commenters' suggestions, concerns, and other feedback into account as we consider future changes to our in policy in this area.

C. Request for Comment on Data Notification Requirements for Coordination-Only D-SNPs (§ 422.107(d))

In the April 2019 final rule, we established an additional contracting requirement at § 422.107(d) for any D-SNP that is not a FIDE SNP or HIDE SNP. Under this new requirement for the contract that is required between the D-SNP and the State Medicaid agency effective January 1, 2021, the D-SNP is required to notify the State Medicaid agency, or individuals or entities designated by the State Medicaid agency, of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dual eligible individuals, as determined by the State Medicaid agency.

These data notification requirements have only been in effect for a short time, all of which coincided with the COVID-19 public health emergency. Through the proposed rule we invited MA organizations, States, and other stakeholders to submit comments on their experience implementing the data notification requirements thus far and any suggested improvements for CMS consideration in future rulemaking.

While we are not responding to specific comments submitted in response to this Hospital Transfers to Post-Acute Care Settings during a Public Health Emergency, Building Behavioral

Health Specialties within MA Networks, Data Notification Requirements for Coordination-Only D-SNPs request for information (RFI) in this final rule, we appreciate all of the comments and interest on these topics. We will continue to take all concerns, comments, and suggestions into account as we continue work to address and develop policies on these topics and may reach out to commenters for further discussion.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a “collection of information” requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA’s implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In our January 12, 2022 (87 FR 1842) proposed rule, we solicited public comment on each of these issues for the following provisions that contain information collection requirements. As indicated below, we received public comments on the collection of information requirements related to the creation of a one-page multi-language insert; the comments and our responses are summarized below under the

applicable Collection of Information subsection. Separately, on February 25, 2022 (87 FR 10761), we published a correction that clarified we will submit information on the number of respondents and the time estimates to the public and OMB for the collection of information requirements related to limiting certain Medicare Advantage contracts to D-SNPs prior to the 2025 plan year application.

A. Wage Data

To derive average costs, we are using data from the U.S. Bureau of Labor Statistics’ (BLS’s) National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm), which, at the time of finalizing of this rule, provides May 2021 wages. In this regard, Table 3 presents BLS’s mean hourly wage along with our estimated cost of fringe benefits and overhead (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 3: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Business Operation Specialists, All Other	13-1199	38.10	38.10	76.20
Compliance Officers	13-1041	36.45	36.45	72.90
Computer and Information Systems Managers	11-3021	78.33	78.33	156.66
Lawyer	23-1011	71.17	71.17	142.34
Software Developers	15-1252	58.17	58.17	116.34

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent to account for fringe benefits and overhead costs that vary from employer to employer and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Revised Wage and Cost Estimates: While our proposed rule’s costs were based on BLS’s May 2020 wages, this final rule uses BLS’s May 2021 wages which are the most current as of the publication date of this rule. The wage changes are presented below in Table 4. Overall, the revised BLS wages

increased our cost estimates by \$74,274 for first year (from \$5,225,170 to \$5,299,444) and a corresponding decrease of \$43,579 for subsequent years (from \$3,647,583 to \$3,604,004). Note these numbers also reflect an adjustment to the numbers published in the January 2022 proposed rule (87 FR 1934) since two provisions described in section IV.B.2 and section IV.B.3. had changes in their estimated number of respondents, and in response to comments one additional provision (section IV.B.7.) was added. Therefore, we recalculated the estimates from the proposed rule with these three changes resulting in \$5,225,170 for first year and \$3,647,583 for subsequent years

representing the updated estimates with 2020 wage estimates. We then recalculated again using the 2021 wage estimates resulting in the \$5,299,444 for first year and the \$3,604,004 for subsequent years numbers so that the difference would compare similar items.

Please note that besides the wage changes there were (i) two changes in occupation codes, 13–1198 is now 13–1199 and 15–1250 is now 15–1252 and (ii) there was one change in occupational title, “Software and Web Developers” is now “Software developers.”

TABLE 4: COMPARISON OF PROPOSED AND FINALIZED ADJUSTED HOURLY WAGES

Occupation Title	Occupation Code	CMS-4192-P: BLS May 2020 (\$/hr)	CMS-4192-F: BLS May 2021 (\$/hr)	Difference (\$/hr)
Business Operation Specialists, All Other	13-1198	81.06	76.20	-4.86
Compliance Officers	13-1041	72.70	72.90	0.20
Computer and Information Systems Managers	11-3021	155.52	156.66	1.14
Lawyer	23-1011	143.18	142.34	-0.84
Software and Web Developers	15-1250	105.72	116.34	10.62

B. Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within section II. of this final rule.

1. ICRs Regarding Enrollee Participation in Plan Governance (§ 422.107) (CMS–10799, 0938–1422)

The requirement and burden for D–SNPs to create one or more enrollee advisory committees will be submitted to OMB for approval under control number 0938–TBD (CMS–10799). The requirement and burden for D–SNPs to update audit protocols to require documentation of the enrollee advisory committees will be submitted to OMB for approval under control number 0938–1395 (CMS–10717).

a. Creating One or More Enrollee Advisory Committees (CMS–10799, OMB 0938–1422)

At § 422.107(f), we are requiring that any MA organization offering a D–SNP must establish one or more enrollee advisory committees at the State level or other service area level in the State to solicit direct input on enrollee experiences. We also require at § 422.107(f) that the committee include at least a reasonably representative sample of the population enrolled in the dual eligible special needs plan, or plans, or other individuals representing those enrollees, and solicit input from these individuals or their representatives on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.

The burden of establishing and maintaining an enrollee advisory committee is variable due to the flexibilities MA organizations would have to implement the requirements. We believe that D–SNPs should work with enrollees and their representatives to establish the most effective and efficient process for enrollee

engagement; therefore, we chose not to establish the: (1) Frequency; (2) location; (3) format; (4) participant recruiting and training methods; (5) use and adoption of telecommunications technology; or (6) other parameters for operation of the required committee. In addition, the final rule requires one committee (for example, one committee at the State level to serve all of the MA organization’s D–SNPs in that State) but MA organizations may establish more than one committee). This rule also permits MA organizations to use existing committees which would meet the requirements of both §§ 422.107(f) and 438.110 (we expect this approach to be used by FIDE and HIDE SNPs).

The only requirements in this rule for an MA organization offering one or more D–SNPs in a State is to establish and maintain one or more enrollee advisory committees that serve the D–SNPs offered by the MA organization and for that committee to solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations. The enrollee advisory committee(s) must include at least a reasonably representative sample of the population enrolled in the D–SNP(s), or other individuals representing those enrollees. The enrollee advisory committee(s) may also advise managed care plans under title XIX of the Act offered by the same parent organization as the MA organization offering a D–SNP.

To determine the burden for MA organizations to establish the enrollee advisory committees, we reviewed two estimates from similar committees. First, the May 2016 final rule (81 FR 27778) estimated it will take 6 hours annually for a business operations specialist to establish and maintain the LTSS member advisory committee required by § 438.110 for Medicaid managed care plans that cover Medicaid LTSS.

Second, in 2021 we conducted an informal survey of the three South Carolina MMPs under the capitated FAI demonstration that are required to conduct meetings quarterly and highly value their advisory committees. The MMPs surveyed estimated an annual average of 240 hours (or 60 hours per meeting) to recruit members and establish and maintain the committee. We expect these efforts to include outreach and communication to members, developing meeting agendas, scheduling participation of presenters, preparing meeting materials, identifying meeting location and technology, D–SNP staff attendance at the meeting, and disseminating enrollee feedback to D–SNP and MA organization staff.

Due to the variety of flexibilities in creating the enrollee advisory committee, detailed previously in this section, we expect the average time and annual cost for an MA organization to establish and hold an enrollee advisory committee meeting(s) to be somewhere between 6 hours estimated for the requirement at § 438.110 and 240 hours as reported by MMPs. We believe this large difference in the time spent comes from two sources: (1) The committees created by MMPs must meet quarterly rather than annually and (2) MMPs find value in their committees and have invested more staff and resources to recruit enrollees, and prepare for and hold meetings; for example, MMPs often provide transportation to meetings, refreshments, and nominal incentives for participation, none of which is required by the capitated FAI demonstration or this rule. With this understanding that a wide variety of approaches would be used, we estimate that on average a business compliance officer will spend 40 hours at \$76.20/hr to establish and hold enrollee advisory committee meetings.

In the proposed rule, we noted that each MA organization offering one or more D–SNPs in a State will decide how to establish an enrollee advisory

committee based on the MA organization's approach to obtaining maximal input from enrollees leading to the highest quality enrollee experience. Because of the wide variability, we solicited stakeholder comments on our assumptions and burden estimates. We received no comments on this issue and therefore we are finalizing our estimates that an MA organization will spend 40 hours at a cost of \$3,048 (40 hr × \$76.20/hr for a business operation specialist) to establish an enrollee advisory committee.

We believe all FIDE SNPs and HIDE SNPs that provide LTSS currently have an enrollee advisory committee since they have a Medicaid managed care plan that must comply with § 438.110. We are updating these estimates from the estimates used in the proposed rule based on the increase in D-SNP PBPs for contract year 2022. There were 596 D-SNP PBPs in 2021 and 703 D-SNP PBPs in 2022. For 2022, we estimate 578 D-SNPs do not have a corresponding Medicaid managed care plan that provides LTSS, with 125 D-SNP PBPs in MA contracts that provide LTSS. Additionally, 268 D-SNP PBPs are in the same State and under the same contract, which means only one enrollee advisory committee is necessary to meet the requirement. Therefore, we estimate MA organizations operating D-SNPs will need to establish 310 (703 D-SNP PBPs minus 125 PBPs in D-SNP contracts that provide LTSS minus 268 PBPs under the same contract in the same State) new enrollee advisory committees.

Thus, the aggregate minimum annual burden for MA organizations operating D-SNPs to meet the requirements of § 422.107(f) is 12,400 hours (310 new committees × 40 hr per committee) at a cost of \$944,880 (12,400 hr × \$76.20/hr). As stated above, the requirement and burden will be submitted to OMB for approval under control number 0938-1422 (CMS-10799).

b. Updates to Audit Protocols (CMS-10717, OMB 0938-1395)

As noted in section II.A.3. of this rule, we anticipate updating the CMS SNP Care Coordination audit protocols⁹⁴ for MA organizations offering one or more D-SNPs to require documentation, such as a committee member list and meeting minutes, of the enrollee advisory committee meetings. In our currently approved collection of information request, we estimated that the audit protocol and data request will take 701

hours per MA organization at an average hourly cost of \$87.00/hr, totaling \$60,987 per MA organization (701 hr × \$87.00/hr). With regard to this final rule, we believe MA organizations offering D-SNPs will prepare and retain a committee member list and meeting minutes a of customary business practices that is exempt from the requirements of the PRA under 5 CFR 1320.3(b)(2). Therefore, we do not believe reporting this documentation on the enrollee advisory committee will impact our currently approved 701-hour audit protocol time estimate.

While we do not anticipate any changes to our active time estimates, we will revise the SNP Care Coordination audit protocol prior to the effective date of the rule to provide stakeholders with an opportunity to comment on the contents of our revised audit protocol. The CMS-10717 collection of information request will be made available to the public for review and comment under the standard PRA process, which includes the publication of 60- and 30-day **Federal Register** notices and the posting of the collection of information documents on our PRA website.

c. Conclusion

We did not receive any public comments on our proposed collection of information requirements, however, as noted and explained previously in this section, we have updated to our estimates based on: (1) The increase of D-SNP PBPs for contract year 2022; and (2) updated hourly wage estimates.

2. ICRs Regarding Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessments (§ 422.101) (CMS-10799, OMB 0938-1422) and (CMS-10717, OMB 0938-1395)

The following HRA requirements will be submitted to OMB for approval prior to the CY 2024 applicability date. The changes to our SNP audit protocols will be submitted to OMB for approval under control number 0938-1395 (CMS-10717).

a. Added HRA Questions

As described in section II.A.4. of this final rule, we are requiring that SNPs include questions on housing stability, food security, and access to transportation as part of their HRAs, although, based on insight from public comments, we are not finalizing our proposal to require standardized questions as proposed in our January 2022 proposed rule. Instead, we will require SNPs to include one or more questions from a list of screening

instruments specified by CMS in sub-regulatory guidance on housing stability, food security, and access to transportation in their HRAs. SNPs will also have the option to use any State-required Medicaid screening instruments that include questions on these domains. We have updated our burden estimates accordingly, as described later in this section. As noted in section II.A.4. of this final rule, we will ensure compliance with the PRA as we strive to post the sub-regulatory guidance by the end of 2022.

This provision will result in SNPs having a more complete picture of the risk factors that may inhibit enrollees from accessing care and achieving optimal health outcomes and independence. We do not believe that collecting this information will require any additional efforts from SNPs outside of customary updates to the HRA tools. Due to the current requirement at § 422.101(f) that the HRA include an assessment of the individual's physical, psychosocial, and functional needs, we believe, and public comments confirmed, that many SNPs are already including questions in their HRA tools related to housing stability, food security, and access to transportation, and many such questions are drawn from the types of validated and widely-used screening instruments that we will specify in sub-regulatory guidance. Therefore, many SNPs will not need to revise their HRA tools. If a SNP is not already asking these questions, we do not predict the addition of questions on these three topics would lengthen the time to administer a typical HRA.

CMS does not currently collect specific data elements from HRAs for all SNP enrollees. CMS will not be collecting data elements from the HRA as part of this collection of information.

We estimate a one-time burden for the parent organizations offering SNPs to update their HRA tools in their care management systems and adopt questions on housing stability, food security, and access to transportation, in cases where the SNPs are not already asking questions on the required topics.

In our proposed estimate, we assumed that each parent organization offering one or more SNP would be impacted. Because we are not finalizing standardized questions but rather requiring SNPs to choose questions from a list of existing screening instruments that comments indicate are widely in use or a State-required Medicaid screening instruments, we assume that many SNPs are already asking questions that we will include on the list; therefore, we estimate about 35 percent of parent organizations with one or

⁹⁴ See <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits>.

more SNPs would update the care management system where an enrollee's HRA responses are recorded. We estimate that it will take a software programmer 3 hours at \$116.34/hr to update the care management system resulting in a cost of \$349 (3 hr × \$116.34/hr) per parent organization. We are updating the number of parent organizations making these updates based on the 2022 contract year numbers from 123 parent organizations with a SNP PBP in 2021 to 133 parent organizations with a SNP PBP in 2022. We therefore estimate 47 parent organizations (35 percent of organizations that update multiplied by 133 parent organizations) will be making these updates. In aggregate, we estimate a one-time burden for updating the HRA tool of 141 hr (47 parent organizations × 3 hr) at a cost of \$16,404 (141 hr × \$116.34/hr).

b. Updates to Audit Protocols (CMS-10717, OMB 0938-1395)

The change to the HRAs would also require an update to the CMS SNP Care Coordination audit protocols⁹⁵ that ensure the completed HRAs include the assessment of housing stability, food security, and access to transportation based on the list of screening instruments specified by CMS in sub-regulatory guidance. Currently, audit protocol and data request burden are estimated at 701 hours per MA organization at an average hourly cost of \$87.00/hr, totaling \$60,987 per MA organization. We do not believe the changes to SNP audit protocols would add more time to the 701-hour audit protocol estimate, as we are adding a confirmation that the SNP's HRA includes the changes as part of the SNP Care Coordination audit protocols.

While we do not anticipate any changes to our active time estimates, we will revise the audit protocol documents to provide stakeholders an opportunity to review and comment on the contents of the protocol documents. The revised collection of information request is not available at this time, but it will be made available to the public for review and comment under the standard PRA process, which includes the publication of 60- and 30-day **Federal Register** notices and the posting of the collection of information documents on our PRA website.

c. Conclusion

We did not receive any public comments on our proposed collection of

information requirements regarding housing, food insecurity, and transportation questions on health risk assessment. As indicated above, (i) we have updated our burden estimates from 123 affected parent organizations to 47 parent organizations and (ii) updated our cost estimates by using BLS' 2021 wages; however, the estimated time per respondent remains the same.

3. ICRs Related To Refining Definitions for Fully Integrated and Highly Integrated D-SNPs (§ 422.2)

The following changes will be submitted to OMB for approval under control number 0938-1410 (CMS-10796).

As described in section II.A.5. of this final rule, we are making several changes to the definitions of FIDE SNPs and HIDE SNPs at § 422.2 that we believe will ultimately help to differentiate various types of D-SNPs and clarify options for beneficiaries and stakeholders. Our changes to the FIDE SNP definition require these plans to: Have exclusively aligned enrollment; cover Medicare cost-sharing; and cover the Medicaid benefits of home health (as defined in § 440.70), medical supplies, equipment, and appliances (as described in § 440.70(b)(3)), and Medicaid behavioral health services through a capitated contract with the State Medicaid agency. We also require that each FIDE SNP's and HIDE SNP's capitated contract with the State Medicaid agency apply to the entire service area for the D-SNP for plan year 2025 and subsequent years. We are also codifying existing policy outlined in sub-regulatory guidance to permit, subject to CMS approval, specific limited benefit carve-outs for FIDE SNPs and HIDE SNPs through the State Medicaid agency contract submission process.

Due to the changes to the definition of FIDE SNP and HIDE SNP, a D-SNP may need to update its contract with the State Medicaid agency. The currently approved annual burden estimate for updating the State Medicaid agency contract is 30 hours per D-SNP as described in OMB control number 0938-0753 (CMS-R-267). While the changes may result in a one-time change to the contract, we believe the changes to the contract language would be relatively minor (even though the changes are substantive in nature) and part of routine updates to contracts such as changes of dates. We also believe that the contract changes would be subsumed in the 30-hour burden estimate for updating the contract annually. Therefore, we do not estimate our changes to these definitions at

§ 422.2 would impact our currently approved annual 30 hour contracting burden estimate for D-SNPs.

The changes to the FIDE SNP and HIDE SNP definitions may change how D-SNPs attest when submitting their State Medicaid agency contract to CMS. The burden is currently estimated under OMB control number 0938-0935 (CMS-10237). We do not estimate D-SNPs would experience an increase in their per response time or effort to submit the State Medicaid agency contract to CMS.

However, we will update the content of the collection of information to reflect the changes to § 422.2 by revising the 5.11 D-SNP State Medicaid Agency Contract Matrix and 5.12 D-SNP State Medicaid Agency Contract Matrix documents connected to control number 0938-0935 (CMS-10237) and move these documents to control number 0938-1410 (CMS-10796). We believe including these forms in a separate OMB control number 0938-1410 (CMS-10796) exclusively for the D-SNP State Medicaid agency contracts is more operationally consistent with the collection of information required from MA organizations. The matrix documents will be removed from 0938-0935 after they are approved by OMB under 0938-1410.

a. Service Area Overlap Between HIDE SNPs and Companion Medicaid Plans (CMS-R-262, OMB 0938-0763)

In addition to the updates described in this section, changes to the FIDE SNP or HIDE SNP definition described in section II.A.5.f. of this final rule will require the service area of a FIDE SNP or HIDE SNP to overlap with companion Medicaid plans; therefore, the 15 HIDE SNPs that have service area gaps with their affiliated Medicaid MCOs would make a business decision regarding how to comply with the requirement in addition to updating the State Medicaid agency contract with the D-SNP. We believe that only one-third of the 15 impacted D-SNPs, or 5 D-SNPs, would choose to remain a HIDE SNP. The remaining 10 D-SNPs would contract with the State as a non-HIDE D-SNP and not incur additional burden.

A D-SNP that wishes to remain a HIDE SNP would submit a new D-SNP PBP for the service area that does not overlap with the D-SNP's companion Medicaid plan during the annual bid submission process (OMB control number 0938-0763 (CMS-R-262)). Also, under the annual bid submission process, the existing HIDE SNP would reduce their MA service area to that which overlaps with the companion Medicaid plan.

⁹⁵ See <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits>.

The currently approved annual burden estimate for D-SNPs to update PBPs is 35.75 hours per MA contract as described in OMB control number 0938-0763 (CMS-R-262). We do not estimate D-SNPs would experience an increase in their response time or effort to submit the bid to CMS.

Alternatively, to remain a HIDE SNP, the MA organization can work with the State Medicaid agency to expand the service area of the companion Medicaid plan to align with the D-SNP service area. However, State Medicaid procurement time frames and contracting strategies may not provide the 15 D-SNPs an opportunity to expand the service area of the companion Medicaid plan in CY 2025.

b. Conclusion

We did not receive any public comments on our proposed collection of information requirements and are therefore finalizing them without modification.

4. ICRs Related to Additional Opportunities for Integration Through State Medicaid Agency Contracts (§ 422.107)

As described in section II.A.6. of this final rule, we are adding new paragraph (e) at § 422.107 to describe conditions through which States may require certain contract terms for D-SNPs and how CMS would facilitate compliance with those contract terms. Paragraph (e)(1) would allow States, through the State Medicaid agency contract with D-SNPs, to require that certain D-SNPs with exclusively aligned enrollment (a) establish MA contracts that only include one or more D-SNPs within a State, and (b) integrate materials and notices for enrollees. A more detailed discussion of these requirements and associated burden follows:

a. State Medicaid Agency Contract Requirements

The following changes will be submitted to OMB for review under control number 0938-1410 (CMS-10796).

For States that opt to require the contract requirements at § 422.107(e), States and plans will need to modify the existing State Medicaid agency contract. These modifications will document the D-SNP's responsibility to only enroll dually eligible individuals who receive coverage of Medicaid benefits from the D-SNP, integrate member materials, and request that CMS establish an MA contract limited to D-SNPs within the State.

(1) State Burden (CMS-10796, OMB 0938-1410)

Section 1903(a)(7) of the Act requires the Federal Government to pay a match rate for administrative expenses. Since cost is split between the State Medicaid agency and the Federal Government, we split in half the total costs associated with administering the Medicaid program, half of which the States incur and half of which the Federal Government incurs. The Federal Government's cost is presented in the RIA section of this rule (see section V.D.3.).

For each State Medicaid agency, it will take a total of 24 hours at \$142.34/hr for State staff to update the State Medicaid agency's contract with the D-SNPs in its market to address the changes in this final rule. This estimate includes the burden to negotiate with the D-SNPs on contract changes and engage with CMS to ensure contract changes meet the requirements that we are finalizing at § 422.107(e).

Based on our experience, we expect that each State Medicaid agency will establish uniform contracting requirements for all D-SNPs operating in their market. We are uncertain of the exact number of States that would opt to require these proposed contract changes over the course of the first 3 years (contract years 2025 to 2027). Based on our previous work with States as part of the capitated FAI demonstration and implementing the D-SNP integrations requirements established by the BBA of 2018, we estimate as few as five and as many as 20 States may opt to make these changes in their contracts with D-SNPs and their administration of their programs. Based on the number of States currently collaborating with CMS on Medicare and Medicaid integration and the States likely to transition from MMP-based to D-SNP-based integrated care approaches, we believe there will be 12 States that implement this rule. In our proposal, we projected that States would implement this one-time change during the first year (contract year 2025). In section II.A.14. of this final rule, we discuss our intent to explore extension of the FAI model test in certain circumstances and consistent with our authority under section 1115A of the Act to convert MMPs to integrated D-SNPs. The discussion in section II.A.14. of this final rule makes us less certain of when States will incur the burden described in this collection of information; however, we do not expect the number of States impacted to change. Therefore, we are not updating

our estimates based on the discussion in section II.A.14. of this final rule.

Section 1903(a)(7) of the Act requires the Federal Government to pay half of the States' administrative costs. In aggregate we estimate a one-time burden of 288 hours (12 States × 24 hr/State) at a cost of \$20,497 (288 hr × \$142.34/hr × 0.5). After this first-year one-time requirement is satisfied, and given the uncertainty involved in estimating State behavior, we are estimating zero burden in subsequent years.

(2) MA Organization Burden (CMS-10796, OMB 0938-1410)

For the initial year, we expect each affected D-SNP will take 8 hours at \$142.34/hr for a lawyer to update the contract with the State Medicaid agency to reflect the revised and new provisions in this rule at § 422.107(e). Based on our assumptions of States likely to opt to require the contract changes, we estimate between 40 to 80 MA organizations would be impacted. Since we are uncertain of which extreme to use, we use the average, 60 MA organizations. We further expect the updates to be completed in the first year (contract year 2025). In aggregate we estimate a one-time burden of 480 hours (60 MA organizations × 8 hr) at a cost of \$68,323 (480 hr × \$142.34/hr).

b. Limiting Certain Medicare Advantage Contracts to D-SNPs (CMS-10237, OMB 0938-0935 and CMS-10137, OMB 0938-0936)

The following changes regarding additional Part C application respondents will be submitted to OMB for approval under control number 0938-0935 (CMS-10237). The following changes regarding additional Part D application respondents will be submitted for OMB approval under control number 0938-0936 (CMS-10137).

At § 422.107(e) we are codifying a pathway by which States can require and CMS would permit MA organizations—through the existing MA application process—to establish MA contracts that only include one or more D-SNPs with exclusively aligned enrollment within a State. This action will allow dually eligible individuals to ascertain the full quality performance of a D-SNP and better equip States to work with their D-SNPs to improve health equity.

We note that creating a new D-SNP-only contract will have several downstream collection of information impacts for an MA organization that are captured under the two aforementioned control numbers, the most immediate of which is the MA organization would

need to complete a new application for Parts C and D.

We estimate that 60 D-SNPs will be impacted by our changes to § 422.107(e). Currently, 32 percent of D-SNPs are in D-SNP-only contracts;⁹⁶ therefore, we estimate that 19 of the 60 D-SNPs (60 D-SNPs × 0.32) impacted would already have a D-SNP-only contract and not need to submit a new Part C and D application. The remaining 41 D-SNPs (60 – 19 D-SNPs) would need to submit both a new Part C and a new Part D application.

The burden per MA organization for an initial Part C application for a SNP is currently approved by OMB under control number 0938–0935 (CMS–10237) at 10 hours at \$72.90/hr for a compliance officer to review instructions and complete the application (including submission) at a cost of \$729 (10 hr × \$72.90/hr). Under this final rule, we estimate 41 D-SNPs will need to submit a new Part C application; therefore, the currently approved total burden for one-time Part C applications will increase by 410 hours (10 hr × 41 D-SNPs) at a cost of \$29,889 (410 hr × \$72.90/hr).

The burden per MA organization for an initial Part D application for an MA-PD plan is currently approved by OMB under control number 0938–0936 (CMS–10137) at 6.41 hours for a compliance officer to review instructions and complete the application (including submission) at a cost of \$467 (6.41 hr × \$72.90/hr). Under this final rule, we estimate 41 D-SNPs will need to submit a new Part D application; therefore, the currently approved total burden for one-time Part C applications will increase by 263 hours (6.41 hr × 41 affected D-SNPs) at a cost of \$19,173 (263 hr × 72.70/hr).

While we anticipate changes to the number of respondents and our active time estimates for the Part C and Part D applications, we will revise control numbers 0938–0935 (CMS–10237) and 0938–0936 (CMS–10137) for the 2025 plan year application. Because States will likely consult with CMS, MA organizations, and other stakeholders on whether and how to pursue this step toward integration and because of the timing of MA applications, bids, and contract execution, we believe the 2025 plan year application is the earliest date that the new policy in § 422.107(e) can be implemented by a State and MA organization. The CMS–10237 and CMS–10137 collection of information materials will be made available to the public for review/comment under the

standard PRA process which includes the publication of 60- and 30-day **Federal Register** notices and the posting of the collection of information documents on our PRA website.

We acknowledged in our proposal that there may be additional downstream collection of information impacts for new contracts related to Part C and D reporting and CMS monitoring at the contract level. For example, MA organizations would experience additional reporting to CMS, calculation of HEDIS measures, and administration of HOS and CAHPS surveys. We are uncertain of the extent of the additional burden incurred for reporting as a separate contract. We requested comments on these impacts for a new contract under an already existing MA organization and if they should be included in our estimates. We received no comments and are finalizing our estimates without including any additional collection of information impacts.

c. Integrated Member Materials

As described in section II.A.6.b. of this final rule, to provide a more coordinated beneficiary experience, at § 422.107(e) we are codifying a pathway by which States and CMS will collaborate to establish model materials when a State chooses to require through its State Medicaid agency contract that certain D-SNPs use an integrated SB, Formulary, and combined Provider and Pharmacy Directory. Section 422.107(e)(1) establishes factual circumstances that would commit CMS to certain actions under paragraphs (e)(2) and (3).

We do not estimate any additional burden for States or plans to implement integrated member materials at § 422.107(e) due to existing State efforts to work with Medicaid managed care plans to comply with information requirements at § 438.10 and to work with D-SNPs to populate Medicaid benefits for Medicare member materials. Since requirements imposed on the Federal Government are not subject to the PRA, we describe costs to the Federal Government's burden to develop integrated member materials in section V.D.3.c. of this final rule.

d. Conclusion

We did not receive any public comments on our proposed collection of information requirements and are finalizing these estimates as is with updated mean hourly wages.

5. ICRs Related to Definition of Applicable Integrated Plan Subject to Unified Appeals and Grievances Procedures (§ 422.561) (CMS–10796, OMB 0938–1410)

The following changes will be submitted to OMB for approval under control number 0938–1410 (CMS–10796).

In § 422.561, we are expanding the universe of D-SNPs with unified grievance and appeals processes by revising the definition of the term “applicable integrated plan,” which establishes the scope of plans that are subject to the requirement to use those unified processes. Unified grievance and appeals processes were originally limited to FIDE SNPs and HIDE SNPs; however, after our implementation experience, we believe that there are models of integrated D-SNPs other than FIDE SNPs and HIDE SNPs that should be required to use, and are capable of using, the unified grievance and appeals processes.

We anticipate that additional D-SNPs will be implementing the unified grievance and appeals procedures under §§ 422.629 through 422.634 and that the D-SNPs impacted by this rule are D-SNPs in California with exclusively aligned enrollment, including those plans receiving Cal MediConnect members at the end of the California capitated FAI demonstration.

We estimate a one-time burden for each new applicable integrated plan to update its policies and procedures to reflect the new integrated organization determination and grievance procedures under § 422.629. We anticipate this task will take a business operation specialist 8 hours at \$76.20/hr. In aggregate, we estimate a one-time burden of 104 hours (8 hr × 13 D-SNPs) at a cost of \$7,925 (104 hr × \$76.20/hr).

While new D-SNPs will use the CMS–10716 denial notice under OMB control number 0938–1386 rather than the CMS–10003 MA denial notice under OMB control number 0938–0829, neither of the notices nor burden estimates would be revised as a result of this rule. As indicated previously, the rule's changes will be submitted to OMB under control number 0938–1410 (CMS–10796).

The CMS–10716 denial notice required under § 422.631(d)(1) includes information about the determination, as well as information about the enrollee's appeal rights for both Medicare and Medicaid covered benefits. Though integrating information on Medicare and Medicaid appeal rights will be a new requirement for the impacted D-SNPs, we note that the timeframe for sending

⁹⁶ HPMS, Contract Management Reports 2020, SNP Type and Subtype Report, August 7, 2020.

a notice and the content of the notice are largely the same as the current requirements in Medicaid (§ 438.404(b)) and MA (§ 422.572(e)); therefore, impacted D-SNPs are not incurring additional burden to send the notification. Setting out such burden would be duplicative.

We did not receive any public comments on our proposed collection of information requirements and are therefore finalizing our estimates as is but with updated mean hourly wages.

6. ICRs Related to Attainment of the Maximum Out-of-Pocket (MOOP) Limit (§§ 422.100 and 422.101)

As described in section II.A.12. of this final rule, we are making a revision to which costs accumulate toward the MOOP limit, with the most significant impact being for dually eligible enrollees with cost-sharing protections under § 422.101 for MA regional plans and § 422.100(f)(4) and (5) for all other MA plans. As established in this final rule, all costs for Medicare Parts A and B services accrued under the plan benefit package, including cost-sharing paid by any applicable secondary or supplemental insurance (such as through Medicaid, employer(s), and commercial insurance) and any cost-sharing that remains unpaid (such as because of limits on Medicaid liability for Medicare cost-sharing under lesser-of policy and the cost-sharing protections afforded certain dually eligible individuals), will count towards the MOOP limit. This will ensure that once an enrollee, including a dually eligible individual with cost-sharing protections, has accrued cost-sharing (deductibles, coinsurance, or copays) that reaches the MOOP limit, the MA plan will pay 100 percent of the cost of covered Medicare Part A and Part B services. MA plans are currently tracking all costs accrued as part of preparing to submit an accurate plan benefit package bid (OMB control number 0938-0763 (CMS-R-262)); therefore, this provision does not add additional requirements or burden.

This final rule will update current guidance governing MA organization bid requirements, which are captured under our active OMB control number 0938-0763 (CMS-R-262). We do not foresee any new or revised burden that would arise from the changes. The non-PRA related burden can be found in section V.D.4. of this final rule.

We did not receive any public comments on regarding the collection of information requirements for this provision and are finalizing them without change.

7. ICRs Related to Network Adequacy (§ 422.116(a)(i)(ii) and (d)(7))

The following changes will be submitted to OMB for approval under control number 0938-1346 (CMS-10636).

In this rule we will require compliance with CMS's network adequacy standards for initial and service area expansion (SAE) applicants as part of the MA application process. Therefore, we will require that initial and SAE provider networks be submitted and reviewed in February instead of June (with plans being reviewed for the triennial review).

Consequently, the number of reviews and the amount of work is the same; rather, it is being re-distributed.

Comment: We did not receive any public comments specific to our proposed collection of information requirements. However, based on comments we received on our proposal to review applicants' provider networks during the time of application in mid-February of each year, we will modify the final regulation to include a change in our collection of information.

We received a number of comments that were not supportive of our proposal to require compliance with CMS's network adequacy standards for initial and SAE applicants as part of the MA application process. Commenters expressed concerns over the proposed timing for submission and review of provider networks, which they said would not allow sufficient time for MA organizations to build high-quality networks. Further, commenters said that our proposal would negatively impact negotiations with provider groups, give providers leverage to negotiate higher rates that would increase healthcare costs and reduce benefits. Commenters also suggested that our proposal would disproportionately impact smaller organizations working to expand to certain regional, rural, and medically underserved areas, thereby inhibiting competition among plans and ultimately limiting choice for beneficiaries; some of these commenters also expressed the view that the proposal would provide an unfair advantage to large health plans with a presence in these areas. Several commenters posited that our proposal would place a substantial administrative burden on MA organizations and on providers, and that establishing contracts with organizations takes a significant amount of time. Finally, a number of commenters asked CMS to consider allowing applicants to use Letters of Intent (LOIs) to contract with providers as a means to meet network adequacy standards, which would

provide flexibility as they work to come into compliance for the coverage year.

Response: We appreciate the commenters' feedback regarding our proposal. As we noted in the proposed rule, we understand that requiring an applicant to establish a full provider network almost a year in advance of the contract becoming operational will be difficult. We also indicated that we previously separated the network adequacy reviews from the application process due to the potential challenge of applicants securing a full provider network almost a year in advance of the contract becoming operational.

Therefore, based on the comments received, we will modify the regulation to allow applicants to use LOIs in lieu of signed provider contracts, at the time of application and for the duration of the application review. The LOI must be signed by both the MA organization and the provider with which the MA organization intends to negotiate. Further, as part of the network adequacy review process, applicants must notify CMS of their use of LOIs to meet network standards in lieu of a signed contract and submit copies upon request and in the form and manner directed by CMS. At the beginning of the contract year, the MA organization must be in full compliance with the section, including having signed provider and facility contracts in place of the LOIs.

We are not estimating the burden of updating systems to receive LOIs since this is done by CMS and its contractors and not subject to PRA requirements. We are not estimating the negotiations between plans and providers since these already occur, as would negotiations of LOIs. While there might be some increase in these negotiations, we do not have access to data on plan negotiations and believe that the assumption that the negotiations remain the same is valid.

There is an increase in burden because we will require applicants to submit the providers with whom LOIs have been entered into when submitting their MA application using CMS systems; previously, the LOIs were internal documents to the plan. We must be prepared that all applicants who may be requesting an exception to the network adequacy standards may submit LOIs. While there might be additional or less we have no way of ascertaining this and believe this a reasonable assumption.

As noted, applicants will use existing processes to submit the LOIs. Currently we have 468 MA applicants of which we expect about 45 percent to submit exceptions through CMS systems (CMS-10636, OMB 0938-1346). Thus, we assume 211 applicants (45 percent × 468

applicants) would submit an exception request. MA applicants are already collecting LOIs, and already submitting zipped files through our application and network adequacy review process. The extra burden to the applicants from this provision would be in gathering documents for the zip file and indicating whether there are LOIs. We are estimating that the extra burden of gathering forms and indicating a check on an application will take 5 minutes (0.083 hr). Therefore, the total burden of this provision is 18 hours (211 applicants \times 0.083 hr) at a cost of \$1,312 (18 hr \times \$72.90/hr for a compliance officer.)

8. ICRs Related to the Disclaimer for Preferred Pharmacy (§ 423.2267(e)(40))

The following disclaimer changes carry no burden. Section 423.2267(e)(40) would require Part D sponsors to insert CMS standard disclaimer on materials that mention preferred pharmacies. The burden associated with this requirement is the time and effort to copy the disclaimer on plan documents during document creation. While these requirements are subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(c)(2). We believe that the time, effort, and financial resources to comply with the information collection requirements will be incurred by persons in the normal course of their activities and therefore considered to be usual and customary business practice.

This disclaimer is currently described in CMS's sub-regulatory guidance, the MCMG, and will be codified in this final rule. The disclaimer provides an important safeguard to Medicare beneficiaries enrolled in a Part D plan that only provide access to preferred cost-sharing through a limited number of pharmacies by alerting them that the preferred costs may not be available at the pharmacy they use, as well as providing information on how to access the list of pharmacies offering prescription drugs as a preferred cost in the beneficiary's area. We did not receive any public comments on our proposed collection of information requirements and are finalizing them without change.

9. ICRs Related to Member Identification Cards (§§ 422.2267(e)(30) and 423.2267(e)(32))

Member Identification Cards burden is exempt from the requirements of the PRA since the issuance of Medicare Identification Cards is a normal and customary practice throughout the insurance industry. Health plans,

whether commercial, through Medicare or Medicaid, or Original Fee-For-Service issue cards that inform providers of the enrollee's insurance.

This final rule is a codification of previously issued sub-regulatory guidance in the MCMG defining standards for member identification cards issued by MA plans and Part D plan sponsors.

CMS created this sub-regulatory guidance to reduce Medicare beneficiary confusion through bringing consistency to member ID card requirements by applying standards so that ID cards from plan to plan contained the same information in the same locations.

The member identification card standard provided in the previously issued sub-regulatory guidance was created using an industry standard for ID cards; these industry standards reflected best practices and consequently plans found the previously issued sub-regulatory guidance implementable with minimal burden. Because of the minimal burden, plans will have no incentive to avoid using them. Additionally, we have received no enrollee complaints on member cards since issuing the sub-regulatory guidance.

Because of the reasons listed previously, we believe plans are following the standards described in this sub-regulatory guidance and therefore no further burden is imposed by codifying these standards in regulation.

We did not receive any public comments on our proposed collection of information requirements and are finalizing them without change.

10. ICRs Related to the Creation of a One-Page Multilanguage Insert (§§ 422.2267(e)(31) and 423.2267(e)(33)) (CMS-10802, OMB 0938-1421)

The following changes will be submitted to OMB for approval under control number 0938-1421 (CMS-10802).

The requirements finalized under §§ 422.2267(e)(31) and 423.2267(e)(33) will require that plans add in their postings or mailings of CMS required materials a one-page document written in the top 15 non-English languages in the U.S. informing enrollees that interpreter services are available at no cost.

We previously required plans to provide this document to enrollees. However, based on section 1557 of the Affordable Care Act, the Office for Civil Rights (OCR) created their own version. Because of the inherent duplication between CMS's MLI requirement and OCR's requirement, CMS issued an

HPMS email on August 25, 2016, that removed the MLI requirement. OCR later vacated their requirement, leaving a gap. Consequently, we proposed to require that MA plans and Part D plan sponsors provide the one-page document.

Because the MLI will be standardized, plans will not be permitted to create their own version and will need to use the standardized template provided by CMS. In estimating the burden of this 1-page standardized document, we assume plans have retained their templates consistent with the record retention requirements at § 422.504(e)(4). Consequently, there is no burden to create the template, as plans will either use their existing templates or the standardized template that CMS will provide to new plans based on the previously-created MLI without change.

The cost of placing an extra page on the plan's web page is incurred by plans as part of their normal course of fluctuating business activities and hence excluded from the PRA (5 CFR 1320.3(b)(2)).

For beneficiaries who request a paper copy, this final rule requires that plans mail it to those beneficiaries along with other CMS required materials (§§ 422.2267(e) and 423.2267(e)). We believe it is reasonable to assume that adding one page (at 0.1696 ounces) to a bulk mailing cost is de minimis and therefore does not create additional postage costs.

Similar estimates have been made in previous final rules where we identified the major burden as paper and toner. We have checked the following assumptions of cost and beneficiary interest in receiving paper copies found in the April 2018 final rule (83 FR 16695), and found them to still be reliable for the purpose of this rule.

A 10-ream box (of 5,000 sheets) of paper costs approximately \$50. Hence the cost per sheet is \$50/5,000 sheets = \$0.01 per page.

Standard toner cartridges which last for about 10,000 pages also cost \$50. Hence the cost per sheet is \$50/10,000 = \$0.005 per page.

Thus, the total paper and toner cost is \$0.015 per page.

As of September 2021, there are 52 million beneficiaries enrolled in MA PD or stand-alone PDP plans.⁹⁷

Of these 52 million beneficiaries we estimate that 40 percent or 20,800,000 beneficiaries (52 million beneficiaries \times 0.40) will request paper copies.

⁹⁷ <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenrolldatamonthly/contract-summary-2021-09>.

It follows that the aggregate cost of providing one extra sheet of paper is \$312,000 (20,800,000 enrollees × \$0.015/page).

There is no labor cost for providing one extra sheet of paper.

We solicited stakeholder input on all assumptions including the estimate that 40 percent of enrollees request paper copies and that the major costs are paper and toner.

Comment: We received comments indicating generally that our estimate of the burden to plans was incorrect. A commenter indicated our estimate of the burden was incorrect without providing any specifics on the nature of the alleged error or its impact on the burden calculation. Another commenter indicated that our estimate of the burden was too low, but they did not indicate to what degree or in what way they felt we had miscalculated.

Response: As the comments did not provide specific parameters as to how our burden estimate is inaccurate, we decline modification of estimates based on the comment. On review, we believe our assessment of the burden on plans is accurate. Regardless, we also believe the burden on plans is acceptable considering the vital nature of the MLI. Additionally, we expect that plans consider the burden acceptable as the MLI improves awareness of health issues; and as plans are committed to the health of their members, they support the MLI as is a bridge to education and awareness of health and health insurance issues.

We did not receive any other comments on our proposed collection of information requirements and are finalizing them without change.

11. ICRs Related to Third-Party Marketing Organizations (TPMOs) Agent (§§ 422.2260, 422.2267(e)(41), 422.2274(g), 423.2260, 423.2267(e)(41), and 423.2274(g))

Sections 422.2260, 422.2267(e)(41), 422.2274(g), 423.2260, 423.2267(e)(41), and 423.2275(g) will require MA organizations and Part D sponsors to insert a CMS standard disclaimer on materials created by Third Party Marketing Organizations.

The burden associated with this requirement will be the time and effort to copy the disclaimer on marketing materials during document creation. The disclaimer is a standardized, required material. In this regard we believe that the disclaimer is not subject to the requirements of the PRA because it does not constitute a “collection of information.” Instead, the disclaimer is a “public disclosure” of information originally supplied by the Federal Government to the recipient (5 CFR 1320.3(c)(2)).

CMS did not receive any other comments on our proposed collection of information requirements and are finalizing them without change.

CMS received no comments on the estimates for this proposal and therefore are finalizing this provision estimate without modification.

12. ICRs Related to the Medicare Medical Loss Ratio (MLR) Reporting Requirements (§§ 422.2460 and 423.2460) (CMS–10476, OMB 0938–1232)

The following changes to the Medicare MLR reporting requirements will be submitted to OMB for approval under control number 0938–1232 (CMS–10476).

In section II.G.2. of this final rule, we note that under current §§ 422.2460 and 423.2460, for each contract year, MA organizations and Part D sponsors must report to CMS only the MLR and the amount of any remittance owed to us for each contract with credible or partially credible experience. For each non-credible contract, MA organizations and Part D sponsors are required to report only that the contract is non-credible. In this rule, our amendments to §§ 422.2460 and 423.2460 would increase the MLR reporting burden by requiring that MA organizations and Part D sponsors report, for each contract year, the data needed to calculate and verify the MLR and remittance amount, if any, for each contract, such as the amount of incurred claims for Medicare-covered benefits, supplemental benefits, and prescription drugs; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory

fees; total revenue; and any remittance owed to CMS under § 422.2410 or § 423.2410.

In estimating impact, we initially focus on hourly burden. Once the hourly burden of this final rule is established, we calculate the per contract and aggregate hourly and dollar burden. The reason for this approach is that the estimates of hourly burden have undergone several changes; focusing on them first provides a clearer exposition.

The following four regulatory sources, final rules and PRA packages, are used as a source for items estimated. These are presented here with brief outlines of their contributions which will be detailed below. (i) The information collection that was previously approved by OMB under 0938–1232 (CMS–10476) in connection with the requirements finalized in the May 2013 Medicare MLR final rule, CMS estimated that, on average, MA organizations and Part D sponsors will spend 47 hours per contract on Medicare MLR reporting, including: Collecting data, populating the MLR reporting forms, conducting internal review, submitting the reports to the Secretary, and conducting internal audits. (ii) This 47-hour figure was also used in the April 2018 final rule (83 FR 16701) to estimate the reduction in burden resulting from that rule’s revisions to the MLR reporting requirements that apply with respect to MLR reporting for contract year 2018 and subsequent contract years. (iii) The June 2020 final rule (84 FR 33796 to 33850), added a deductible-based adjustment to the MLR calculation for MA medical savings account (MSA) contracts. (iv) The current final rule, which introduces three changes: Automation of the MLR reporting for MA organizations including the MSA reporting requirement, reinstatement of detailed MLR reporting requirement used in 2014–2017, and addition of data fields related to expenditures on supplemental services.

Five items must be estimated to perform the impact analysis. They are presented in Table 5. Table 5 indicates if these items have undergone change for this final rule.

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**TABLE 5: SUMMARY OF KEY ITEM ASSUMPTIONS USED IN
CALCULATIONS**

Item	Information Collection previously approved under OMB Control Number 0938-1232; April 2018 final rule	June 2020 rule	Final Rule
Total assumed administrative burden related to MLR form used as a starting point and then apportioned into i) the burden for the completion of the form and ii) other administrative burden. See next three rows.	47 hours; 36.75 hours	36.75055 hours	61.1 hours
Burden for completion of MLR forms (There are three forms: (1) the 2014-2017 form, (2) the 2018-current form, (3) the form that will be used starting in 2023 (under this final rule)	(1) 11.5 hours for completing the 2014-2017 form. (2) 0.5 hour for completing the 2018 form.	(2) 0.5 hour for completing the 2018 form.	Discussed below. Compared with the 2014-2017 form, there is an increase of 33.3 percent of fields for MA organizations; there is a 5 percent increase for sponsors of stand-alone Part D contracts. The 11.5 estimate presented in the April 2018 rule and included in the June 2020 rule burden estimate was classified as an error in the proposed rule (and this final rule) and has been corrected (for purposes of estimating the burden increase) to 10.75 hours. (3) 24.85 hours for completing the form that will be used starting in 2023 (under this final rule)
Other administrative burden	This is a derived calculation. It equals total administrative burden minus burden for completion of forms		
Burden for MSA deductible factor calculation	Not present	Introduced in June 2020 final rule. The annual burden was estimated to be 0.00055/hr.	Eliminated in proposed rule and this final rule
Average number of contracts	601		

requirements is based on the average number of MA and Part D contracts subject to the reporting requirements for each contract year. For contract years (CYs) 2014 to 2020, the average number of such contracts is 601. The total number of MA and Part D contracts is relatively stable year over year varying from 533 to 691 during CYs 2014–2020, such that we are applying the 601 average in this rule's burden estimates.

Total hourly burden related to MLR: It is necessary to estimate the total effort (time) related to the Medicare MLR requirements that applied with respect to MLR reporting for contract years 2014 through 2017. In the information collection request that was previously approved by OMB under 0938–1232 (CMS–10476), CMS estimated the total time spent on MLR reporting to be 47 hours. The April 2018 final rule

subsequently divided this 47 hour estimate into two components: Time to complete the MLR form and time spent on other administrative tasks related to MLR reporting.

Time to complete the MLR form: In the April 2018 final rule (83 FR 16701), we estimated that it would take an MA organization or Part D sponsor 11.5 hours to complete the MLR reporting form that was used to collect MLR data for CYs 2014 through 2017. We explained that we developed this estimate by considering the amount of time it would take an MA organization or Part D sponsor to complete *each* of the following tasks:

- Review the MLR report filing instructions and external materials referenced therein and to input all figures and plan-level data in accordance with the instructions.

- Draft narrative descriptions of methodologies used to allocate expenses.

- Perform an internal review of the MLR report form prior to submission.
- Upload and submit the MLR report and attestation.

- Correct or provide explanations for any suspected errors or omissions discovered by CMS or our contractor during initial review of the submitted MLR report.

In 2018, we finalized a less detailed form which we estimated takes 0.5 hours to complete.

The calculations for hourly burden per contract that were included in the April 2018 final rule are summarized in Table 6. These calculations do not reflect the corrections to the April 2018 rule that were taken into account in our burden estimate for the proposed rule.

TABLE 6: TIME PER CONTRACT USED IN APRIL 2018 FINAL RULE (HOURS)

Row ID	Item	Estimate	Notes
(1)	Total administrative burden (assuming use of MLR form for CYs 2014-2017) (hr)	47	Estimate used in former approved Information Collection Request that included MLR form used for CYs 2014-2017
(2)	Original estimate of burden for completing MLR form used for CYs 2014-2017 (hr)	11.5	Assumption in April 2018 final rule about amount of time needed to complete MLR form used for CYs 2014-2017
(3)	Burden for administrative tasks other than completing MLR form (hr)	35.5	(3) = (1) - (2)
(4)	Estimate of burden for completing current MLR form (hr)	0.5	Assumption in April 2018 final rule
(5)	Total administrative burden for current MLR form (hr)	36	(5) = (3) + (4)

The following explanations apply to the rows in Table 6:

Row (1): The 47-hour figure, as explained in the opening paragraphs of this ICR, is CMS's estimate for the total amount of time MA organizations and Part D sponsors will spend per contract on Medicare MLR reporting when the MLR was reported using the MLR form for CYs 2014 through 2017, including: Collecting data, populating the MLR reporting form, conducting internal review, submitting the report to the Secretary, and conducting internal audits.

Row (2): The 11.5-hour burden is the portion of the burden in Row (1) that the April 2018 final rule assumed was

associated with completing the MLR form used for CYs 2014 through 2017. This burden is discussed in the paragraph immediately preceding Table 6.

Row (3): 35.5 hours, the administrative burden associated with the MLR requirements, excluding the April 2018 final rule's estimate of the burden for completing and submitting the MLR form used for CYs 2014 through 2017. This number represents the difference between total per contract burden, 47 hours, and the form burden per contract, 11.5 hours.

Row (4): Estimated burden to complete the current MLR data form, which is vastly simplified and is

estimated to take only a half-hour to complete.

Row (5): The total burden per contract, as written in the April 2018 final rule, and as adjusted for the current number of contracts is 36.00 (35.5 hours non-form burden + 0.5 hours current form burden).

However, we cannot use Table 6 as a basis for comparing the burden of this final rule with the current burden. The reason we cannot use Table 6 is because the 11.5 hours (Row (2)) in Table 6 was corrected in the proposed rule. As indicated in Tables 5 and 6, the other Administrative burden is a calculated number equal to the difference between the total burden of 47 hours and the

burden of filling out the form (Row (3)). Consequently, if Row (2) changes, then Row (3) must change also. We next discuss the revisions of the April 2018 estimates just summarized in Table 6.

In the proposed rule, we explained that after further consideration, we believe that the April 2018 final rule overstated the burden of completing the detailed MLR reporting form because it did not take into account the number of MA organizations and Part D sponsors that were actually required to provide explanations for suspected errors or omissions discovered by CMS or our contractor during initial review of the submitted MLR report. Unlike the first four tasks previously listed (the first four of the bullets immediately listed prior to Table 6), the need to correct or provide explanations for errors and omissions discovered by CMS or our contractor during desk reviews and estimated at 11.5 hours (Row (2)) was not applicable to all plans when our detailed MLR data reporting requirements were in effect.

Based on the percentage of contracts per contract year (for years 2014 through

2017) for which the annual MLR filing was flagged for potential errors during desk reviews, the number of MA organizations and Part D sponsors that were required to correct or explain suspected errors during desk reviews, and a review of the correspondence between such organizations or sponsors and CMS or our contractor, we estimated the last task previously listed (to correct or provide explanations for suspected errors or omissions flagged in desk reviews) would take an MA organization or Part D sponsor an average of 3 hours per affected contract, depending on the number and complexity of issues that required additional explanation, whether the MA organization or Part D sponsor had to recalculate any of the figures included in its original MLR submission, and whether the MA organization or Part D sponsor had to submit a corrected MLR Report to address any of the errors or omissions in its original submission.

Table 7 presents a revision of Table 6 with the primary change being replacing 11.5 (Row (2) in Table 6) with 10.75

(Row (7) in Table 7), with the other rows following by computation. Table 7 also differs from Table 6 is the addition of the per contract burden of calculation of the MSA deductible factor. This is explained in the narrative to Table 7.

This refinement to our prior 11.5-hour time estimate does not affect our estimate that MA organizations and Part D sponsors spent 47 hours per contract under the MLR reporting requirements in effect for CYs 2014 through 2017 (Row (1) in Table 6) which as we have noted was an aggregate number estimated by CMS in the information collection that was previously approved by OMB under control number 0938–1232 (CMS–10476). Instead, it causes the estimated time to complete the detailed MLR reporting form to decrease from 11.5 hours to 10.75 hours (Row (2) in Table 6 and Row (7) in Table 7), with the remaining administrative tasks, a derived calculation, now estimated as taking the other 36.25 hours (47 hours – 10.75 hours) (Row (8) in Table 7).

TABLE 7: TIME PER CONTRACT IN APRIL 2018 FINAL RULE REVISED (HOURS)

Row ID	Item	Estimate	Notes
(6)	Total administrative burden (assuming use of MLR form for CYs 2014-2017) (hr)	47	(1)
(7)	Revised estimate of burden for completing MLR form used for CYs 2014-2017 (hr)	10.75	Reduced from original 11.5 hr estimate
(8)	Burden for administrative tasks other than completing MLR form (hr)	36.25	(8)=(6)-(7)
(9)	Estimate of burden for completing current form (hr)	0.5	(4)
(10)	Burden for calculation of MSA deductible factor (hr)	0.00055	Burden per contract of calculation of MSA deductible factor. This is explained in the narrative below.
(11)	Total administrative burden for current MLR form (hr)	36.75055	(11)=(8)+(9)+(10)

We next explain row (10), calculation of the deductible factor. In the June 2020 final rule, CMS estimated that it would take 5 minutes ($\frac{1}{12}$ hour) to

calculate and verify the deductible factor for an MSA contract. At the time of the 2020 rule, there were 8 MSA contracts. As of 2021, there are only 4

MSA contracts. However, the calculations presented in Table 7 are per contract, not aggregate. Thus, the hourly burden for calculation of the MSA

deductible factor adjusted for the number of current contracts is 0.00055 hours ($\frac{1}{12}$ hour per contract \times 4 MSA contracts divided by 601 total contracts). We round to 5 decimal places because if we had rounded to two decimal places the burden would be 0 (zero).

This final rule finalizes three items affecting per contract hourly burden that were introduced in the proposed rule. These changes are summarized in Table 9 which will be referred to throughout the following discussion of the three changes. First, as noted in section II.G.3. of this final rule, in connection with the changes to the reporting requirements CMS is adopting in this final rule, we expect to resume development of the MLR reporting software, and to update the data collection fields and built-in formulas so that the MLR reporting software calculates the MLR consistent with all amendments to the MLR regulations that CMS has finalized since contract year 2017. In making these updates, CMS is revising the programming of the MLR reporting software so that it automatically calculates and applies the appropriate deductible factor for MA MSA contracts, as determined under § 422.2440. Because MA organizations would no longer be responsible for calculating the deductible factor, the burden associated with performing that calculation will be eliminated. Thus Row (19) in Table 9 is 0 contrasting with Row (10) in Table 7 which had a positive amount.

Second, as discussed in section II.G.2. of this final rule, CMS is finalizing our proposal to reinstate the detailed MLR reporting requirements in effect for CYs

2014 through 2017. This changes the 0.5 hour estimate in Rows (4) and (9) to 10.75 hours (Row (18)).

Third, we are finalizing our proposal to require a detailed MLR report that provides details on several categories of data and costs (for example, the amount of incurred claims for original Medicare covered benefits, supplemental benefits, and prescription drugs; total revenue; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; and any remittance owed to CMS) and also permits CMS to break down the general categories and require additional details or line items to be included in the report. As discussed in section II.G.3. of this final rule, to collect this information, we are adding additional fields to the MLR Report template in which MA organizations will enter their total expenditures for different types or categories of supplemental benefits. We are also adding narrative fields in which users will describe the methodologies used to allocate supplemental benefit expenditures.

In total, we estimate that the addition of these fields, as well as an information-only field in which MA organizations and Part D sponsors will enter the low-income cost-sharing subsidy amount that they deducted when calculating the amount of prescription drug costs to include in the MLR report, will increase the number of fields that will require user input and validation by approximately one-third, or 33.3 percent. We believe this increase would cause a proportional increase in the amount of time needed both to complete and submit the MLR Report to

CMS, and to perform the data collection activities that make up the remaining portion of the 47 hours per contract that we previously estimated MA organizations and Part D sponsors would spend on tasks related to the MLR reporting requirements.

However, because the new supplemental benefits fields do not affect the MLR reporting burden for sponsors of standalone Part D contracts, we calculate the MLR reporting burden separately for MA contracts and standalone Part D contracts. Thus, we estimate the burden to stand-alone Part D contracts would only increase 5 percent in contrast to the 33.3 percent increase for MA contracts and Part D sponsors estimated in the previous paragraph. This is summarized in Row (12) of Table 8. To aggregate this increase on a per-contract level, we take a weighted average of the 33 percent increase and the 5 percent increase. The weights correspond to the percentage of contracts that represent MA contracts (about 89 percent) and standalone Part D contracts (about 11 percent). This aggregate net increase per contract is 29.92 percent ($89\% \times 33\% + 11\% \times 5\%$). The computations are presented in Table 8. It is simpler to use one aggregate figure (29.92 percent) for all contracts rather than estimate each contract type separately and then adding them together. This weighted average on Row (14) in Table 8 is used to estimate the increased burden finalized in this rule of filling out MLR forms as calculated in Row (21) in Table 9.

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TABLE 8: CALCULATION OF (WEIGHTED) AVERAGE INCREASE IN TIME PER CONTRACT

Row ID	Contract Type	Percent of contracts	Increase for new fields	Product of Increase and Percent (weight) of contract type	Notes
(12)	Stand-alone prescription drug contracts	11%	5%	0.55%	Rounded to 4 decimal places. Rounding to two decimal places would make this 1, a misleading increase.
(13)	MA (including MA-PD and MSA) contracts	89%	33%	29.37%	Rounded to 4 decimal places for consistency with previous row.
(14)	Aggregate burden increase per contract			29.92%	(14)=(12)+(13)

TABLE 9: BURDEN (AGGREGATE and PER CONTRACT)

Row ID	Item	Burden	Notes
(15)	Total time (hr) per contract	47	(6)
(16)	Revised (2018 rule) time (hr) per contract for then-current detailed form	10.75	(7)
(17)	Time (hr) per contract for non-form items	36.25	(17)=(8) or (17)=(15)-(16)
(18)	Per contract burden for return to detailed form used for CYs 2014-2017	10.75	Removal of current form; return to form used for CYs 2014-2017 (see row (7))
(19)	Per contract burden for calculation of deductible factor for MSA contracts (hr)	0	Software now automatically calculates the MSA deductible factor
(20)	Per contract revised time (hr) for return to detailed form used for CYs 2014-2017 and removal of calculation of MSA deductible factor	47	(20)=(17)+(18)
(21)	Per contract time (hr) for detailed form with new fields, this rule	61.1	(21)=(20)+(14)*(20)
(22)	Current per contract time (hr)	36.75055	(22) = (11)
(23)	Average increase time (hours/contract)	24.34945	(23) = (21) - (22)
(24)	Wage/hr	156.66	Wage Table
(25)	Per contract cost (\$) for detailed form, this rule, with new fields	\$3,815	(25)=(24)*(23)
(26)	Number of current contracts affected by MLR provisions	601	Estimate explained in opening paragraph of this ICR
(27)	Aggregate increase in time (hr), all contracts, with new fields, this rule	14,634	(27)=(26)*(23)
(28)	Aggregate cost (\$), all contracts, with new fields, this rule	\$2,292,562	(28)=(27)*(24)

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Table 9 incorporates these three changes—removing the deductible factor calculation burden, reinstating the form used for MLR reporting for CYs 2014 through 2017, and increasing the fields in the form—to arrive at a final increased hourly burden per contract, and then calculates dollar burden per contract as well as aggregate burden for all contracts. The following presents further information about the rows in Table 9 as compared to Table 7.

- Rows (15)–(17) are identical to Rows (6)–(8). This provides the per-

contract administrative hours on non-form items connected with the MLR provisions before adding the form-related burdens.

- Row (18): The 0.5 hours in Row (9) is replaced by the 10.75 hours in Row (16) since this final rule requires returning to the detailed form used for MLR reporting for CYs 2014 through 2017 whose cost is estimated in Row (7).

- Row (19): Row (10), the time for calculation of the MSA deductible factor, is replaced with 0 hours, since the changes CMS is finalizing would

entail having CMS-developed software automatically calculate and apply the deductible factor.

- Row (20): The total hourly burden per contract, 47 hours, reflecting returning to the detailed form used for contract year 2014 through 2017 MLR reporting and removal of calculation of the MSA deductible factor (but not yet reflecting additional fields) is obtained by adding 10.75 (form burden) + 36.25 (non-form burden), (Rows (17) and (18)).

- Row (21): The total hourly burden per contract, 61.1 hours under the

requirements we are adopting in this final rule, is obtained by increasing the 47 hours (Row (20)) by 29.92 percent, which is the weighted effect of adding new fields (Row (14)) ($61.1 = 47 + 29.92 \text{ percent} \times 47$).

- Row (22): The current contract burden of 36.75055 hours is obtained from Row (11). The five decimal places assure that the effect of the provision on MSAs is not removed.

- Row (23): The average increase in time under the requirements we are finalizing of 24.34945 is obtained by subtracting from the total burden under the regulation requirements we are finalizing of 61.1 hours on Row (21) the current-form burden of 36.75055 hours on Row (22).

- Row (25): The increased contract cost (\$) \$3,815 on Row (25) is obtained by multiplying the average increase in time (hours) of 24.34945 on Row (23) by the wages (\$156.66/hr) on Row (24).

- Row (26): The total number of contracts is presented in Table 5

- Row (27): The average increase in time (hours) across all contracts of 14,634 is obtained by multiplying the 601 contracts (Row (26)) by the per contract increase in time (hours) of 24.34945 on Row (23).

- Row (28): The aggregate increase in cost (\$) across all contracts, \$2,292,562 is obtained by multiplying the increase in time (hours) of 14,634 on Row (27) by the wages per hour on Row (24).

We estimate that MA organizations and Part D sponsors will incur minimal

one-time start-up costs associated with developing processes for capturing the necessary data, as they should already have been allocating their expenses by line of business and contract in order to comply with our current regulations regarding the calculation of the MLR, and they should already have been tracking their supplemental benefit expenditures for purposes of bid development. We estimate that MA organizations and Part D sponsors will incur ongoing annual costs relating to data collection, populating the MLR reporting form, conducting an internal review, submitting the MLR reports to the Secretary, and conducting internal audits.

Table 10 summarizes the relevant calculations as one combined line item.

TABLE 10: BURDEN ASSOCIATED WITH THE MLR PROVISIONS

Respondent	Number of Respondents	Responses per Respondent	Time per Response (hours)	Total Annual Time (hours)	Hourly Labor Cost (\$/hr)	Total Cost (\$)
Contracts subject to MLR reporting requirement	601	1	24.34945	14,634	\$156.66	\$2,292,562

The average burden per contract as given on Row (25) of Table 8 is \$3,815. We note that this is a weighted average. Stakeholders may be interested in a more careful analysis based on contract type. We do this for 3 types of contracts.

MA MSA contracts have reduced burden since the new software automatically calculates the deductible factor and uses that to adjust the applicable credibility factor, relieving them of the need to perform this calculation and adjustment on their own.

For each MA contract (including MA-PD and MA MSA contracts), we estimate, on average, 25.92 hours of additional burden at an additional cost of \$4,061. Row (11) (which excludes the burden on Row (10) associated with calculating the MSA deductible factor) shows the current hour burden to be 36.75 hours. (The removal of the 0.00055 hours has negligible effect and is appropriate for the majority of contracts which are non-MSAs). Row (20) shows that the new burden without considering the additional fields is 47 hours. Row (13) shows that this would result in 62.67 hours total burden ($47 \text{ hours} \times 1.33$ due to increased fields). Comparing the 62.67 total burden under the MLR reporting requirement we are

adopting in this final rule with the 36.75 hours under the reporting requirements that have been in effect since contract year 2018 shows an increase time of 25.92 hours ($62.67 - 36.75$) at a cost of \$4,061 ($25.92 \text{ hours} \times \$156.66/\text{hr}$).

For Part D contracts, we estimate 12.6 additional hours of burden at an additional cost of \$1,974. As in the preceding analysis for MA contracts, Row (11) (which excludes burden on Row (10) associated with calculating the MSA deductible factor) shows the current hour burden to be 36.75 hours. Row (20) shows that the new burden without taking into effect the new fields is 47 hours. Row (12) shows a 5 percent increase for new fields for Part D contracts, such that this would result in a total burden of 49.35 hours ($47 \text{ hours} + 47 \text{ hours} \times 5 \text{ percent}$). Thus, there is an additional hour burden of 12.6 hours ($49.35 \text{ hours} - 36.75 \text{ hours}$) at an additional cost of \$1,974 ($12.6 \text{ hours} \times \$156.66/\text{hr}$ per contract).

As indicated above, the total increased impact of finalizing the MLR provision is presented in Table 10.

We did not receive any comments on our proposed collection of information requirements and are finalizing them without change.

13. ICRs Related to Pharmacy Price Concessions in the Part D Negotiated Price (§§ 423.100 and 423.2305) (CMS–10174, OMB 0938–0982)

The requirement and burden for Part D Sponsors to implement the proposals related to pharmacy price concessions that we are now finalizing, as discussed in section II.H. of this final rule will be submitted to OMB for approval under control number 0938–0982 (CMS–10174), as needed. Below we discuss in greater detail the burden associated with the requirements we are finalizing.

Revisions to §§ 423.100 and 423.2305 will require that Part D sponsors apply all pharmacy price concessions to the point of sale price in all phases of the Part D benefit. Under this rule, beneficiaries will see lower prices at the pharmacy point-of-sale and on Plan Finder beginning immediately in the year the policy will apply, 2024. We anticipate that the change will require that Part D sponsors make certain system changes related to the calculation of the amounts they report in one or two fields in the PDE data collection form.

In the NPRM we only estimated the impact of annual costs for PDE Data transmission. Although we received no

external comments on our burden estimates, we made two changes from the NPRM. First, we anticipate that this provision will cause sponsors to incur both one-time costs for updating software, and annual costs for PDE Data transmission. Second, our estimates of PDE data transmission used an estimate of a \$35.50/hr cost for electronic submission. This is incorrect and should be \$17.75/hr.

Update of Software: The systems for submitting PDE transmission are already in place as required by the regulations. A software update is required to deal with transmitting data at the time of sale. We believe it reasonable that this software update will be done at the parent organization level rather than the contract level. Based on internal CMS data, currently there are 298 parent organizations. The burden of update requires that 2 software developers will each spend 20 hours (2 and one half days) performing the necessary designs. Therefore, the aggregate burden across all parent organization is 11,920 hours (2 software developers \times 20 hr a programmer \times 298 parent organizations) at a total cost of \$1,386,773 (11,920 hr \times 116.34/hr). The burden per parent organization would be 40 hours (20 hr \times 2 software developers) at a cost of \$4,654 (40 hr \times \$116.34/hr).

PDE Data Submission: The calculations discussed in the narrative are presented in Table 11. The number of prescription drug events (PDE) for 2020 is 1.5 billion (Row C). The average number of Part D contracts for the past 3 years (2019–2021) is 856 (Row B). To compute the average number of responses per respondent, that is, the number of PDEs per contract, we divide the average number of PDEs per year (Row C) by the average number of contracts (Row B). This computation leads to an average of 1,752,336.449 PDEs/contract (Row D (1.5 billion divided by 856)). The extra decimal places listed in Row D and other rows are to assure consistency in two methods at arriving at the final burden. A similar computation shows that the average number of PDEs per Part D enrollee is 30.5047 (1.5 billion PDE (Row C) divided by 49,229,626 enrollees (as of November 2021) (Row A)).

Since our regulations require Part D sponsors to submit PDE data to CMS that can be linked at the individual level to Medicare Part A and Part B data in a form and manner similar to the process provided under § 422.310, the data transaction timeframes will be based on risk adjustment and prescription drug industry experiences.

Moreover, our PDE data submission format only supports electronic formats.

The drug industry's estimated average processing time for electronic data submission is 1 hour for 500,000 records (Row F). The drug industry further estimates that on average it costs \$17.75/hr (for 2020) to process PDEs (Row E).

Using these numbers, we can compute individual contract and aggregate burden.

It would take 3.5047 hours (Row G) on average for each respondent (contract) to process its 1,752,336.449 PDEs at a rate of 500,000 per hour (1,752,336.449 PDEs per contract (Row D) divided by 500,000/hr (Row F)). The aggregate hours to process all 1.5 billion claims is therefore 3,000 hours (Row H) (3.5047 hours/contract (Row G) \times 856 contracts (Row B)).

The average cost per contract (Row I) is \$62.2084 hours (3.5047 hours (Row G) \times \$17.75/hr (Row E)). The ongoing cost for all contracts (Row J) is therefore \$53,250, which can be obtained either by multiplying total hours (3,000 (Row H)) by cost per hours (\$17.75/hr (Row E)) or by multiplying the cost per contract (\$62.2084 (Row I)) by the number of contracts (856 (Row B)).

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TABLE 11: ESTIMATED ADMINISTRATIVE COSTS RELATED TO SUBMISSION OF PRESCRIPTION DRUG EVENT (PDE) DATA

Row ID	Item	Estimate	Source/Derivation	Description
A	Part D Enrollees	49,229,626	Internal CMS data	Number of Part D Enrollees as of November 2021
B	Number of respondents	856	Internal CMS data	Average Number of Contracts 2019-2021
C	Total responses	1,500,000,000	Internal CMS data	PDEs per year
D	Average responses per respondent	1,752,336.449	(C) / (B)	Average PDEs per contract
E	Cost per hour (Non labor)	\$17.75/hr	Drug industry's estimated cost/hr of electronic processing	Cost/hr of processing PDEs electronically
F	Electronic PDEs processed per hour	500,000	Drug industry's estimated average processing volume per hour	Number of Electronic PDEs processed per hour
G	Hours/respondent	3.5047	(D) / (F)	Number of hours needed to process one contract's PDEs
H	Aggregate hours	3,000	(G) x (B)	Total hours to process all contracts
I	Cost per respondent	62.2084	(G) x (E)	Cost per contract to process PDEs
J	Total cost all contracts	53,250	Either (H) x (E) or (I) x (B)	Total cost for all contracts

The aggregate burden for the provision is \$1,440,023 in the first year (\$1,386,773 for software updates plus

\$53,250 for transmission costs) and \$53,250 in subsequent years.

C. Summary of Finalized Information Collection Requirements and Associated Burden Estimates

TABLE 12. SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN

Section in Title 42 of the CFR	Item	OMB Control No. (CMS ID No.)	Respondent	Number of Respondents	Responses per Respondent	Total Responses	Time per Respondent (hours)	Total Time (hours)	Hourly Labor Cost (\$/hr)	Total Cost First Year (\$)	Total Cost Subsequent Years (\$)
422.107(f)	Solicit committee members	0938-1422 (CMS-10799)	D SNPS	310	1	310	40	12,400	76.20	944,880	944,880
422.101	Update HRA System	0938-1422 (CMS-10799)	SNP Parent Organizations	47	1	47	3	141	116.34	16,404	0
422.107(e)	Update Contracts with D-SNPs	0938-1410 (CMS-10796)	State	12	1	12	24	288	142.34	20,497*	0
422.107(e)	Update Contracts	0938-0935 (CMS-10237)	D SNPS	60	1	60	8	480	142.34	68,323	0
422.107(e)(1)	Part C Contracts with only D SNPS	0938-0935 (CMS-10237)	D SNPS	41	1	41	10	410	72.90	29,889	0
422.107(e)(1)	Part D Contracts with only D SNPS	0938-0936 (CMS-10137)	D SNPS	41	1	41	6.41	263	72.90	19,173	0
422.561	Update Contracts	0938-1410 (CMS-10796)	D SNPS	13	1	13	8	104	76.20	7,925	0
422.116(f)	Update Network Adequacy	0938-1346 (CMS-10636)	MA Contracts	211	1	211	0.0833	18	72.90	1,312	1,312
422.2267(e)(31) and 423.2267(e)(33))	1 pager multi-language insert	0938-1421 (CMS-10802)	MA Plans and Part D Sponsors	961	21,644	20,800,000	n/a	a/a	n/a	312,000 (non-labor)	312,000 (non-labor)
422.2460 and 423.2460	MLR	0938-1232 (CMS-10476)	MA and Part D Contracts	601	1	601	24.34945	14,634	156.66	2,292,562	2,292,562
423.100 and 423.2305	Part D Pharmacy Price Concessions (ongoing costs of reporting PDEs)	0938-0982 (CMS-10174)	Part D Sponsors Contracts	856	1,752,336.449	1,500,000,000	3.5047	3000	17.75	53,250	53,250
423.100 and 423.2305	Part D Pharmacy Price Concessions (one-time system change costs)	0938-0982 (CMS-10174)	Part D Sponsors Parent Organizations	298	1	298	40	11,920	116.34	1,386,773	0
	Totals			1,271***	1,773,990	Varies	Varies	43,658	Varies	5,152,988	3,604,004

NOTES:

*This number is halved because the Federal Government covers half the cost.

**Includes MA only, MA PD, and PDP plans.

*** To avoid double counting, the 1,271 is the sum of distinct parent organizations (298), distinct contracts (961) and distinct states (12) Note that the 961 contracts already include specific types of contracts such as D-SNPs. Similarly, the 298 parent organizations include specific types of parent organizations such as those for D-SNPs.

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V. Regulatory Impact Analysis**A. Statement of Need**

This final rule will revise the MA and Part D program regulations to improve transparency in, and oversight of, these programs and to revise regulations to improve the integration of Medicare and Medicaid programs for individuals enrolled in dual eligible special needs plans (D-SNPs). This final rule will also revise regulations related to MA and Part D plans, D-SNPs, other special needs plans, and cost contract plans. Additional revisions will implement changes related to requirements during disasters or public emergencies, past performance, MLR reporting, pharmacy price concessions, marketing and communications, Star Ratings, and network adequacy.

Through provisions that apply to D-SNPs, we intend to improve beneficiary experiences by amplifying the voices of dually eligible individuals in health plan governance and operations by requiring an enrollee advisory committee and requiring assessment of certain social risk factors. Additionally, our final rule will improve partnership with States through better Federal-State collaboration on oversight and performance improvement activities and establishing new pathways for CMS and States to collaborate to integrate care for dually eligible individuals.

The past performance proposals hold plans more accountable for their performance under MA and Part D and protect the best interest of the Medicare program by preventing those with poor past performance from entering new MA or Part D applications or service area expansions. The Star Ratings provisions allow CMS to calculate 2023 Star Ratings for three Healthcare Effectiveness Data and Information Set measures that are based on the Health Outcomes Survey; due to the COVID-19 PHE in place nationwide during 2020, applying the 60 percent rule in the current regulations would result in removal of all contracts from threshold calculations and CMS would be unable to calculate ratings for these three measures. In sections II.D.3. and II.D.4. of this final rule, we are also responding to comments about and finalizing Star Ratings provisions from the March 31st COVID-19 IFC and the September 2nd COVID-19 IFC without modification: §§ 417.472(i) and (j), 422.152(b)(6), 422.166(a)(2)(i), (f)(1)(i), (g)(3), (i)(11), and (j)(1)(i) through (iv), 422.252, 423.182(c)(3), and 423.186(a)(2)(i), (f)(1)(i), (g)(3), (i)(9), and (j)(1)(i) through (iii). We are not finalizing the following provisions in the March 31st COVID-19

IFC: §§ 422.164(i), 422.166(j)(1)(v) and (j)(2), 423.184(i), and 423.186(j)(1)(iv) and (j)(2).

Due to a rule change that took effect with CY 2018 MLR reporting, MA organizations and Part D sponsors only submit to CMS the MLR percentage and amount of any remittance that must be repaid to CMS for failure to meet the 85 percent minimum MLR requirement. CMS is finalizing our proposal to change our regulations to reinstate the former requirement for MA organizations and Part D sponsors to submit the underlying information needed to calculate, and verify the accuracy of, the MLR and remittance amount. We believe reinstating this detailed data submission requirement and the desk review process will allow us to detect errors in the MLR calculation which can result in significant losses to the Government.

We are deleting the existing definition of “negotiated prices” at § 423.100 and adopting a new definition for the term “negotiated price” at § 423.100, which we define as the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor’s intermediary (that is, the amount the pharmacy would receive net of the maximum negative adjustment that could result from any contingent pharmacy payment arrangement and before any additional contingent payment amounts, such as incentive fees). This provision will reduce out-of-pocket prescription drug costs, improve price transparency and market competition under the Part D program. As discussed in the proposed rule, based on stakeholder feedback and sponsor-reported DIR data, we understand that the share of pharmacies’ reimbursement that is contingent upon their performance under such arrangements has grown steadily each year. When pharmacy price concessions received by Part D sponsors are not reflected in lower drug prices at the point of sale and are instead used to reduce plan liability, beneficiaries generally see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing. Thus, beneficiaries who utilize drugs end up paying a larger share of the actual cost of a drug. Moreover, when the point-of-sale price of a drug that a Part D sponsor reports on a prescription drug event (PDE) record as the negotiated price does not include such discounts, the negotiated price of each individual prescription is rendered less transparent and less representative of the actual cost of the drug for the sponsor.

President Biden’s Executive Order (E.O.) 14036, “Promoting Competition in the American Economy” (86 FR 36987), section 5 (“Further Agency Responsibilities”), called for agencies to consider how regulations could be used to improve and promote competition throughout the prescription drug industry. Because variation in the treatment of pharmacy price concessions by Part D sponsors may have a negative effect on the competitive balance under the Medicare Part D program, and given the programmatic impacts laid out above and the charge from the E.O., CMS proposed changes that would standardize how Part D sponsors apply pharmacy price concessions to negotiated prices at the point of sale.

We are clarifying our regulations regarding the special requirements for disasters and emergencies at § 422.100(m) to address stakeholder concerns about the end of a disaster or emergencies and to codify previous guidance. We also are finalizing the proposed updates to them to allow smoother transitions for enrollees who during a disaster or emergency may have been obtaining services from out-of-network providers.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also

referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with economically significant effects (\$100 million or more in any 1 year). While the total annualized costs for this rule are estimated at \$3.1 million a year, as indicated in Table 20, the net transfers from the Trust Fund to enrollees and manufacturers exceed \$100 million annually. Therefore, based on our estimates, OMB’s Office of Information and Regulatory Affairs has determined this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

Section 202 of the Unfunded Mandates Reform Act of 1995 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 2022, that threshold is approximately \$165 million. This rule will not mandate on an unfunded basis any requirements for State, local, or tribal governments nor would it result in expenditures by the private sector meeting that threshold in any 1 year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications.

Under Executive Order 13132, this final rule will not significantly affect the States. It follows the intent and letter of the law and does not usurp State authority beyond what the Act requires. This rule describes the processes that must be undertaken by CMS, the States, and D–SNPs in order to implement and administer the requirements of the MA program. In accordance with the

provisions of Executive Order 12866, this final rule was reviewed by OMB.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this final rule, then we should estimate the cost associated with regulatory review. As of November 2021, there are 962 contracting organizations with CMS (which includes MA, MA–PD, and PDP contracts). Additionally, there are 55 State Medicaid agencies and 300 Medicaid MCOs. We also expect a variety of other organizations to review (for example, consumer advocacy groups, major PBMs). A reasonable maximal number is 1,500 total entities who will review this rule. We note that other assumptions are possible. We assume each organization will designate two people to read the rule.

Using the BLS wage information for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this final rule is \$114.24 per hour, which includes 100 percent increase for fringe benefits and overhead costs (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it will take approximately 8 hours for each person to review this entire final rule. For each person that reviews this final rule, the estimated cost is therefore \$900 (8 hours × \$114.24). Therefore, we estimate that the maximum total cost of reviewing this entire final rule is \$7 million (\$900 × 1,500 entities × 2 reviewers/entity).

We note that this analysis assumed two readers per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers. However, we expect it is more reasonable to estimate review time based on the number of contracting organizations because a parent organization might have local reviewers assessing potential region-specific effects from this final rule.

C. Regulatory Flexibility Act (RFA)

Executive Order 13272 requires that HHS thoroughly review rules to assess and take appropriate account of their potential impact on small business, small governmental jurisdictions, and small organizations (as mandated by the RFA). If a final rule may have a significant economic impact on a substantial number of small entities, then the final rule must discuss steps taken, including alternatives, to minimize burden on small entities. The RFA does not define the terms “significant economic impact” or “substantial number.” The Small

Business Administration (SBA) advises that this absence of statutory specificity allows what is “significant” or “substantial” to vary, depending on the problem that is to be addressed in the rulemaking, the rule’s requirements, and the preliminary assessment of the rule’s impact. Nevertheless, HHS typically considers a “significant” impact to be 3 to 5 percent or more of the affected entities’ costs or revenues.

For purposes of the RFA, we estimate that many affected payers are small entities as that term is used in the RFA, either by being nonprofit organizations or by meeting the SBA definition of a small business. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The North American Industry Classification System (NAICS) is used to classify businesses by industry and is used by the United States, Canada, and Mexico. While there is no distinction between small and large businesses among the NAICS categories, the SBA develops size standards for each NAICS category.⁹⁸ Note that the most recent update to the NAICS classifications went into effect for the 2017 reference year. The latest size standards are for 2019.

As can be seen from the Summary of Annual Information Collection Requirements and Burden table (Table 12) in section IV.C. of this final rule, as well as Table 21 of this section, on average, the net cost to each plan to implement all provisions is significantly below \$10,000 (the annualized cost over 10 years of \$3.6 million divided by the number of contracts, about 1,000, is significantly below \$10,000). Additionally, not all provisions apply to all plans. We do not believe this to be excessive burden even to small entities. Nevertheless, a more complete analysis is provided immediately below supporting the position that burden is not excessive.

Although States are also affected by these provisions, States are not classified as small entities and in any event the burden as just indicated is small.

The relevant NAICS category is Direct Health and Medical Insurance Carriers, NAICS 524114, with a \$41.5 million threshold for “small size,” with 75 percent of insurers having under 500

⁹⁸ North American Industry Classification System (2017). Retrieved from: https://www.census.gov/eos/www/naics/2017NAICS/2017_NAICS_Manual.pdf. https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%202019%2C%202019.pdf.

employees meeting the definition of small business.

MA organizations and Medicaid managed care plans have their costs funded by the Federal Government or State and therefore there is no significant burden. We discuss the details of this in this section. This discussion will establish that there is no significant burden to a significant number of entities from this final rule for these provisions.

1. Medicare Advantage

Each year, MA plans submit a bid for furnishing Part A and B benefits and the entire bid amount is paid by the government to the plan if the plan's bid is below an administratively set benchmark. If the plan's bid exceeds that benchmark, the beneficiary pays the difference in the form of a basic premium (note that a small percentage of plans bid above the benchmark, whereby enrollees pay a basic premium, thus this percentage of plans is not "significant" as defined by the RFA and as justified below). Payments to MA plans of the bid (or benchmark) amounts are risk adjusted and are higher for enrollees with risk scores above 1.0 and lower for enrollees with risk scores below 1.0.

MA and MA-PD plans can also offer supplemental benefits, that is, benefits not covered under Original Medicare or under Part D. These supplemental benefits are paid for through enrollee premiums, extra Government payments, or a combination. Under the statutory payment formula, if the bid submitted by a Medicare Advantage plan for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a "beneficiary rebate." The rebate must be used to provide supplemental benefits (that is, benefits not covered under Original Medicare or Part D) and/or lower beneficiary Part B or Part D premiums. Some examples of these supplemental benefits include vision, dental, hearing, fitness and worldwide coverage of emergency and urgently needed services.

To the extent that the Government's risk adjusted payments to plans for the bid plus the rebate exceeds costs in Original Medicare, those additional payments put upward pressure on the Part B premium which is paid by all Medicare beneficiaries, including those in Original Medicare who do not have the supplemental coverage available in many MA plans.

Part D plans, including MA-PD plans, submit bids and those amounts are paid to plans through a combination of

Medicare funds and beneficiary premiums. In addition, for enrolled low-income beneficiaries Part D plans receive government funds to cover most of premium and cost-sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by these insurers is funded by a variety of government funding and in some cases by enrollee premiums. As a result, MA and Part D plans are not expected to incur burden or losses since the private companies' costs are being supported by the Government and enrolled beneficiaries. This lack of expected burden applies to both large and small health plans.

Small entities that must comply with MA regulations, such as those in this final rule, are expected to include the costs of compliance in their bids, thus avoiding additional burden, since the cost of complying with any final rule is funded by payments from the government and, if applicable, enrollee premiums.

For Direct Health and Medical Insurance Carriers, NAICS 524114, MA plans estimate their costs for the upcoming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to making risk adjusted payments to the plan of either—(1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from Original Medicare data; or (2) the benchmark, if the bid amount is greater than the benchmark.

If an MA plan bids above the benchmark, section 1854 of the Act requires the MA plan to charge enrollees a premium for that amount. Historically, only two percent of plans bid above the benchmark, and they contain roughly one percent of all plan enrollees. The CMS threshold for what constitutes a substantial number of small entities for purposes of the RFA is 3 to 5 percent. Since the number of plans bidding above the benchmark is two percent, this is not considered substantial for purposes of the RFA.

The preceding analysis shows that meeting the direct cost of this final rule does not have a significant economic impact on a substantial number of small entities, as required by the RFA.

There are certain indirect consequences of these provisions which also create impact. We have already explained that 98 percent of the plans bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal Government. However, the government additionally

pays the plan a "beneficiary rebate" amount that is an amount equal to a percentage (between 50 and 70 percent depending on a plan's quality rating) multiplied by the amount by which the benchmark exceeds the bid. The rebate is used to provide additional benefits to enrollees in the form of reduced cost-sharing or other supplemental benefits, or to lower the Part B or Part D premiums for enrollees. (Supplemental benefits may also partially be paid by enrollee premiums.) It would follow that if the provisions of this final rule cause the MA bid to increase and if the benchmark remains unchanged or increases by less than the bid does, the result would be a reduced rebate and, possibly fewer supplemental benefits, or higher premiums for the health plans' enrollees. However as noted above, the number of plans bidding above the benchmark to whom this burden applies do not meet the RFA criteria of a significant number of plans.

It is possible that if the provisions of this rule would otherwise cause bids to increase, plans will reduce their profit margins, rather than substantially change their benefit packages. This may be in part due to market forces; a plan lowering supplemental benefits even for 1 year may lose its enrollees to competing plans that offer more generous supplemental benefits. Thus, it can be advantageous to the plan to temporarily reduce profit margins, rather than reduce supplemental benefits.

2. Medicaid

We include Medicaid in this section since it is relevant to the proposed change to the applicable integrated plan definition at § 422.561. At § 422.561, we are expanding the universe of D-SNPs that are required to have unified grievance and appeals processes by revising the definition of an applicable integrated plan. Section 50311(b) of the BBA of 2018 amended section 1859(f)(8)(B) of the Act to direct establishment of procedures, to the extent feasible, unifying Medicare and Medicaid grievances and appeals. The April 2019 final rule introduced the concept of applicable integrated plans, which we defined as FIDE SNPs and HIDE SNPs whose Medicare and Medicaid enrollment is exclusively aligned (meaning State policy limits a D-SNP's enrollment to those whose Medicare and Medicaid enrollment is aligned as defined in § 422.2) and the companion Medicaid MCOs for those D-SNPs, thereby making it feasible for these plans to implement unified grievance and appeals processes. We believe that unified grievance and

appeals procedures are feasible for the additional D-SNPs and MCOs included in the revisions to the definition. While we are not imposing new Medicaid requirements, the applicable integrated plan definition change would expand the universe of Medicaid managed plans subject to the unified appeals and grievances provisions codified in the April 2019 final rule. However, the burden imposed by this final rule on Medicaid managed care plans is the one-time requirement to update their grievance and appeals procedures, which as estimated in Table 12, is a one-time cost of \$7,582. Consequently, we have determined that this final rule will not have a significant impact on Medicaid managed care plans.

Therefore, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities. Based on the above, we conclude that the requirements of the RFA have been met by this final rule.

Comment: We received support, thanks, and encouragement from a large number of small business stakeholders including several organizations representing large numbers of small businesses. This support frequently echoed comments already made in the analysis: (i) The enormous expenses and rise of DIR, (ii) the lack of transparency resulting from pharmacy price concessions being collected a year or so after a small pharmacy had gained a profit and resulted in a net loss, (iii) the increased cost-sharing to enrollees, which can result in increased levels of medication non-compliance and lead to poorer health incomes. Commenters' criticism consisted of: (1) Requests for CMS to regulate the PBMs; (2) requests for extending the pharmacy price concessions provisions to the coverage gap; (3) requests for a delay of the effective date pointing to the burden of updating software and preparing for the 2023 bid; and (4) requests for further protections for small businesses and specialty pharmacies, which the commenters stated were very vulnerable and at risk for going out of business. Some commenters also noted that although this final rule is a step in the right direction, it does so on average and may not meet the needs of very small pharmacies not belonging to chains or pharmacies specializing in certain types of drugs.

Response: We thank the stakeholders for their support. With respect to the criticisms received: (1) We did not propose to impose any requirements directly on PBMs in the proposed rule. (2) After consideration of the comments, however, we modified our proposal to

require pharmacy price concessions be applied to the negotiated price in the coverage gap. (3) We agree with the comment that pharmacies, including small pharmacies, need time to prepare software updates and that Part D sponsors will need time to prepare their 2023 bids. In response to comments here and as addressed previously, we are finalizing the proposal with a 2024 applicability date. We are also sympathetic to specialty pharmacies. CMS does not collect data on pharmacy price concessions at the pharmacy level, and this information is not publicly available. In order to estimate, for example, the effects on specialty pharmacies in particular, we would need to speculate on the relative difference between price concessions to those pharmacies versus retail pharmacies. As we do not have any basis for developing this difference, it is not possible to meaningfully analyze impacts by type of pharmacy.

We are therefore finalizing our analysis as presented above.

3. Rural Hospitals

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. This analysis must conform to the provisions of section 604 of the RFA. 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 rule however is directed to plans and enrollees. Providers including hospitals receive the contracted rate or at least the original Medicare rate depending on whether the providers are contracted or not. Consequently, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities.

D. Anticipated Effects

1. Enrollee Participation in Plan Governance (§ 422.107)

As described in section II.A.3. of this final rule, at § 422.107(f), we are finalizing our proposal that any MA organization offering a D-SNP must establish one or more enrollee advisory committees at the State level or other service area level in the State to solicit direct input on enrollee experiences. We are also finalizing at § 422.107(f) that the committee include a reasonably representative sample of individuals enrolled in the D-SNP(s) and solicit input on, among other topics, ways to improve access to covered services,

coordination of services, and health equity for underserved populations. This final rule intends to ensure enrollees are engaged in defining, designing, participating in, and assessing their care systems. Section IV.B.1. of this final rule presents the collection of information burden for this provision.

To support D-SNPs in establishing enrollee advisory committees that meet the objective of this final rule in achieving high-quality, comprehensive, and coordinated care for dually eligible individuals, CMS would provide technical assistance to D-SNPs to share engagement strategies and other best practices. CMS can leverage the body of technical assistance developed for MMPs. For example, the CMS contractor Resources for Integrated Care partnered with Community Catalyst, a non-profit advocacy organization, to offer a series of webinars and other written technical assistance to help enhance MMPs' operationalization of these committees.⁹⁹ CMS will be able to realize efficiencies by repurposing and building on these resources. Based on the existing technical assistance contracts held by CMS, we estimate an annual cost to the Federal Government of \$15,000.

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

2. Refining Definitions for Fully Integrated and Highly Integrated D-SNPs (§ 422.2)

We have presented a discussion of collection of information burden associated with this provision in section IV.B.3. of this final rule. In this section, we describe the impacts of our definition changes of: (1) Requiring exclusively aligned enrollment for FIDE SNPs; (2) capitation of Medicare cost-sharing; (3) clarifying the scope of services covered by a FIDE or HIDE; (4) Medicaid carve-outs; and (5) requiring service area overlap with the corresponding Medicaid plan. We anticipate all changes to the definition of FIDE SNP and HIDE SNP will result in additional time for CMS staff to review D-SNPs' contracts with State Medicaid agencies. We estimate that a GS level 13, step 5 (GS-13-5), employee will take an additional 20 minutes per State to confirm the contract meets the updated definitions. For CY 2022, 21 States have FIDE SNPs, HIDE SNPs, or both. Therefore, we estimate that the

⁹⁹ Resources for Integrated Care and Community Catalyst, "Member Engagement in Plan Governance Webinar Series", 2019. Retrieved from: <https://www.resourcesforintegratedcare.com/article/member-engagement/>.

final rule would result in 7 hours (20 minutes × 21 State contracts) of additional work for a GS–13–5 Federal employee. The 2021 hourly wage for a GS–13–5 Federal employee for the Baltimore Washington Area, which is close to the average hourly wage over all localities, is \$56.31.¹⁰⁰ We allow 100 percent for fringe benefits and overtime, increasing the hourly wage to \$112.62. Thus, the expected additional annual cost for reviewing the contract is \$788.

a. Exclusively Aligned Enrollment for FIDE SNPs

As described in section II.A.5.a. of this final rule, we are requiring exclusively aligned enrollment for FIDE SNPs beginning in 2025. We noted that 12 D–SNPs may lose FIDE SNP status and no longer qualify for the frailty adjustment described in section 1853(a) of the Act and the regulation at § 422.308(c)(4). Of these 12 FIDE SNPs, six are currently receiving the frailty adjustment. We believe that these six FIDE SNPs are likely to have exclusively aligned enrollment by CY 2025 as only a small fraction of their current enrollment is currently unaligned and there are multiple options through which MA organizations can meet the requirement. Therefore, we do not believe the final rule will result in a significant reduction of Medicare payments from FIDE SNPs losing the frailty adjustment.

b. Capitation for Medicare Cost-Sharing and Behavioral Health Services for FIDE SNPs

We do not anticipate any cost transfers from the State to FIDE SNPs resulting from the final rule amendment of the definition of FIDE SNP (at § 422.2) to require that the capitated contract with the State Medicaid agency for a FIDE SNP must include coverage of Medicare cost-sharing (that is, payment by Medicaid of Medicare cost-sharing for the dually eligible individual), where applicable, and Medicaid behavioral health services. We initially estimated that all FIDE SNPs include coverage of Medicare cost-sharing in their capitated contracts with the State Medicaid agency; however, we learned that Tennessee does not capitate FIDE SNPs for cost-sharing. In this final rule, we are making the requirement related to cost-sharing applicable starting in 2025. We expect policy changes in Tennessee before 2025 will allow all current FIDE SNPs to meet the new definition. As noted in section

II.A.5.b. of this final rule, most FIDE SNPs already include Medicaid behavioral health benefits in their capitated contracts with the State Medicaid agency. The remaining FIDE SNPs in California and Pennsylvania that do not currently cover Medicaid behavioral health benefits would likely become HIDE SNPs, which is also defined at § 422.2 (with revisions adopted in this final rule). These impacted D–SNPs would not experience a direct impact on costs when becoming a HIDE SNP as benefits covered by the impacted D–SNP would not change. Nor would impacted D–SNPs experience a change to Medicare revenue, as none of the impacted D–SNPs receive the frailty adjustment.

We received no comments on our analysis and are finalizing it without modification.

3. Additional Opportunities for Integration Through State Medicaid Agency Contracts (§ 422.107)

As described in section II.A.6. of this final rule, we are finalizing new paragraph (e) at § 422.107 to describe conditions through which States may require certain contract terms for D–SNPs with exclusively aligned enrollment and how CMS would facilitate compliance with those contract terms. This final rule allows States to further promote integration using the State Medicaid agency contract with D–SNPs, with the goal of improving beneficiary experiences and health plan oversight. Section 422.107(e) applies only for State Medicaid agency contracts through which the State requires exclusively alignment enrollment, as defined in § 422.2, and establishes that States may choose to require and CMS would permit MA organizations—through the existing MA application process—to establish MA contracts that only include one or more State-specific D–SNPs and require that all such D–SNPs use integrated member materials.

a. State Medicaid Agency Contract Requirements

Section IV.B.4. of this final rule describes the total cost for the State to update the State Medicaid agency's contract with the D–SNPs in its market to address the changes in this final rule and consult with CMS to ensure contract changes meet the requirements at § 422.107(e). Half of the cost (\$20,618) could be claimed by the State as Federal financial participation for administrative costs of the Medicaid program, born by the Federal Government. In addition to updating the State Medicaid agency contract, a State

choosing to further integration through § 422.107(e) would need to determine readiness and make changes to State policy. The State's time and cost for adopting this final rule would depend on the State's current level of integration. For example, 11 States currently have a policy requiring some or all of the D–SNPs in the State to have exclusively aligned enrollment, and Massachusetts, New Jersey, and New York have worked with CMS to integrate some member materials. These States that have taken steps toward integration may use less time and resources to take advantage of the new processes at § 422.107(e) than States just beginning to integrate Medicare and Medicaid using D–SNPs. Given the uncertainty involved in estimating State behavior and levels of existing integration, we are not estimating any additional burden outside of updating the State Medicaid agency contract with D–SNPs. We did not receive any comments on what State resources would be needed to use the pathway for requiring or achieving higher integration and collaboration with CMS as described in § 422.107(e) in a State with limited D–SNP integration (for example, a State with no FIDE SNPs or HIDE SNPs).

b. Limiting Certain MA Contracts to D–SNPs

At § 422.107(e), we are codifying a pathway that would result, in certain circumstances, in contracts that only include one or more D–SNPs with exclusively aligned enrollment within a State. Because Star Ratings are reported at the contract level, having a contract with only the D–SNPs in a particular State would allow dually eligible individuals in that State to ascertain the full quality performance of a D–SNP and better equip States to work with their D–SNPs to improve health equity.

We describe the collection of information burden for MA organizations resulting from establishing a D–SNP-only contract in section IV.B.4.b. of this final rule. However, the additional Part C and D applications necessary to create separate contracts covering only D–SNPs in a particular state also result in additional Federal costs. While the collection of information packages lay out the Federal burden to process Part C and D applications, they do not list out the cost per contract application. We estimate the additional contract submissions for D–SNP only contracts would at most cost an additional \$50,000 in labor burden for the Federal Government annually.

¹⁰⁰ See the locality pay tables for 2021 at <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2021/general-schedule/>.

We note impacted D–SNP contracts may have changes to their quality bonus payments (QBP), as the new contract's payment will initially be calculated from the parent organization's enrollment-weighted average quality rating and eventually only on the performance under the new contract. We are unable to predict if QBPs will increase or decrease for these MA organizations due to separating D–SNPs from the original contracts into separate contracts.

c. Integrated Member Materials

As described in section II.A.6.b. of this final rule, to provide a more coordinated beneficiary experience we are finalizing at § 422.107(e) a pathway by which States and CMS would collaborate to establish model materials when a State chooses to require through its State Medicaid agency contract that certain D–SNPs use an integrated SB, Formulary, and combined Provider and Pharmacy Directory. Section 422.107(e)(1) establishes factual circumstances that commit CMS to certain actions under paragraphs (e)(2) and (3).

In section IV.B.4.c. of this final rule, we note that we do not intend to significantly change timelines for D–SNPs to prepare materials, nor do we intend to mandate that States require D–SNPs to use integrated materials. We do not estimate any additional costs for States or plans to implement integrated member materials at § 422.107(e) due to existing State efforts to work with Medicaid managed care plans to comply with information requirements at § 438.10 and to work with D–SNPs to populate Medicaid benefits for Medicare member materials. This final rule assures interested States that, under the conditions outlined in § 422.107(e), CMS would do its part to make it possible for D–SNPs to comply with State Medicaid agency contract terms for D–SNP-only contracts and integrated enrollee materials. Therefore, we do not estimate any additional burden for States or plans to implement integrated member materials at § 422.107(e).

We anticipate costs to CMS will be similar to past work done to collaborate with States to improve the integration and effectiveness of materials for dually eligible beneficiaries. To test materials, we conducted individual interviews with dually eligible individuals and desk reviews by contractors, CMS subject matter experts, and advocacy organizations. Since 2015, we have tested an integrated EOC, ANOC, SB, Formulary, and combined Provider and Pharmacy Directory.

We estimate that each of the model documents under § 422.107(e)—the SB, Formulary, and combined Provider and Pharmacy Directory—will require 40 hours of work from CMS staff (a GS–13–5 Federal employee) working at \$112.62/hr. The projected cost to the Federal Government for 120 hours (40 hours × 3 documents) of a GS–13–5 employee is \$13,500.

In our experience, a desk review from a contractor is approximately \$10,000 per document and a study of the documents consisting of dually eligible individuals' interviews costs \$25,000 per document. Therefore, we anticipate the contractor costs for integrated member materials to be \$105,000 (\$10,000 × 3 documents + \$25,000 × 3 documents). Therefore, the total cost to the Federal Government of our final rule on integrating member materials is \$118,500.

d. Joint State/CMS Oversight

In section II.A.6.c. of this final rule, we discuss our changes at § 422.107(e)(3) to better coordinate State and CMS monitoring and oversight of D–SNPs that operate under the conditions described at paragraph (e)(1). These coordination mechanisms include sharing relevant plan information, coordinating program audits, and consulting on network exception requests. We cannot estimate the cost of uncoordinated State and Federal oversight, but we believe this provision would result in a reduction in administrative burden for D–SNPs. States will have the ability to determine what level of resources is needed for their related work, and we believe States likely to elect to use the pathway described in § 422.107(e) would already have resources invested in coordinating care between MCOs and D–SNPs and would otherwise make choices that avoid significant increases in State burden.

At paragraph (e)(3)(i), we are finalizing that CMS would grant State access to HPMS, or any successor system, to facilitate monitoring and oversight for a D–SNP with exclusively aligned enrollment in an MA contract that only includes one or more D–SNPs operating within the State. Our final rule will require the State officials and employees accessing HPMS to comply with applicable laws and CMS policies and standards for access to that system, including keeping information confidential and maintaining system security. This access will allow State users the ability to directly view D–SNP information without requiring or asking the D–SNP to send the information to the States and would facilitate State-

CMS communication on D–SNP performance since more people are able to review the data and information. MA organizations may benefit when it reduces the need for States to separately obtain the same information that is already available in HPMS.

Providing this HPMS access to State users would require HPMS contractors to update several modules, including user access and coding changes needed to implement the necessary access. HPMS contractors estimated that there would be a one-time update costing approximately \$750,000.

We received no comments on our analysis and are finalizing it without modification.

4. Attainment of the Maximum Out-of-Pocket (MOOP) Limit (§§ 422.100 and 422.101)

As described in section II.A.12. of this final rule, we are finalizing a revision to which costs are tracked and accumulate toward the MOOP limit for dually eligible enrollees in MA plans under § 422.101(d) for MA regional plans and § 422.100(f)(4) and (5) for all other MA plans. Our rule will result in MA organizations that, under current policy, rarely or never pay cost-sharing above the MOOP limit for dually eligible enrollees being held responsible for payment of cost-sharing amounts above the MOOP limit. As a result, our final rule may lead to an increase in the plan bids relative to the benchmark for dually eligible individuals who would receive the same cost-sharing protection provided by the MOOP that is now afforded to non-dually eligible individuals. However, in the short term, as we note above, MA organizations may prefer to reduce their profit margins, rather than raise their bids and thereby reduce the rebate dollars available for supplemental benefits.

Specifically, we are finalizing that all cost-sharing for Medicare Parts A and B services accrued under the plan benefit package, including cost-sharing paid by any applicable secondary or supplemental insurance (such as through Medicaid, employer(s), and commercial insurance) and any cost-sharing that remains unpaid (such as because of limits on Medicaid liability for Medicare cost-sharing under the lesser-of policy and the cost-sharing protections afforded certain dually eligible individuals), is counted towards the MOOP limit. This will ensure that once an enrollee, including a dually eligible individual with cost-sharing protections, has accrued cost-sharing (deductibles, coinsurance, or copays) that reaches the MOOP limit, the MA plan must pay 100 percent of the cost

of covered Medicare Part A and Part B services. As a result, the State Medicaid agency will no longer be responsible for any Medicare cost-sharing for the remainder of the year. In addition, providers serving dually eligible MA enrollees with Medicare cost-sharing above the MOOP limit will be fully reimbursed for this cost-sharing for the remainder of the year. Now, some of that cost-sharing is unpaid because of limits on State payment of Medicare cost-sharing and prohibitions on collection of Medicare cost-sharing from certain dually eligible beneficiaries. We believe this change to the cost-sharing that MA organizations must use to determine when the MOOP limit has been reached will mitigate existing provider payment disincentives related to serving dually eligible MA enrollees. This change will also eliminate the perceived need for providers to bill dually eligible for non-paid coinsurance, which although prohibited, is not uncommon. As a result, this final rule may improve access to providers, including specialists, who currently limit the number of dually eligible MA enrollees they serve or decline to contract with D-SNPs. However, we are unable to quantify the extent to which any improved access would affect utilization of services by dually eligible MA enrollees and thereby affect Medicare spending.

Our final rule will increase the amount of MA organization payments to providers serving dually eligible individuals enrolled in MA plans after the MOOP limit is reached. As a result, our final rule may lead to an increase in the plan bids relative to the benchmark for dually eligible individuals who would receive the same cost-sharing protection provided by the MOOP that is now afforded non-dually eligible individuals.

To estimate the costs of the final rule, we started with CY 2022 bid data to

estimate the Medicare cost-sharing accrued by dually eligible beneficiaries with cost-sharing protections (full-benefit dually eligible individuals and QMB enrollees) above the mandatory MOOP level (\$7,550 in 2022). We estimated the cost of Medicare cost-sharing above this MOOP level to be on average \$22.99 per person per month. Then we multiplied this amount by 41 percent to reflect the portion of dually eligible enrollees in MA organizations that already accrue cost-sharing towards the MOOP level to arrive at \$9.43 as the additional per person per month bid cost. Based on projected MA enrollment of dually eligible beneficiaries and other factors described in this section, this final rule would result in additional payments from MA organizations to health care providers serving high cost dually eligible MA enrollees, represented in the annual MA bid costs shown in column 2 of Table 13.

Only a portion of the projected higher MA organization bids for MOOP benefits represent higher costs to Medicare. MA rebates are calculated as an average of 68 percent of the difference between the bids and benchmarks. The additional cost to the Medicare Trust Funds is estimated to be the remaining 32 percent increase in bids. After reflecting the change in rebates, the per member per month cost to Medicare of the final rule is 32 percent of \$9.43, or \$3.

To project annual costs, we used projected enrollment by dually eligible beneficiaries in MA plans, as well as Trustee's Report U.S. Per Capita Costs (USPCC) cost and utilization trends. We also projected annual increases in the mandatory MOOP amounts under current regulations. The cost to Medicare based on our final rule will be partly offset by the savings to Medicaid for payment of Medicare cost-sharing over the MOOP limit for dually eligible individuals. While some State Medicaid agencies may save as much as the

projected increase in bid costs per dually eligible MA enrollee in their State, the savings from this final rule will likely be less for most States. The majority of States have a "lesser-of" policy, under which the State caps its payment of Medicare cost-sharing so that the sum of Medicare payment and cost-sharing does not exceed the Medicaid rate for a particular service. We estimate that, based on average differences in State Medicaid and Medicare provider contracted rates, 39 percent of the costs of MOOP coverage under our final rule represents Medicaid savings. Of those savings, 57 percent accrue to the Federal Government based on the average FMAP rate of 57 percent. Those annual savings are shown in column 4 of Table 13.

Finally, 25 percent of the additional Medicare costs that represent Part B costs (Part B accounts for 60 percent of the costs of Parts A and B benefits provided by Medicare Advantage organizations) are offset by beneficiary premiums for Part B, as shown in column 6 of Table 13. The total Federal costs of the final rule, net of Federal Medicaid savings and the Part B premium offset are shown in column 7 of Table 13.

We note that there is uncertainty inherent in this analysis. In using the bid data, we made some assumptions about the extent to which MA organizations are already counting all cost-sharing in the plan benefit, including amounts paid by Medicaid programs, towards the MOOP limit. In addition, MA organizations may prefer to reduce their gain/loss margins, rather than substantially change their benefit package, when rebates are reduced in the short term. However, our estimate of the added bid benefit costs does not assume that MA organizations will absorb any portion of these costs by reducing their gain/loss margins.

TABLE 13: 10-YEAR AGGREGATE PROJECTED COSTS (\$ MILLIONS) FROM MOOP PROVISION*

Year	Additional Bid Benefit Costs for MA Organizations for Cost-Sharing Above the MOOP	Total Medicare-Only Benefit Costs	Federal Savings to Medicaid from MOOP Provision	Medicare Costs minus Medicaid Savings	Part B Premium Offsets	Impact of MOOP Provision
(1)	(2)	(3) = 32% * (2)	(4) = 39% * 57% * (2)	(5) = (3) - (4)	(6) = 60% * 25% * (3)	(7) = (5) - (6)
2023	805.8	257.9	179.1	78.7	38.7	40.0
2024	879.5	281.4	195.5	85.9	42.2	43.7
2025	963.2	308.2	214.1	94.1	46.2	47.9
2026	1,052.5	336.8	234.0	102.8	50.5	52.3
2027	1,145.8	366.7	254.7	111.9	55.0	56.9
2028	1,279.2	409.3	284.4	125.0	61.4	63.6
2029	1,391.1	445.2	309.2	135.9	66.8	69.1
2030	1,502.2	480.7	333.9	146.8	72.1	74.7
2031	1,619.7	518.3	360.1	158.2	77.7	80.5
2032	1,730.6	553.8	384.7	169.1	83.1	86.0
Totals	12,369.5	3,958.2	2,749.7	1,208.5	593.7	614.8

*Explanatory equations in the second row of the table are further elaborated on in the narrative.

No additional goods or services are being created. Rather, the money that States would pay or that would remain unpaid for Parts A and B services is now being paid by the plans and hence by the Trust Fund. Hence these amounts are considered transfers from the Trust Fund to the States.

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

5. Special Requirements During a Disaster or Emergency for Medicare Advantage Plans (§ 422.100(m))

We are not scoring the finalized revisions to § 422.100(m) (Special Requirements during a Disaster or Emergency). As stated in the February 12, 2015 final rule (80 FR 7953), we recognize that disasters can create unavoidable disruptions and increased costs for MA organizations. Our primary goal during a disaster is the provision of continued and uninterrupted access to medically necessary plan-covered services for all enrollees. Our intention is to facilitate achievement of this goal by ensuring that plans facilitate increased access to providers from whom enrollees in the disaster area may seek high quality services at in-network cost-sharing. We do not believe that these temporary and unusual episodes of increased access will incentivize enrollees in a negative way or result in significant cost increases for affected

MA organizations. We believe this is still relevant as most of our final revisions clarify our current policy. More detailed arguments for not scoring are presented after a discussion of the finalized revisions.

Our final amendments to § 422.100(m) include codifying our current practice of imposing the special requirements at § 422.100(m)(1) on MA organizations only when there is a disruption of access to health care as stated in the preamble to the February 12, 2015, final rule (80 FR 7953) and in our responses to comments and questions from MA organizations and others in administration of the existing requirement during the pandemic. We receive many questions and inquiries during a disaster or emergency so we believe this has been fully complied with; because we are clarifying through notice and comment rulemaking, these clarifications may result in enhanced compliance with this requirement and may contribute to reduced costs. Consequently, we do not believe the proposal to clarify what amounts to a disruption of access to health care and how the special requirements only apply when there is a disruption in connection with a declared emergency or disaster has an impact because it is consistent with current application of the regulation and MA organizations are already complying.

We are also finalizing adding a transition period of 30 days between a disaster or emergency ending and the end of the special requirements to § 422.100(m)(3). We do not believe these provisions would create impact. Some MA organizations may already allow flexibilities to enrollees following a disaster or emergency, such as a transition period to allow additional time for enrollees to return to in-network providers. Additionally, many MA plans have experience with disasters or other changes in cost that arise annually. The nature of the business cycle shows that MA plans may experience losses due to short-term disasters or emergencies in certain years, which may be offset with profits in the following years. Although the cost burden for a longer disaster or emergency is different than that for a shorter disaster, our recent experience with the COVID-19 PHE shows that CMS is aware of this cost burden and as each specific situation develops, is responding with certain flexibilities.

For these reasons, we are not further scoring the special requirements during a disaster or emergency provision.

6. Provisions Relating to Past Performance (§§ 422.504 and 423.505)

We are finalizing an update the past performance measures at 42 CFR 422.504 and 423.505 in order to better ensure CMS' capacity to limit new

applications and applications for service area expansions by low performers when these new plans and/or service area expansions would not be in the best interest of the Medicare program. Although there are no tangible costs to organizations, there may be future costs that may or may not occur.

Organizations that fail to meet CMS' requirements will have applications denied, resulting in their inability to gain enrollment, thus losing potential future dollars. On the other hand, some organizations may actually improve performance, because of the ramifications of being a poor performer. In these cases, these organizations will actually be in a better position, potentially having higher Star Ratings, resulting in additional funds if the organization receives performance pay for their Star Ratings. The CMS costs are as follows:

- To perform the calculations, we estimate—
 - ++ 2 staff at the GS 13–5 level working at \$112.62/hr would have to perform a total of 24 hours of work (12 hours for each staff); and
 - ++ 2 staff at the GS 14–9 level working at \$148.74/hr would have to perform 10 hours of work.
- To notify plans, we estimate that 1 staff at the GS–13–5 level working at \$112.62/hr will have to perform 3 hours of work.

The aggregate annual cost to the government is therefore \$4,528.

7. Marketing and Communications Requirements on MA and Part D Plans To Assist Their Enrollees (§§ 422.2260, 423.2260, 422.2267, and 423.2267)

We have presented a discussion of collection of information burden associated with this provision in section IV.B.11. of this final rule. In this section, we summarize comments on the impacts of these provisions.

Comment: Comments suggested that the MLI as proposed would impose a greater burden on plans than we anticipated in the proposed rule.

However, the comments suggesting this did not indicate why this was the case or what aspect of the burden we failed to address.

Response: On review, we believe our assessment of the burden on plans as discussed in the Regulatory Impact Assessment of this rule is accurate. We also believe the burden on plans is acceptable considering the vital nature of the MLI. As indicated earlier in the preamble and the response to a previous comment, certain required documents (under §§ 422.2267(e) and 423.2267(e)) are vital to a beneficiary's understanding of the MA, Part D, and

cost plan programs. While those organizations must provide translation services, the requirement is less effective if beneficiaries are not aware of the availability of and right to the translation services. As such, the requirement to provide the MLI with required documents alerts the beneficiary to services that may help to prevent misunderstanding of the program and thus avoid beneficiary harm. Additionally, the MLI replaces OCR's analogous language assistance tagline requirement that was, based on scope and size, more burdensome than the MLI. Furthermore, CMS required plans to deliver the MLI until 2016, when it was replaced by OCR's analogous requirement. Finally, the MLI improves communication affecting a variety of health issues, acting as a bridge to education and awareness. This should ultimately improve beneficiary health and reduce the cost of beneficiary care.

8. Revisions to the Medical Loss Ratio Reporting Requirements (§§ 422.2460 and 423.2460)

As discussed in section II.G. of this final rule, we are finalizing our proposal to reinstate the detailed MLR reporting requirements in effect for CYs 2014 through 2017, and to require separate reporting of amounts spent on supplemental benefits.

The paperwork burden associated with these provisions, \$2.3 million, is estimated in section IV.B.12. of this final rule and included in the summary table below. There is also additional anticipated impact to the Federal Government. Most of the impact will arise from projections of future increases or decreases in MLR remittances, which are amounts that were originally paid from CMS to MA organizations or Part D sponsors, which they have to return to CMS (although the remittances go to the Treasury General Fund and not the Medicare Trust Funds from which they originated).

In the proposed rule, we explained that if we reinstate and add to the detailed MLR reporting requirements, as we proposed and are now finalizing, we will continue to pay a contractor to perform desk reviews and analyses of the reported data in order to identify omissions or suspected inaccuracies and to communicate its findings to MA organizations and Part D sponsors in order to resolve potential compliance issues, at a level comparable to the amount we paid for similar services for the contract years for which MA organizations and Part D sponsors were previously required to submitted

detailed MLR data (that is, contract years 2014 through 2017). As a starting point for our analysis of the estimated cost increase associated with the additional desk review and analysis services that we anticipate a contractor will perform for us starting with contract year 2023 MLR reporting, we noted that, in the Regulatory Impact Analysis for the April 2018 final rule which had previously eliminated the detailed MLR reporting requirements, we assumed that by significantly reducing the amount of MLR data that MA organizations and Part D sponsors would be required to report to CMS annually starting with CY 2018, we had also eliminated the need for CMS to continue paying a contractor approximately \$390,000 each year in connection with desk reviews of the detailed MLR reports. However, the April 2018 final rule indicated that the entire amount we paid to our desk review contractor would no longer be necessary once we stopped collecting detailed MLR data on an annual basis. As noted in the proposed rule, this has not been our experience, and in the years since we scaled back the reporting requirements, we have continued to find value in having our contractor perform MLR-related administrative tasks. Prior to CY 2018, the funding for these administrative tasks was included in the \$390,000 figure that the April 2018 final rule identified as representing payment for desk reviews only. These administrative tasks include sending reminders to MA organizations and Part D Sponsors to submit their MLR data and attestations by the applicable deadlines, following up with MA organizations and Part D sponsors about their questions regarding their MLR submissions, and triaging communications to CMS so that matters requiring additional input from us are brought to our attention timely. CMS currently pays the contractor approximately \$230,000 per year to perform these services.

The proposed rule estimated that, if we finalized the detailed MLR reporting requirements as we had, and if we resume conducting desk reviews of the detailed MLR data, we will increase the amount that we pay our contractor for desk reviews and MLR-related administrative services so that the total payment amount will approximately equal to the total amount we paid to our contractor for those services prior to the elimination of the detailed MLR reporting requirements (that is, \$390,000). In other words, we expect that we will need to pay our contractor an additional \$160,000 per year to

perform MLR desk reviews of the detailed MLR data that CMS will be requiring MA organizations and Part D sponsors to submit to us on an annual basis, starting with CY 2023, under the requirements we are now finalizing.

In addition, CMS currently pays a contractor \$300,000 each year for software development, data management, and technical support related to MLR reporting. The Regulatory Impact Analysis for the April 2018 final rule estimated that we would be able to reduce this amount by \$100,000 because we would no longer need to maintain and update the MLR reporting software with validation features, to receive certain data extract files, or to provide support for desk review functionality. However, contrary to our expectations, since CY 2018, CMS has continued to require technical support related to submission of the MLR Data Forms, such that, even without requiring significant updates to

the MLR reporting software, we have continued to pay a contractor \$300,000 for data management and technical support services. The proposed rule noted that we anticipate that we will continue to pay this amount for software development, data management, and technical support related to MLR reporting if the proposed changes to the MLR reporting requirements are finalized.

Table 14 presents expected additional payments (transfers) from MA organizations and Part D sponsors to the Treasury arising because they are projected to pay more in MLR remittances to the Treasury. These additional payments are transfers since no goods or services are being created. The impact to the Medicare Trust Funds is \$0.

Based on internal CMS data, the raw average of total remittances for CYs 2014–2019 is \$153 million. As discussed in section II.G.2. of this final

rule, when CMS collected detailed MLR data pursuant to the reporting requirements that were in effect for CYs 2014–2017, the desk review contractor frequently detected potential errors or omissions in the reported data, which were brought to the attention of the MA organization or Part D sponsor that submitted the data, with a request to explain or correct the data. This process often resulted in the MA organization or Part D sponsor finding it necessary to resubmit the contract's MLR Report after revising the figures in the Report or attaching supplementary materials to explain details of its expense allocation methodology. A summary of the MLR remittances for the initial MLR submission versus the final MLR submission for CYs 2014–2017 can be found in Table 14. These 4 years represent the time period when detailed MLR data was submitted to CMS and subjected to desk reviews.

TABLE 14: CHANGE IN MLR REMITTANCES BETWEEN INITIAL AND FINAL MLR SUBMISSION

Contract Year (CY)	Initial MLR Submission	Final MLR Submission	Change	Percent Change
2014	36,884,719	37,074,217	189,498	0.5%
2015	28,128,535	22,064,688	(6,063,847)	-27.5%
2016	200,308,358	242,402,915	42,094,557	17.4%
2017	223,244,933	222,058,179	(1,186,754)	-0.5%
2014–2017	488,566,545	523,599,999	35,033,454	6.7%
2018	92,639,916	94,502,390	1,862,474	-----
2019	298,124,406	298,124,406	-----	-----
Average (2016–2019): ¹		204,045,022	-----	-----

¹The average remittance is calculated using the initial MLR submission for CYs 2016 and 2017 and the final MLR submission for CYs 2018 and 2019.

The percent change in MLR remittances increased on average 6.7 percent between the initial and final MLR submissions during the MLR desk review periods for CYs 2014–2017. We anticipate that, if finalized, the amendments to §§ 422.2460 and 423.2460 would increase future remittance amounts by an average of 6.7 percent due to CMS receiving detailed MLR data and conducting desk reviews of the detailed MLR data.

To estimate the amount of additional remittances under the regulations we are adopting in this final rule, we evaluated the MLR for those contracts that failed to meet the 85 percent minimum MLR requirement for CYs

2016–2019. The MLR remittances for CYs 2014 and 2015 were much lower than those for the more recent years and so these older years were excluded from the base period that is used to project future remittances. For CYs 2016 and 2017, we examined the MLR prior to desk reviews, or in the Initial MLR Submission. For CYs 2018 and 2019, when there were not desk reviews of detailed MLR data, we examined the finalized total MLR remittances. The average remittances for these years (CYs 2016 and 2017 prior to desk reviews and CYs 2018 and 2019) equaled \$204.0 million. In order to project the increase in remittances for CYs 2023–2032, the \$204.0 million was inflated using

estimated enrollment and per capita increases based on Tables IV.C1. and IV.C3. of the 2021 Medicare Trustees Report, with ordinary inflation (Table II.D1. of the 2021 Medicare Trustees Report) carved out of the estimates. We continued to assume that remittance amounts would increase by 6.7 percent for the entire projection period due to the restatement of desk reviews of detailed MLR data, after the application of enrollment and per capita increases.

Table 15 is based on data from the Office of the Actuary, some of which may be found in the annual Trustees Report. The calculations started with a \$13.7 million additional cost to MA organizations and Part D sponsors in CY

2019 (This amount is not shown in the table which is a 10 year table starting from CY 2023). The cost in each successive contract year is obtained by adding the MA enrollment increases expressed as a percentage in column (2),

then adding the average annual per capita increase in expenditures, expressed as a percentage in column (3), and then dividing by ordinary inflation expressed as a percentage column (4). The calculations can be illustrated

starting with the CY 2023 net cost (\$20.3 million) and deriving the \$21.5 million CY 2024 cost. We have \$20.3 million * (1+3.8%) * (1+4.8%) / (1+2.5%) = \$21.5 million.

TABLE 15: MLR COST (TRANSFERS) FROM MA ORGANIZATIONS AND PART D SPONSORS (\$ MILLIONS) TO THE TREASURY

Contact Year	MA Enrollment Increase	Average Annual Per Capita Increase in Expenditures	Ordinary Inflation	Net Cost (Savings) (\$ millions)
(1)	(2)	(3)	(4)	(5)
2023	4.1%	4.8%	2.5%	20.3
2024	3.8%	4.8%	2.5%	21.5
2025	3.7%	5.4%	2.5%	22.9
2026	3.6%	5.4%	2.5%	24.4
2027	3.3%	5.3%	2.5%	25.9
2028	3.1%	5.5%	2.5%	27.5
2029	2.8%	5.5%	2.5%	29.1
2030	2.6%	4.4%	2.5%	30.4
2031	2.3%	7.2%	2.4%	32.6
2032	1.8%	4.9%	2.4%	34.0
Totals				268.6

We are finalizing our impact analysis without change.

9. Pharmacy Price Concessions in the Part D Negotiated Price (§§ 423.100 and 423.2305)

As discussed in section II.H.3. of this final rule, at §§ 423.100 and 423.2305, we are finalizing our proposal to adopt a new definition of “negotiated price” to include all pharmacy price concessions received by the plan sponsor for a covered Part D drug, and to reflect the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug through all phases of the Part D benefit. In response to comments, we will retain the current regulatory definition of “negotiated prices” for 2023 and delete the current definition of “negotiated prices” (in the plural) and add a definition of “negotiated price” (in the singular) to make clear that a negotiated price can be set for each covered Part D drug, and the amount of the pharmacy price concessions may differ on a drug by drug basis for 2024 and thereafter. We are finalizing the definition of “negotiated price” that was proposed and that is intended to ensure that the prices available to Part D enrollees at the point of sale are inclusive of all

pharmacy price concessions beginning with plan year 2024 onward. The requirement to apply pharmacy price concessions the negotiated price will apply in all phases of the Part D benefit.

The provision would have several impacts on prescription drug costs for government, beneficiaries, Part D sponsors, and manufacturers. Tables 16, 17, and 18 summarize these impacts, which are discussed in more detail in the narrative that follows. We note that this provision would also have one-time administrative costs for Part D sponsors. This cost is discussed in the Collection of Information section of this final rule.

a. Impact on Prescription Drug Costs for Government, Beneficiaries, Part D Sponsors, and Manufacturers

Tables 16, 17, and 18 summarize the 10-year impacts we have modeled for requiring that sponsors apply all pharmacy price concessions to the negotiated price in all phases of the Part D benefit. These tables estimate a modest potential indirect effect on pharmacy payment as a result of pharmacies’ independent business decisions. Specifically, the estimates assume that pharmacies will seek to retain 2 percent of the existing pharmacy price concessions they

negotiate with plan sponsors and other third parties to compensate for pricing risk and differences in cash flow and we assume that these business decisions will result in a slight increase in pharmacy payments of 0.2 percent of Part D gross drug cost.

Tables 16, 17, and 18 reflect the impact of these provisions to enrollees, manufacturer gap discounts, and the Federal Government respectively. Overall beneficiaries are expected to save \$26.5 billion, manufacturers pay \$16.8 billion less in gap discounts, and the government cost is expected to increase \$46.8 billion dollars over 2024–2032.

Under this provision, we anticipate that beneficiaries would see lower prices at the pharmacy point-of-sale and on Plan Finder for most drugs, beginning immediately in the year the proposed change would take effect (2024). (This is summarized in Table 16 in the row “Beneficiary Costs” which reflects a sum of the rows “Cost-sharing” and “Premiums.”) Lower point-of-sale prices would result directly in lower cost-sharing costs for non-low-income beneficiaries, and on average we expect these cost-sharing decreases would exceed the premium increases. While the amounts will vary

depending on an individual beneficiary's prescriptions, plan sponsor benefits, and contractual arrangements, we expect more than half of the non-low-income, non-employer group beneficiaries to see lower total costs, inclusive of cost-sharing decreases and premium increases. For example, a beneficiary who takes no medications will probably see a premium increase and no cost-sharing decreases, whereas a beneficiary who takes several medications each month is likely to see cost-sharing decreases that are greater than the premium increase. For low-income beneficiaries, whose out-of-pocket costs are funded through Medicare's low-income cost-sharing payments, cost-sharing savings resulting from lower point-of-sale prices would accrue to the Government. Plan premiums would likely increase as a result of the change to the definition of negotiated price—if pharmacy price concessions are required to be passed through to beneficiaries at the point of sale, fewer such concessions could be apportioned to reduce plan liability in the bid, which would have the effect of increasing the cost of coverage under the plan. At the same time, the reduction in cost-sharing obligations

would be large enough to lower beneficiaries' overall out-of-pocket costs on average.

The increasing cost of coverage under Part D plans as a result of pharmacy price concessions being applied at the point of sale as proposed would likely have a more significant impact on Government costs, which would increase overall due to the significant growth in Medicare's direct funding of plan premiums and low-income premium payments. However, partially offsetting the increase in direct funding and low-income premium payment costs for the government would be decreases in Medicare's reinsurance and low-income cost-sharing payments. Decreases in Medicare's reinsurance payments result when lower negotiated prices slow down the progression of beneficiaries through the Part D benefit and into the catastrophic phase, and when the Government's 80 percent reinsurance payments for allowable drug costs incurred in the catastrophic phase are based on lower negotiated prices. Similarly, low-income cost-sharing payments would decrease if beneficiary cost-sharing obligations decline due to the reduction in prices at the point of sale. Finally, the slower

progression of beneficiaries through the Part D benefit would also have the effect of reducing aggregate manufacturer gap discount payments as fewer beneficiaries would enter the coverage gap phase or progress entirely through it. These effects are presented in Table 18.

These impacts assume that the definition of "negotiated price" would apply for Part D drugs in all phases of the Part D benefit (applicable drugs in the coverage gap phase of the benefit). While we initially proposed excluding the coverage gap phase from this policy, we are finalizing the alternative proposal which applies this policy to the entire benefit. This policy increases beneficiary savings and government costs relative to the initial proposal, but simplifies administration and provides greater transparency to beneficiaries.

Table 16 shows the increased total savings to enrollees which is projected to be \$26.5 billion for the period from 2024–2032. As explained in the previous narratives, the total savings to enrollees' accounts for both cost-sharing savings and expected premium increases.

TABLE 16. TOTAL IMPACTS TO ENROLLEES (BILLIONS \$) FOR 2024 THROUGH 2032 WITH APPLICATION TO APPLICABLE DRUGS IN COVERAGE GAP

Year	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	Total With Gap	Total Without Gap
Beneficiary Costs	\$0.00	\$0.00	(\$1.73)	(\$1.88)	(\$2.04)	(\$2.39)	(\$2.77)	(\$3.20)	(\$3.65)	(\$4.15)	(\$4.69)	(\$26.5)	(\$20.4)
Cost-Sharing	\$0.00	\$0.00	(\$2.62)	(\$2.85)	(\$3.10)	(\$3.63)	(\$4.22)	(\$4.86)	(\$5.57)	(\$6.33)	(\$7.16)	(\$40.3)	(\$31.8)
Premium	\$0.00	\$0.00	\$0.89	\$0.97	\$1.05	\$1.24	\$1.44	\$1.67	\$1.91	\$2.18	\$2.47	\$13.8	\$11.4

*Negative numbers indicate savings; positive numbers indicate costs. Numbers are in billions of \$

TABLE 17: TOTAL IMPACTS TO MANUFACTURERS (BILLIONS \$) FOR 2024 THROUGH 2032 WITH APPLICATION IN COVERAGE GAP

Year	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	Total With Gap	Total Without Gap
Manufacturer Gap Discount	\$0.00	\$0.00	(\$1.25)	(\$1.37)	(\$1.51)	(\$1.66)	(\$1.83)	(\$2.00)	(\$2.19)	(\$2.38)	(\$2.59)	(\$16.8)	(\$13.8)

*Negative numbers indicate savings; positive numbers indicate costs. Numbers are in billions of dollars (\$).

TABLE 18: TOTAL IMPACTS TO GOVERNMENT FOR 2024 THROUGH 2032 WITH APPLICATION TO APPLICABLE DRUGS IN THE COVERAGE GAP

	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	TOTAL With Gap	Total Without Gap
Government Costs	\$0.00	\$0.00	\$3.27	\$3.56	\$3.88	\$4.41	\$4.98	\$5.60	\$6.27	\$7.00	\$7.78	\$46.8	\$38.1
Direct Payments	\$0.00	\$0.00	\$6.74	\$7.29	\$7.95	\$8.83	\$9.78	\$10.80	\$11.90	\$13.07	\$14.32	\$90.7	\$72.4
Reinsurance	\$0.00	\$0.00	(\$1.92)	(\$2.08)	(\$2.29)	(\$2.28)	(\$2.26)	(\$2.22)	(\$2.16)	(\$2.09)	(\$1.98)	(\$19.3)	(\$13.9)
LI Cost-Sharing	\$0.00	\$0.00	(\$1.83)	(\$1.96)	(\$2.12)	(\$2.53)	(\$2.98)	(\$3.48)	(\$4.02)	(\$4.62)	(\$5.27)	(\$28.8)	(\$23.8)
LI Premium	\$0.00	\$0.00	\$0.29	\$0.31	\$0.33	\$0.38	\$0.44	\$0.50	\$0.56	\$0.63	\$0.71	\$4.2	\$3.4

*Negative numbers indicate savings; positive numbers indicate costs. Numbers are in billions of dollars (\$).

We received comments on our impact analysis.

Comment: A commenter stated that while this final rule is a step in the right

direction CMS must conduct a complete regulatory impact analysis of how this

rule affects all types of specialty pharmacies. There was concern that because of the more expensive drugs sold by specialty pharmacies that this final rule would not meet their needs even though in aggregate it improved the program.

Response: CMS does not collect data on pharmacy price concessions at the pharmacy level, and this information is not publicly available. In order to estimate, for example, the effects on specialty pharmacies in particular, we would need to speculate on the relative difference between price concessions to those pharmacies versus retail pharmacies. As we do not have any basis for developing this difference, it is not possible to meaningfully analyze impacts by type of pharmacy.

Comment: A commenter offered that in addition to the financial impacts described in the rule, there may be additional improvements in health outcomes and medical costs resulting from improved medication adherence as a result of lower negotiated prices.

Response: We agree that it is possible that there will be effects on health outcomes. We do not have adequate information to quantify these impacts at this time because the actual cost-sharing effects will vary considerably with how plan sponsors reflect this in their benefit design. For example, it is possible that the plans will concentrate these effects on certain categories of drugs, and many health effects may take several years to realize.

Comment: We received several comments requesting that the financial impacts include analysis by type of retail pharmacy.

Response: We do not have sufficient data to determine impacts by type of pharmacy, as the pharmacy price concessions are not reported in connection to a particular pharmacy or type of pharmacy.

Comment: A commenter stated that CMS did not disclose their assumptions in developing the tables. These would include future Part D membership, trends in drug utilization, drug cost, network contracting, manufacturer rebates, drug mix, benefit designs, and general inflation. The commenter noted that CMS did disclose that they assumed pharmacies would seek to retain 2 percent of the existing pharmacy concessions for risk and cashflow. Most importantly, CMS did not disclose how lowest reimbursement was applied in the model.

Response: We modeled the lowest reimbursement as the negotiated price, rather than having bonus payments to pharmacies that would lower DIR and therefore lead to higher premiums.

Aggregate forecasts for the Part D program payments, including cost and DIR trends similar to those used in our analysis, may be found in the Medicare Trustees Report for 2021, a publicly available resource (<https://www.cms.gov/files/document/2021-medicare-trustees-report.pdf>). More detailed assumptions are based on CMS internal data that is not public, and if made public could adversely affect Part D bid submissions, such as drug mix or beneficiary progression through the benefit. For example, sharing the assumptions on the projected mix of price concessions by drug could allow sponsors to infer whether their current mix presents opportunities for greater price concessions on certain drugs.

Comment: Several commenters commissioned an independent actuarial analysis to gain additional insight into the proposed rule's potential impacts. The actuary performing the independent analysis believed that the CMS assumption of pharmacies negotiating 2 percent of the concessions would produce a different value than what was shown in the proposed rule.

Response: We assumed that 2 percent of only the existing pharmacy price concessions impacted by this policy are reflected as an offset to pharmacies for the change in cashflow and risk. As the proposed rule specified that the new definition for the term "negotiated price" would not apply in the coverage gap, we did not apply the 2 percent assumption to price concessions in the coverage gap in the proposed rule. This difference between applying the 2 percent assumption to the entire benefit or excluding the coverage gap explains the discrepancy.

As the proposed rule specified that the new definition for the term "negotiated price" would not apply in the coverage gap, we did not apply the 2 percent assumption to price concessions in the coverage gap in the proposed rule.

Comment: Several commenters commissioned an independent actuarial analysis to gain additional insight into the proposed rule's potential impacts. The actuary performing the independent analysis noted that premium is an important factor—perhaps the most important factor—in the purchase decisions of members.

Response: We agree that Part D sponsors are highly motivated to keep premiums low. CMS agrees that premiums are a key factor influencing insurance purchasing decisions and we have taken premium levels into account in our analysis.

Comment: A commenter questioned the difference between the calculations

provided in the Alternative Analysis section of the proposed rule (section V.E.2.) and the calculations provided in the narrative in section V.D.8. of the proposed rule, the difference between them being inclusion of the coverage gap. The commenter questioned the validity of assuming a 6% drop in manufacturer cost between the two tables.

Response: We thank the commenter for their feedback. The manufacturer cost is impacted not only directly by the change in negotiated price used for calculating the coverage gap discount on a particular drug, but also by changing the amount of spending in the gap phase of the benefit. As negotiated prices decrease from this policy, there is less spending in the coverage gap phase of the benefit.

Comment: A commenter provided an alternative analysis that considered the effects of an incentive payment of 4.3 percent of drug cost to the pharmacies after the point of sale, rather than the net payment to the pharmacy paid at the point of sale assumed in the RIA. They noted that this is another possible payment arrangement under the proposed rule.

Response: While an interesting example, we believe this approach is unlikely. A bonus payment to pharmacies would further increase premiums because it would decrease the DIR paid to the plan sponsor. Recent data indicate an increase in DIR of 512 percent between 2009 and 2018, which suggests plan sponsors are very focused on increasing DIR.

Comment: A few commenters commissioned an independent actuarial analysis to gain additional insight into the proposed rule's potential impacts. These analyses assumed pharmacy DIR was applied at the POS in all phases including the coverage gap. The results were generally consistent with the direction and magnitude of CMS's overall findings by stakeholder. The independent analyses assumed no behavior changes among stakeholders, which, if considered, could have a material impact on the estimates. The independent analyses indicated that at best 29 percent of beneficiaries may see cost-sharing savings that exceed their increases in premiums. By contrast, at least 38 percent of beneficiaries may realize higher net costs, as their premium increases typically outweigh their cost-sharing savings, and 33 percent (low income enrollees) may see little or no change in OOP costs.

Response: We appreciate the feedback and additional analysis shared in this comment. As noted by the commenter, the overall magnitude and direction of

cost impacts is broadly similar to the results in the regulatory impact analysis. We agree that low income beneficiaries will not see significant impacts from the rule. We do not wholly agree with the percentages of beneficiaries described in the analysis. For non-low income beneficiaries, we disagree with the characterization in the comment that no beneficiaries ending in the deductible phase will benefit. On the contrary, those beneficiaries who are nearly at the end of the deductible could see substantial cost decreases as they are paying the full negotiated price of any drug in that phase. This is also implicitly acknowledged in the independent analysis with the caveat that beneficiaries in this phase would “typically” not see a cost decrease.

We are finalizing our impact analysis without change. We appreciated the additional analysis provided by commenters. For the more complete analysis providing a range of potential future impacts, we note that our estimates of government cost are within the range they estimated. We believe the independent analysis largely confirms our results and the majority of differences are due to more granular data in the CMS analysis.

E. Alternatives Considered Analysis

The major drivers of cost and transfers in this rule include the MLR and Part D pharmacy price concessions provisions. The aggregate impact of each of these over 10 years exceeds \$100 million. Alternative analysis is provided below for these provisions.

1. Alternatives Related to the Medical Loss Ratio Reporting Requirements (42 CFR 422.2460, 423.2460)

As an alternative to our proposal to reinstate and add to the detailed MLR reporting requirements in effect for CYs 2014–2017, we considered continuing to collect minimal MLR data, as required under current §§ 422.2460 and 423.2460, and to use our authority under §§ 422.2480 and 423.2480 to require that entities selected for MLR audits provide us with more detailed MLR data, and with any underlying records that can be used to substantiate amounts included in the calculation of each contract’s MLR and the amount of any remittance owed to CMS. In addition to their primary function as a mechanism for obtaining information that can be used to validate audited MA organizations’ and Part D sponsors’ compliance with the applicable

requirements for calculating and reporting MLR information to CMS, we believe that audits are in general well-suited for examining matters such as where and how calculation errors occur, and identifying areas where we might be able to reduce the incidence of errors through revisions to our regulations and guidance. By contrast, desk reviews of detailed MLR data are more useful for quickly reviewing large amounts of data in order to identify possible errors or omissions that might affect the MLR calculation, and for identifying market-wide trends in how MA organizations and Part D sponsors might be adjusting their expenditures in response to rule or policy changes that affect how MLRs are calculated. Given CMS’ interest in better understanding how MA organizations and Part D sponsors’ are calculating their MLRs in general, and in flagging areas where calculation errors might be impacting the MLR calculation so that they can be addressed promptly, we decided that our goals would be better served if we were to require MA organizations and Part D sponsors to report detailed MLR data to us directly, and to subject that data to desk reviews, rather than to attempt to collect the same or similar MLR data using our audit authority.

An additional reason we chose at this time not to rely solely on MLR audits to identify errors in MA organizations’ and Part D sponsors’ MLR submissions is that we believe this approach would result in a greater burden for the Federal Government and cumulatively across all MA organizations and Part D sponsors than would the proposed reinstatement of the detailed MLR reporting requirements. We note that, in the April 2018 final rule, CMS indicated that we did not believe that eliminating the detailed MLR reporting requirements would weaken MLR compliance oversight, and in connection with this we noted that had not changed our authority under § 422.2480 or § 423.2480 to conduct selected audit reviews of the data reported under §§ 422.2460 and 423.2460 for purposes of determining that remittance amounts under §§ 422.2410(b) and 423.2410(b) and sanctions under §§ 422.2410(c) and (d) and 423.2410(c) and (d) were accurately calculated, reported, and applied (73 FR 16675). However, in that rule, we did not account for the increased cost to CMS, or the additional cumulative burden across all MA organization and Part D sponsors, if we were to scale up our MLR audit

operations to a sufficient degree to perform effective compliance oversight in the absence of detailed MLR reporting requirements.

Based on CMS’ historical costs in auditing MLRs, we estimate that individual audits would cost the government approximately \$71,000 per audit. We anticipate that, in order to effectively monitor MLR compliance using audits, we would need to audit one-third of MA and Part D contracts, or an average of 194 contracts per year, at a cost of approximately \$13.8 million per year. By contrast, we estimate that the proposed reinstatement of the detailed MLR reporting requirements would result in a relatively small increase in burden for MA organizations and Part D sponsors, as we expect that they would already need to be tracking most of the information included in the detailed MLR Report template in order to calculate their MLRs in accordance with current requirements.

2. Alternatives Related to Pharmacy Price Concessions in the Part D Negotiated Price (§ 423.100)

As discussed in section II.H.3. of this final rule, we proposed to adopt a new definition of “negotiated price” to include all pharmacy price concessions received by the plan sponsor for a covered Part D drug, and to reflect the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug.

In the analysis provided in section IV.D.8. of this final rule, we estimate the impact of our proposal to require application of pharmacy price concessions to the negotiated price at the point-of-sale in all phases of the Part D benefit. In this alternative analysis, we consider the added impact of only requiring application of pharmacy price concessions to the negotiated price of applicable drugs outside of the coverage gap phase.

This alternative proposal would be more complex, but produces a smaller premium impact. Given that Part D sponsors are highly focused on premium targets for their competitive position, we would expect the pharmacy price concessions to be held back from the point of sale transaction and reimbursed at a later date.

Table 19 shows decreased savings to pharmaceutical manufacturers if pharmacy price concessions are applied to applicable drugs in the coverage gap.

TABLE 19*: IMPACT (\$ BILLIONS) OF CONCESSIONS EXCLUDES APPLICATION TO APPLICABLE DRUGS IN THE COVERAGE GAP AND USES A 2023 STARTING DATE

TA

Label	Item/Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
(A)	Gross Drug Covered Cost (GDCC)	-\$14.4	-\$15.8	-\$17.2	-\$19.0	-\$20.9	-\$22.9	-\$25.0	-\$27.3	-\$29.8	-\$32.4
(B)	Drug Cost Covered by Plan (Supplemental and non-Part D) CCP	-\$10.5	-\$11.6	-\$12.7	-\$13.6	-\$14.6	-\$15.6	-\$16.7	-\$17.9	-\$19.1	-\$20.3
(C)	OOP including Gap Discount	-\$3.9	-\$4.2	-\$4.6	-\$5.4	-\$6.3	-\$7.2	-\$8.3	-\$9.4	-\$10.7	-\$12.1
(D)	General Premium Payment	\$4.8	\$5.2	\$5.6	\$6.3	\$7.0	\$7.8	\$8.6	\$9.5	\$10.4	\$11.4
(E)	Reinsurance	-\$1.4	-\$1.6	-\$1.7	-\$1.7	-\$1.7	-\$1.7	-\$1.6	-\$1.6	-\$1.5	-\$1.4
(F)	LIS Cost-Sharing	-\$1.2	-\$1.3	-\$1.4	-\$1.7	-\$2.1	-\$2.4	-\$2.8	-\$3.3	-\$3.8	-\$4.3
(G)	LIS Premium	\$0.2	\$0.2	\$0.2	\$0.3	\$0.3	\$0.4	\$0.4	\$0.5	\$0.5	\$0.6
(H)	Total Government	\$2.3	\$2.5	\$2.7	\$3.1	\$3.6	\$4.0	\$4.5	\$5.1	\$5.7	\$6.3
(I)	Enrollee Cost-Sharing	-\$1.7	-\$1.9	-\$2.0	-\$2.4	-\$2.8	-\$3.3	-\$3.8	-\$4.4	-\$5.0	-\$5.7
(J)	Enrollee Premiums	\$0.6	\$0.7	\$0.7	\$0.9	\$1.0	\$1.2	\$1.4	\$1.6	\$1.8	\$2.0
(K)	Total Enrollee Costs	-\$1.1	-\$1.2	-\$1.3	-\$1.5	-\$1.8	-\$2.1	-\$2.5	-\$2.8	-\$3.2	-\$3.6
(L)	Total Benefits	2.9	3.2	3.5	4.0	4.6	5.2	5.9	6.7	7.5	8.4
(M)	Gap Discount	-\$0.9	-\$1.0	-\$1.1	-\$1.2	-\$1.4	-\$1.5	-\$1.6	-\$1.8	-\$1.9	-\$2.1

*Negative numbers indicate savings. Positive numbers indicate costs. Row totals are found in Table 17.

Table 20 shows the impact to the Government. As explained in the

narrative of section IV.D.8. of this final rule, the total Government cost reflects

four separate components including direct payments, reinsurance, low

income cost-sharing payments, and low-income premium payments. We note,

that this cost is a transfer. More specifically, the identical Rx that was

formerly paid for by enrollees is now being paid for by the Government.

TABLE 20*: TOTAL IMPACTS FOR 2023 THROUGH 2032 WITHOUT APPLICATION TO APPLICABLE DRUGS IN COVERAGE GAP

	Total (in \$ billions)	Per Member-Per-Year 2023–2032^[1]	Percent Change
Beneficiary Costs (K)	(\$21.30)	(\$36.66)	-2%
Cost-Sharing (I)	(\$33.10)	(\$57.03)	-6%
Premium (J)	\$11.80	\$20.37	5%
Government Costs	\$40.00	\$69.17	3%
Direct Payment (D)	\$76.70	\$132.47	83%
Reinsurance (E)	(\$15.80)	(\$27.27)	-2%
LI Cost-Sharing (F)	(\$24.40)	(\$42.15)	-5%
LI Premium (G)	\$3.50	\$6.13	7%
Manufacturer Gap Discount (M)	(\$14.60)	(\$25.19)	-6%

*Negative numbers indicate savings; positive numbers equal costs. Minor discrepancies between the sums in Tables 16 and 17 are due to rounding.

Note: These values represent the annualized average impacts divided by the average total Part D projected enrollees. Actual impacts will vary depending on beneficiary status and plan.

F. Accounting Statement and Table

In accordance with OMB Circular A–4, Table 21 depicts an accounting

statement summarizing the assessment of the benefits, costs, and transfers associated with this regulatory action.

TABLE 21: ACCOUNTING STATEMENT

Category	Estimate at 7% (In 2022 Dollars)	Estimate at 3% (In 2022 Dollars)	Years Covered	Affected Stakeholders
Net Annualized Monetized Cost (\$ Millions)	3.1	3.1	CYs 2023-2032	MA organizations, Part D sponsors, and contractors for the Federal Government
Net transfers from the Medicare Trust Fund (\$ Millions)	4,341.7	4,564.1	CYs 2023-2032	The transfers in this row combine: (1) transfers arising from the pharmacy price concessions provision from the Medicare Trust Fund to plan enrollees and pharmaceutical manufacturers; and (2) transfers arising from the MOOP provision from the Medicare Trust Fund to States and providers of duals.
Transfers to the United States Treasury (\$ Millions)	26.0	26.5	CYs 2023-2032	The transfers in this row arising from the MLR provision are from MA organizations and Part D sponsors to the United States Treasury.

Table 21 is based on the summary of costs presented in Tables 22 and 23. Tables 22 and 23 reflect all costs in both the COI and RIA sections. This summary table allocates impact by year

and by whether it is a cost or transfer (no provisions of this rule have a savings impact). In all tables, costs are expressed as positive amounts.

However, in the transfer row negative numbers correspond to payments by the government (which in the provisions of this rule may come from the Treasury or Medicare Trust Fund) while positive

numbers indicate savings. There are 3 transfers in this rule: The MOOP provision is a cost to the Medicare Trust Fund (TF) (the corresponding gain to States and providers of duals in equal amounts is not shown in Tables 22 and 23). The MLR provision is a savings to the Treasury (the corresponding loss in equal amount to the plans is not shown in the Tables 22 and 23). The pharmacy price concessions provision incurs a cost to the Medicare Trust Fund, and savings to enrollees and manufacturers.

However, there is a small difference between what the Trust Fund pays and what beneficiaries and manufacturers gain. The difference is due to the assumption that pharmacies will seek to retain a small portion of the current DIR to compensate for differences in cash flow and pricing risk. Therefore, Tables 22 and 23 list separately the impacts on the Trust Fund, the enrollees, and the manufacturers. However, the row “Total transfers from the Trust Fund” only reflects the sum of the Trust Fund

payments for the pharmacy price concessions provision and the MOOP provision (it does not offset this amount by the savings to enrollees and manufacturers). Similarly, Table 21 reflects separately, annualized transfers to the Treasury and annualized transfers from the Trust Fund for the MOOP and pharmacy price concessions provision. Thus, complete detailed amounts on all provisions may be found in Tables 22 and 23.

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TABLE 22: SUMMARY TABLE OF COSTS and TRANSFERS BY PROVISION AND YEAR (\$ MILLIONS)

	2023 Costs	2023 Transfers	2024 Cost	2024 Transfers	2025 Cost	2025 Transfers	2026 Cost	2026 Transfers	2027 Cost	2027 Transfers
Total Costs	2.8		4.2		3.9		2.8		2.8	
Total transfers (United States Treasury)		20.3		21.5		22.9		24.4		25.9
Total Transfers (Medicare Trust Fund)		(40.0)		(3312.0)		(3604.2)		(3933.1)		(4464.2)
MOOP		(40.0)		(43.7)		(47.9)		(52.3)		(56.9)
Enrollee Advisory Committee					1.0		1.0		1.0	-
HRAs			0.0							
Network Adequacy	0.0		0.0		0.0		0.0		0.0	
HIDE, FIDE Definition					0.0					
D-SNP contracts					1.1					
Past Performance					0.0					
Unified Appeals/Grievances	0.0									
Marketing Multi- language insert	0.3		0.3		0.3		0.3		0.3	
MLR Paperwork	2.3		2.3		2.3		2.3		2.3	
MLR Treasury		20.3		21.5		22.9		24.4		25.9
MLR Contractor	0.2		0.2		0.2		0.2		0.2	
Rx PDE Transmission Costs			1.4		0.1		0.1		0.1	
Rx cost to TF (expressed as a negative number)				(3268.3)		(3556.3)		(3880.8)		(4407.2)
Rx Savings Enrollees				1731.1		1882.9		2044.0		2393.0
Rx Savings Manufacturers				1251.6		1368.2		1512.6		1664.3

NOTE: Entries of \$0.0 reflect rounding to tenths of a million. However, the sum of these numbers adds a total of about \$0.1 million and hence these numbers were included. The numbers are obtained by dividing the corresponding numbers in the Summary COI table by 1,000,000. Positive numbers in the cost columns represent costs. In the transfer columns, positive numbers indicate savings to the Federal Government while negative numbers indicate costs to the Federal Government.

TABLE 23: SUMMARY TABLE OF COSTS AND TRANSFERS BY PROVISION AND YEAR (\$ MILLIONS)

	2028 Costs	2028 Transfers	2029 Cost	2029 Transfers	2030 Cost	2030 Transfers	2031 Cost	2031 Transfers	2032 Cost	2032 Transfers	Raw 10 Year Totals
Total Costs	2.8		2.8		2.8		2.8		2.8		30.6
Total transfers (United States Treasury)		27.5		29.1		30.4		32.6		34	268.6
Total Transfers (Medicare Trust Fund)		(5041.7)		(5670.6)		(6348.9)		(7082.2)		(7869.6)	(47366.6)
MOOP		(63.6)		(69.1)		(74.7)		(80.5)		(86.0)	(614.8)
Enrollee Advisory Committee	1		1		1		1		1		7.7
HRA											0.0
Network Adequacy	0.0		0.0		0.0		0.0		0.0		0.0
HIDE, FIDE Definition											
D-SNP contracts											1.1
Past Performance											
Unified Appeals/Grievances											
Marketing Multi- language insert	0.3		0.3		0.3		0.3		0.3		3.1
MLR Paperwork	2.3		2.3		2.3		2.3		2.3		22.9
MLR Treasury		27.5		29.1		30.4		32.6		34	268.6
MLR Contractor	0.2		0.2		0.2		0.2		0.2		1.6
Rx Admin	0.1		0.1		0.1		0.1		0.1		1.9
Rx cost to TF (expressed as a negative number)		(4978.1)		(5601.4)		(6274.2)		(7001.7)		(7783.6)	(46751.8)
Rx Savings Enrollees		2775.0		3195.0		3652.0		4150.3		4690.3	26513.5
Rx Savings Manufacturers		1826.1		2000.6		2185.9		2382.4		2588.9	16780.7

NOTE: Entries of \$0.0 reflect rounding to tenths of a million. However, the sum of these numbers adds a total of about \$0.1 million and hence these numbers were included. The numbers are obtained by dividing the corresponding numbers in the Summary COI table by 1,000,000. Positive numbers in the cost columns represent costs. In the transfer columns, positive numbers indicate savings to the Federal Government while negative numbers indicate costs to the Federal Government.

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F. Conclusion

The previous analysis, together with the preceding preamble, provides an RIA. This rule at an annualized average cost of 3.1 million, during the first 10 years after implementation, provides efficiencies and improves marketing and communications, past performance measures, Star Ratings, network adequacy, medical loss ratio reporting, requirements during disasters or public emergencies, D-SNP program, MOOP, as well as cost efficiencies to enrollees for prescription drugs. Additionally, there are a variety of transfers to and from the Federal Government (the Medicare Trust Fund and the United States Treasury) which in aggregate will increase dollar spending by \$4.3 to \$4.5 billion annually. We estimate that this rule generates \$2.0 million in annualized costs, discounted at 7 percent relative to year 2016, over an infinite time horizon.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 22, 2022.

List of Subjects**42 CFR Part 417**

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the interim rule amendments to 42 CFR 417.472, 422.152, 422.166, 422.252, 423.182, and 423.186, which published at 85 FR 19230 (April 6, 2020) and 85 FR 54820 (September 2, 2020), are adopted as final and the Centers for Medicare & Medicaid Services further amends 42 CFR chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 422.2 is amended by—

- a. In the definition of “Fully integrated dual eligible special needs plan”:
- i. Revising paragraphs (2) and (3);
- ii. Removing the period at the end of paragraph (4) and adding a semicolon in its place; and
- iii. Adding paragraphs (5) and (6); and
- b. Revising the definition of “Highly integrated dual eligible special needs plan”.

The revisions and additions read as follows:

§ 422.2 Definitions.

* * * * *

Fully integrated dual eligible special needs plan * * *

(2) Whose capitated contract with the State Medicaid agency requires coverage of the following benefits, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a fully integrated dual eligible special needs plan (FIDE SNP) in the State, except as approved by CMS under § 422.107(g) and (h):

- (i) Primary care and acute care, and for plan year 2025 and subsequent years 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;
- (ii) Long-term services and supports, including coverage of nursing facility services for a period of at least 180 days during the plan year;
- (iii) For plan year 2025 and subsequent years, behavioral health services;
- (iv) For plan year 2025 and subsequent years, home health services as defined in § 440.70 of this chapter; and
- (v) For plan year 2025 and subsequent years, medical supplies, equipment, and appliances, as described in § 440.70(b)(3) of this chapter;

(3) That coordinates the delivery of covered Medicare and Medicaid services using aligned care management and specialty care network methods for high-risk beneficiaries;

* * * * *

(5) For plan year 2025 and subsequent years, that has exclusively aligned enrollment; and

(6) For plan year 2025 and subsequent years, whose capitated contract with the State Medicaid agency covers the entire

service area for the dual eligible special needs plan.

* * * * *

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) The capitated contract is between the State Medicaid agency and—

- (i) The MA organization; or
- (ii) The MA organization’s parent organization, or another entity that is owned and controlled by its parent organization;

(2) The capitated contract requires coverage of the following benefits, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a highly integrated dual eligible special needs plan (HIDE SNP) in the State, except as approved by CMS under § 422.107(g) or (h):

(i) Long-term services and supports, including community-based long-term services and supports and some days of coverage of nursing facility services during the plan year; or

(ii) Behavioral health services; and

(3) For plan year 2025 and subsequent years, the capitated contract covers the entire service area for the dual eligible special needs plan.

* * * * *

■ 3. Section 422.100 is amended by—

■ a. In paragraph (f)(4), removing the word “incurred” and adding in its place the word “accrued”.

■ b. In paragraph (f)(5)(iii), removing the word “incurred” and adding in its place the word “accrued”.

■ c. Revising paragraphs (m)(1) introductory text and (m)(2) introductory text;

■ d. Removing paragraph (m)(2)(ii)(B);

■ e. Redesignating paragraph (m)(2)(ii)(A) as paragraph (m)(2)(ii);

■ f. Revising paragraphs (m)(3) and (4) and (m)(5)(i); and

■ g. Adding paragraph (m)(6).

The revisions and addition read as follows:

§ 422.100 General requirements.

* * * * *

(m) * * *

(1) *Access to covered benefits during disasters or emergencies.* When a disaster or emergency is declared as described in paragraph (m)(2) of this section and there is disruption of access to health care as described in paragraph (m)(6) of this section, an MA organization offering an MA plan must, until the end date specified in paragraph (m)(3) of this section occurs,

ensure access to covered benefits in the following manner:

* * * * *

(2) *Declarations of disasters or emergencies.* A declaration of a disaster or emergency will identify the geographic area affected by the event and may be made as one of the following:

* * * * *

(3) *End of the special requirements for the disaster or emergency.* An MA organization must continue furnishing access to benefits as specified in paragraphs (m)(1)(i) through (iv) of this section for 30 days after the conditions described in paragraph (m)(3)(i) or (ii) of this section occur with respect to all applicable emergencies or after the condition described in paragraph (m)(3)(iii) of this section occurs, whichever is earlier:

(i) All sources that declared a disaster or emergency that include the service area declare an end.

(ii) No end date was identified as described in paragraph (m)(3)(i) of this section, and all applicable emergencies or disasters declared for the area have ended, including through expiration of the declaration or any renewal of such declaration.

(iii) There is no longer a disruption of access to health care as defined in paragraph (m)(6) of this section.

(4) *MA plans unable to operate.* An MA plan that cannot resume normal operations by the end of the disaster or emergency as described in paragraph (m)(3)(i) or (ii) of this section must notify CMS.

(5) * * *

(i) Indicate the terms and conditions of payment during the disaster or emergency for non-contracted providers furnishing benefits to plan enrollees residing in the affected service area(s).

* * * * *

(6) *Disruption of access to health care.* A disruption of access to health care for the purpose of paragraph (m) of this section is an interruption or interference in the service area (as defined at § 422.2) such that enrollees do not have the ability to access contracted providers or contracted providers do not have the ability to provide needed services to enrollees, resulting in MA plans failing to meet the normal prevailing patterns of community health care delivery in the service area under § 422.112(a).

■ 4. Section 422.101 is amended by—

■ a. In paragraph (d)(4), removing “(d)(3)” and “incurred” and adding in their places “(3)” and “accrued”, respectively.

■ b. Revising paragraph (f)(1)(i).

The revision reads as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(f) * * *

(1) * * *

(i) Conduct a comprehensive initial health risk assessment of the individual’s physical, psychosocial, and functional needs as well as annual health risk reassessment, using a comprehensive risk assessment tool that CMS may review during oversight activities, and ensure that the results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individuals’ individualized care plan as required under paragraph (f)(1)(ii) of this section. Beginning in 2024, the comprehensive risk assessment tool must include one or more questions from a list of screening instruments specified by CMS in sub-regulatory guidance on each of the following domains:

- (A) Housing stability;
- (B) Food security; and
- (C) Access to transportation.

* * * * *

■ 5. Section 422.107 is amended by—

■ a. Revising the section heading and paragraphs (c)(6) and (d);

■ b. Redesignating paragraph (e) as paragraph (i); and

■ c. Adding new paragraph (e) and paragraphs (f) through (h).

The revisions and additions read as follows:

§ 422.107 Requirements for dual eligible special needs plans.

* * * * *

(c) * * *

(6) The verification of an enrollee’s Medicaid eligibility.

* * * * *

(d) *Additional minimum contract requirement.* (1) For any dual eligible special needs plan that is not a fully integrated or highly integrated dual eligible special needs plan, except as specified in paragraph (d)(2) of this section, the contract must also stipulate that, for the purpose of coordinating Medicare and Medicaid-covered services between settings of care, the SNP notifies, or arranges for another entity or entities to notify, the State Medicaid agency, individuals or entities designated by the State Medicaid agency, or both, of hospital and skilled nursing facility admissions for at least one group of high-risk full-benefit dual eligible individuals, identified by the State Medicaid agency. The State Medicaid agency must establish the timeframe(s) and method(s) by which notice is provided. In the event that a

SNP authorizes another entity or entities to perform this notification, the SNP must retain responsibility for complying with the requirement in this paragraph (d)(1).

(2) For a dual eligible special needs plan that, under the terms of its contract with the State Medicaid agency, only enrolls beneficiaries who are not entitled to full medical assistance under a State plan under title XIX of the Act, paragraph (d)(1) of this section does not apply if the SNP operates under the same parent organization and in the same service area as a dual eligible special needs plan limited to beneficiaries with full medical assistance under a State plan under title XIX of the Act that meets the requirements at paragraph (d)(1) of this section.

(e) *Additional opportunities in certain integrated care programs.* (1) CMS facilitates operationalization as described in paragraphs (e)(2) and (3) of this section if a State Medicaid agency requires MA organizations offering dual eligible special needs plans with exclusively aligned enrollment to do both of the following:

(i) Apply for, and seek CMS approval to establish and maintain, one or more MA contracts that only include one or more dual eligible special needs plans with a service area limited to that State.

(ii) Use required materials that integrate Medicare and Medicaid content, including at a minimum the Summary of Benefits, Formulary, and combined Provider and Pharmacy Directory that meets Medicare and Medicaid managed care requirements consistent with applicable regulations in parts 422, 423, and 438 of this chapter.

(2) The requirements, processes, and procedures applicable to dual eligible special needs plans and the MA program, including for applications, bids, and contracting procedures under §§ 422.250 through 422.530, remain applicable. Because implementation of the contract provisions described in paragraph (e)(1) of this section may require administrative steps that cannot be completed between reviewing the contract and the start of the plan year, CMS begins good faith work following receipt of a letter from the State Medicaid agency indicating intent to include the provisions described in paragraph (e)(1) of this section in a future contract year and collaborate with CMS on implementation.

(3) When the conditions of paragraph (e)(1) of this section are met—

(i) Following a State request, CMS grants access for State Medicaid agency officials to the Health Plan Management

System (HPMS) (or its successor) for purposes of oversight and information-sharing related to the MA contract(s) described in paragraph (e)(1)(i) of this section, as long as State Medicaid agency officials agree to protect the proprietary nature of information to which the State Medicaid agency may not otherwise have direct access. State access to the Health Plan Management System (or its successor) is subject to compliance with HHS and CMS policies and standards and with applicable laws in the use of HPMS data and the system's functionality. CMS may terminate a State official's access to the Health Plan Management System (or its successor) if any policy is violated or if information is not adequately protected; and

(ii) CMS coordinates with States on program audits, including information-sharing on major audit findings and coordination of audits schedules for the D-SNPs subject to paragraph (e)(1) of this section.

(f) *Enrollee advisory committee.* Any MA organization offering one or more D-SNPs in a State must establish and maintain one or more enrollee advisory committees that serve the D-SNPs offered by the MA organization in that State.

(1) The enrollee advisory committee must include at least a reasonably representative sample of the population enrolled in the dual eligible special needs plan or plans, or other individuals representing those enrollees, and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.

(2) The enrollee advisory committee may also advise managed care plans that serve D-SNP enrollees under title XIX of the Act offered by the same parent organization as the MA organization offering the D-SNP.

(g) *Permissible carve-outs of long-term services and supports for FIDE SNPs and HIDE SNPs.* A plan meets the FIDE SNP or HIDE SNP definition at § 422.2, even if its contract with the State Medicaid agency for the provision of services under title XIX of the Act has carve-outs of long-term services and supports, as approved by CMS, that—

(1) Apply primarily to a minority of the beneficiaries eligible to enroll in the dual eligible special needs plan who use long-term services and supports; or

(2) Constitute a small part of the total scope of long-term services and supports provided to the majority of beneficiaries eligible to enroll in the dual eligible special needs plan.

(h) *Permissible carve-outs of behavioral health services for FIDE SNPs and HIDE SNPs.* A plan meets the FIDE SNP or HIDE SNP definition at § 422.2, even if its contract with the State Medicaid agency for the provision of services under title XIX of the Act has carve-outs of behavioral health services, as approved by CMS, that—

(1) Apply primarily to a minority of the beneficiaries eligible to enroll in the dual eligible special needs plan who use behavioral health services; or

(2) Constitute a small part of the total scope of behavioral health services provided to the majority of beneficiaries eligible to enroll in the dual eligible special needs plan.

* * * * *

■ 6. Section 422.116 is amended by revising paragraph (a)(1)(ii) and adding paragraph (d)(7) to read as follows:

§ 422.116 Network adequacy.

(a) * * *

(1) * * *

(ii) Beginning with contract year 2024, an applicant for a new or expanding service area must demonstrate compliance with this section as part of its application for a new or expanding service area and CMS may deny an application on the basis of an evaluation of the applicant's network for the new or expanding service area.

* * * * *

(d) * * *

(7) *New or expanding service area applicants.* Beginning with contract year 2024, an applicant for a new or expanding service area receives a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the contracted network in the pending service area, at the time of application and for the duration of the application review. In addition, applicants may use a Letter of Intent (LOI), signed by both the MA organization (MAO) and the provider or facility with which the MAO has started or intends to negotiate, in lieu of a signed contract at the time of application and for the duration of the application review, to meet network standards. As part of the network adequacy review process, applicants must notify CMS of their use of LOIs to meet network standards in lieu of a signed contract and submit copies upon request and in the form and manner directed by CMS. At the beginning of the applicable contract year, the credit and the use of LOIs no longer apply and if the application is approved, the MA organization must be in full compliance with this section, including having

signed contracts with the provider or facility.

* * * * *

§ 422.164 [Amended]

■ 7. Section 422.164 is amended by removing and reserving paragraph (i).

■ 8. Section 422.166 is amended by—

■ a. Revising paragraph (a)(2)(i);

■ b. Adding paragraph (i)(12); and

■ c. Removing and reserving paragraphs (j)(1)(v) and (j)(2).

The revision and addition read as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and Part D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

(i) * * *

(12) *Special rules for the 2023 Star Ratings only.* For the 2023 Star Ratings only, for measures derived from the Health Outcomes Survey only, CMS does not apply the provisions in paragraph (i)(9) or (10) of this section and CMS does not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms or from the determination of the performance summary and variance thresholds for the Reward Factor.

* * * * *

■ 9. Section 422.252 is amended by revising the definition of “New MA plan” to read as follows:

§ 422.252 Terminology.

* * * * *

New MA plan means a MA contract offered by a parent organization that has

not had another MA contract in the previous 3 years. For purposes of 2022 quality bonus payments based on 2021 Star Ratings only, new MA plan means an MA contract offered by a parent organization that has not had another MA contract in the previous 4 years.

* * * * *

■ 10. Section 422.502 is amended by revising paragraphs (b)(1) introductory text and (b)(1)(i) to read as follows:

§ 422.502 Evaluation and determination procedures.

* * * * *

(b) * * *

(1) Except as provided in paragraphs (b)(2) through (4) of this section, if an MA organization fails during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part C program under any current or prior contract with CMS under title XVIII of the Act, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant does any of the following:

(A) Was subject to the imposition of an intermediate sanction under subpart O of this part or a determination by CMS to prohibit the enrollment of new enrollees in accordance with § 422.2410(c), with the exception of a sanction imposed under § 422.752(d).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(b)(14).

(C) Filed for or is currently in State bankruptcy proceedings.

(D) Received any combination of Part C or D summary ratings of 2.5 or less in both of the two most recent Star Rating periods, as identified in § 422.166.

(E) Met or exceeded 13 points for compliance actions for any one contract.

(1) CMS determines the number of points each MA organization accumulated during the performance period for compliance actions based on the following point values:

(i) Each corrective action plan issued during the performance period under § 422.504(m) counts for 6 points.

(ii) Each warning letter issued during the performance period under § 422.504(m) counts for 3 points.

(iii) Each notice of noncompliance issued during the performance period under § 422.504(m) counts for 1 point.

(2) CMS adds all the point values for each MA organization to determine if any organization meets CMS' identified threshold.

* * * * *

■ 11. Section 422.503 is amended by revising paragraphs (b)(5)(i) and (ii) to read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(5) * * *

(i) Not accept, or share a corporate parent organization owning a controlling interest in an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan that is not a dual eligible special needs plan.

(ii) Not accept, or be either the parent organization owning a controlling interest of or subsidiary of an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan that is not a dual eligible special needs plan.

* * * * *

■ 12. Section 422.504 is amended by revising paragraph (m) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(m) Issuance of compliance actions for failure to comply with the terms of the contract. The MA organization acknowledges that CMS may take compliance actions as described in this section or intermediate sanctions as defined in subpart O of this part.

(1) CMS may take compliance actions as described in paragraph (m)(3) of this section if it determines that the MA organization has not complied with the terms of a current or prior Part C contract with CMS.

(i) CMS may determine that an MA organization is out of compliance with a Part C requirement when the organization fails to meet performance standards articulated in the Part C statutes, regulations in this chapter, or guidance.

(ii) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that an MA organization is out of compliance when its performance in fulfilling Part C requirements represents an outlier relative to the performance of other MA organizations.

(2) CMS bases its decision on whether to issue a compliance action and what

level of compliance action to take on an assessment of the circumstances surrounding the noncompliance, including all of the following:

(i) The nature of the conduct.

(ii) The degree of culpability of the MA organization.

(iii) The adverse effect to beneficiaries which resulted or could have resulted from the conduct of the MA organization.

(iv) The history of prior offenses by the MA organization or its related entities.

(v) Whether the noncompliance was self-reported.

(vi) Other factors which relate to the impact of the underlying noncompliance or the lack of the MA organization's oversight of its operations that contributed to the noncompliance.

(3) CMS may take one of three types of compliance actions based on the nature of the noncompliance.

(i) Notice of noncompliance. A notice of noncompliance may be issued for any failure to comply with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section.

(ii) Warning letter. A warning letter may be issued for serious and/or continued noncompliance with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section and as assessed in accordance with paragraph (m)(2) of this section.

(iii) Corrective action plan. (A) Corrective action plans are requested for particularly serious or continued noncompliance with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section and as assessed in accordance with paragraph (m)(2) of this section.

(B) CMS issues a corrective action plan if CMS determines that the MA organization has repeated or not corrected noncompliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its noncompliance, or must implement a detailed plan to correct the underlying causes of the noncompliance.

* * * * *

■ 13. Section 422.530 is amended by revising paragraph (c)(4) to read as follows:

§ 422.530 Plan crosswalks.

* * * * *

(c) * * *

(4) When—

(i) A renewing D–SNP has another new or renewing D–SNP, and the two D–SNPs are offered to different populations, enrollees who are no longer eligible for their current D–SNP may be moved into the other new or renewing D–SNP offered by the same MA organization if they meet the eligibility criteria for the new or renewing D–SNP and CMS determines it is in the best interest of the enrollees to move to the new or renewing D–SNP in order to promote access to and continuity of care for enrollees relative to the absence of a crosswalk exception. For the crosswalk exception in this paragraph (c)(4)(i), CMS does not permit enrollees to be moved between different contracts; or

(ii) An MA organization creates a new MA contract when required by a State as described in § 422.107(e), eligible enrollees may be moved from the existing D–SNP that is non-renewing, reducing its service area, or has its eligible population newly restricted by a State, to a D–SNP offered under the D–SNP-only contract, which must be of the same plan type operated by the same parent organization. For the crosswalk exception in this paragraph (c)(4)(ii), CMS permits enrollees to be moved between different contracts.

* * * * *

■ 14. Section 422.561 is amended by revising the definition of “Applicable integrated plan” to read as follows:

§ 422.561 Definitions.

* * * * *

Applicable integrated plan means either of the following:

(1) *Before January 1, 2023.* (i) A fully integrated dual eligible special needs plan with exclusively aligned enrollment or a highly integrated dual eligible special needs plan with exclusively aligned enrollment; and

(ii) The Medicaid managed care organization, as defined in section 1903(m) of the Act, through which such dual eligible special needs plan, its parent organization, or another entity that is owned and controlled by its parent organization covers Medicaid services for dually eligible individuals enrolled in such dual eligible special needs plan and such Medicaid managed care organization.

(2) *On or after January 1, 2023.* (i)(A) A fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan with exclusively aligned enrollment; and

(B) The Medicaid managed care organization, as defined in section 1903(m) of the Act, through which such dual eligible special needs plan, its

parent organization, or another entity that is owned and controlled by its parent organization covers Medicaid services for dually eligible individuals enrolled in such dual eligible special needs plan and such Medicaid managed care organization; or

(ii) A dual eligible special needs plan and affiliated Medicaid managed care plan where—

(A) The dual special needs plan, by State policy, has enrollment limited to those beneficiaries enrolled in a Medicaid managed care organization as described in paragraph (2)(ii)(B) of this definition;

(B) 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; and

(1) A Medicaid agency; or

(2) A Medicaid managed care organization as defined in section 1903(m) of the Act that contracts with the Medicaid agency; and

(C) Through the capitated contract described in paragraph (2)(ii)(B) of this definition, 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 of this chapter, medical supplies, equipment, and appliances as described in § 440.70(b)(3) of this chapter, or nursing facility services are covered for the enrollees.

* * * * *

■ 15. Section 422.629 is amended by—

■ a. Revising paragraph (d);

■ b. In paragraph (k)(4)(ii), removing the phrase “integrated organization determination decision” and adding in its place the phrase “integrated reconsideration determination”;

■ c. Revising paragraph (l)(1); and

■ d. Adding paragraph (l)(4).

The revisions and addition read as follows:

§ 422.629 General requirements for applicable integrated plans.

* * * * *

(d) *Evidence.* The applicable integrated plan must do the following:

(1) Provide the enrollee—

(i) A reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments for integrated grievances, and integrated reconsiderations; and

(ii) Information on how evidence and testimony should be presented to the plan.

(2) Inform the enrollee of the limited time available for presenting evidence sufficiently in advance of the resolution timeframe for appeals as specified in this section if the case is being considered under an expedited timeframe for the integrated grievance or integrated reconsideration.

* * * * *

(l) * * *

(1) The following individuals or entities can request an integrated grievance, integrated organization determination, and integrated reconsideration, and are parties to the case:

(i) The enrollee.

(ii) The enrollee’s representative, including any person authorized under State law.

* * * * *

(4) The following individuals or entities may request an integrated reconsideration and are parties to the case:

(i) An assignee of the enrollee (that is, a physician or other provider who has furnished or intends to furnish a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service).

(ii) Any other provider or entity (other than the applicable integrated plan) who has an appealable interest in the proceeding.

■ 16. Section 422.631 is amended by adding paragraph (d)(3) to read as follows:

§ 422.631 Integrated organization determinations.

* * * * *

(d) * * *

(3) *Timeframe for requests for payment.* The applicable integrated plan must process requests for payment according to the “prompt payment” provisions set forth in § 422.520.

* * * * *

■ 17. Section 422.633 is amended by revising the section heading and paragraphs (e)(1) and (f)(3)(i) introductory text to read as follows:

§ 422.633 Integrated reconsiderations.

* * * * *

(e) * * *

(1) Applicable integrated plans must accept requests to expedite integrated reconsiderations from either of the following:

(i) An enrollee.

(ii) A provider making the request on behalf of an enrollee, when the request is not a request for expedited payment.

* * * * *

(f) * * *
(3) * * *

(i) The applicable integrated plan may extend the timeframe for resolving any integrated reconsideration other than those concerning Part B drugs by 14 calendar days if—

* * * * *

■ 18. Section 422.634 is amended by revising paragraph (d) to read as follows:

§ 422.634 Effect.

* * * * *

(d) *Services not furnished while the appeal is pending.* (1) If an applicable integrated plan reverses its decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than the earlier of—

(i) 72 hours from the date it reverses its decision; or

(ii)(A) With the exception of a Part B drug, 30 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration (or no later than upon expiration of an extension described in § 422.633(f)); or

(B) For a Part B drug, 7 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration.

(2) For a Medicaid benefit, if a State fair hearing officer reverses an applicable integrated plan's integrated reconsideration decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

(3) Reversals by the Part C independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council must be effectuated under same timelines applicable to other MA plans as specified in §§ 422.618 and 422.619.

* * * * *

■ 19. Section 422.2260 is amended by adding the definition of "Third-party marketing organization (TPMO)" in alphabetical order to read as follows:

§ 422.2260 Definitions.

* * * * *

Third-party marketing organization (TPMO) 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 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 plan or an MA plan's FDR.

■ 20. Section 422.2265 is amended by adding paragraphs (b)(13) and (14) to read as follows:

§ 422.2265 Websites.

* * * * *

(b) * * *

(13) Instructions on how to appoint a representative including a link to the downloadable version of the CMS Appointment of Representative Form (CMS Form-1696).

(14) Enrollment instructions and forms.

* * * * *

■ 21. Section 422.2267 is amended by—

■ a. Redesignating paragraphs (e)(30) through (38) as paragraphs (e)(32) through (40).

■ b. Adding new paragraphs (e)(30) and (31) and paragraph (e)(41).

The additions read as follows:

§ 422.2267 Required materials and content.

* * * * *

(e) * * *

(30) *Member ID card.* The member ID card is a model communications material that plans must provide to enrollees as required under § 422.111(i). The member ID card—

(i) Must be provided to new enrollees within ten calendar days from receipt of CMS confirmation of enrollment or by the last day of the month prior to the plan effective date, whichever is later;

(ii) Must include the plan's—

(A) Website address;

(B) Customer service number (the member ID card is excluded from the hours of operations requirement under § 422.2262(c)(1)(i)); and

(C) Contract/PBP number;

(iii) Must include, if issued for a PPO and PFFS plan, the phrase "Medicare limiting charges apply.";

(iv) May not use a member's Social Security number (SSN), in whole or in part;

(v) Must be updated whenever information on a member's existing card

changes; in such cases an updated card must be provided to the member;

(vi) Is excluded from the translation requirement under paragraph (a)(2) of this section; and

(vii) Is excluded from the 12-point font size requirement under paragraph (a)(1) of this section.

(31) *Multi-language insert (MLI).* This is a standardized communications material which states, "We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who speaks [language] can help you. This is a free service." in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

(i) Additional languages that meet the 5-percent service area threshold, as required under paragraph (a)(2) of this section, must be added to the MLI used in that service area. A plan may also opt to include in the MLI any additional language that do not meet the 5-percent service area threshold, where it determines that this inclusion would be appropriate.

(ii) The MLI must be provided with all required materials under paragraph (e) of this section.

(iii) The MLI may be included as a part of the required material or as a standalone material in conjunction with the required material.

(iv) When used as a standalone material, the MLI may include organization name and logo.

(v) When mailing multiple required materials together, only one MLI is required.

(vi) The MLI may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

* * * * *

(41) *Third-party marketing organization disclaimer.* This is standardized content. The disclaimer consists of the 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 MA organization must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 422.2260, that sells plans on behalf of more than one MA organization unless the TPMO sells all commercially available MA plans in a given service area.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any marketing materials, including print materials and television advertisements, developed, used or distributed by the TPMO.

■ 22. Section 422.2274 is amended by revising the section heading and adding paragraph (g) to read as follows:

§ 422.2274 Agent, broker, and other third-party requirements.

* * * * *

(g) *TPMO oversight.* In addition to any applicable FDR requirements under § 422.504(i), when doing business with a TPMO, either directly or indirectly through a downstream entity, MA plans must implement the following as a part of their oversight of TPMOs:

(1) When a TPMO is not otherwise an FDR, the MA organization is responsible for ensuring that the TPMO adheres to any requirements that apply to the MA plan.

(2) Contracts, written arrangements, and agreements between the TPMO and an MA plan, or between the TPMO and an MA plan's FDR, must ensure the TPMO:

(i) Discloses to the MA organization any subcontracted relationships used for marketing, lead generation, and enrollment.

(ii) Records all calls with beneficiaries in their entirety, including the enrollment process.

(iii) Reports to plans monthly any staff disciplinary actions or violations of any requirements that apply to the MA plan associated with beneficiary interaction to the plan.

(iv) Uses the TPMO disclaimer as required under § 422.2267(e)(41).

(3) Ensure that the TPMO, when conducting lead generating activities, either directly or indirectly for an MA organization, must, when applicable:

(i) Disclose to the beneficiary that his or her 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 he or she is being transferred to a licensed

agent who can enroll him or her into a new plan.

■ 23. Section 422.2460 is amended by revising paragraphs (a), (b) introductory text, and (d) and adding paragraph (e) to read as follows:

§ 422.2460 Reporting requirements.

(a) Except as provided in paragraph (b) of this section, for each contract year, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, a report that includes the data needed by the MA organization to calculate and verify the medical loss ratio (MLR) and remittance amount, if any, for each contract under this part, including the amount of incurred claims for original Medicare covered benefits, supplemental benefits, and prescription drugs; total revenue; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; and any remittance owed to CMS under § 422.2410.

(b) For contract years 2018 through 2022, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, the following information:

* * * * *

(d) Subject to paragraph (e) of this section, the MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

(e) With respect to an MA organization that has already submitted to CMS the MLR report or MLR data required under paragraph (a) or (b) of this section, respectively, for a contract for a contract year, paragraph (d) of this section does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. Such resubmission must be authorized or directed by CMS, and upon receipt and acceptance by CMS, is regarded as the contract's MLR report or data submission for the contract year for purposes of this subpart.

■ 24. Section 422.2490 is amended by redesignating paragraph (b)(2) as paragraph (b)(2)(i) and adding paragraph (b)(2)(ii) to read as follows:

§ 422.2490 Release of Part C MLR data.

* * * * *

(b) * * *

(2) * * *

(ii) Amounts that are reported as expenditures for a specific type of supplemental benefit, where the entire amount that is reported represents costs incurred by the only plan under the contract that offers that benefit.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 25. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w-101 through 1395w-152, and 1395hh.

■ 26. Section 423.100 is amended by adding in alphabetical order the definition of "Price concession" to read as follows:

§ 423.100 Definitions.

* * * * *

Price concession means any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Examples of price concessions include but are not limited to: Discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.

* * * * *

■ 27. Effective January 1, 2024, § 423.100 is further amended by removing the definition of "Negotiated prices" and adding in alphabetical order the definition of "Negotiated price" to read as follows:

§ 423.100 Definitions.

* * * * *

Negotiated price means the price for a covered Part D drug that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;

(2) Meets all of the following:

(i) Includes all price concessions (as defined in this section) from network pharmacies or other network providers;

(ii) Includes any dispensing fees; and

(iii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices; and

(3) Is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor passes through to Part D enrollees at the point of sale.

* * * * *

§ 423.184 [Amended]

■ 28. Section 423.184 is amended by removing and reserving paragraph (i).

■ 29. Section 423.186 is amended by—

■ a. Revising paragraphs (a)(2)(i) and (i)(9); and

■ b. Removing and reserving paragraph (j)(1)(iv).

The revisions read as follows:

§ 423.186 Calculation of Star Ratings.

- (a) * * *
(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years of the program.

* * * * *

- (i) * * *

(9) Special rules for the 2022 Star Ratings only. For the 2022 Star Ratings only, CMS will not apply the provisions in paragraph (i)(7) or (8) of this section and CMS will not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms or from the determination of the performance summary and variance thresholds for the Reward Factor.

* * * * *

■ 30. Section 423.503 is amended by revising the section heading and paragraphs (b)(1) introductory text and (b)(1)(i) to read as follows:

§ 423.503 Evaluation and determination procedures.

* * * * *

- (b) * * *

(1) Except as provided in paragraphs (b)(2) through (4) of this section, if a Part D plan sponsor fails during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part D program under any current or prior contract with CMS under title XVIII of the Act CMS may deny an application based on the applicant's failure to comply with the requirements of the Part D program under any current or prior contract with CMS even if the

applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant:

(A) Was subject to the imposition of an intermediate sanction under subpart O of this part, or a determination by CMS to prohibit the enrollment of new enrollees under § 423.2410(c).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 423.505(b)(23).

(C) Filed for or is currently under state bankruptcy proceedings.

(D) Received any combination of Part C or Part D summary ratings of 2.5 or less in both of the two most recent Star Rating periods, as identified in § 423.186.

(E) Met or exceeded 13 points for compliance actions on any one contract.

(1) CMS determines the number of points each Part D plan sponsor accumulated during the performance period for compliance actions based on the following point values:

(i) Each corrective action plan issued during the performance period under § 423.505(n) counts for 6 points.

(ii) Each warning letter issued during the performance period under § 423.505(n) counts for 3 points.

(iii) Each notice of noncompliance issued during the performance period under § 423.505(n) counts for 1 point.

(2) CMS adds all the point values for each Part D plan sponsor to determine if any organization meets CMS' identified threshold.

* * * * *

■ 31. Section 423.505 is amended by revising paragraph (n) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(n) Issuance of compliance actions for failure to comply with the terms of the contract. The Part D plan sponsor acknowledges that CMS may take compliance actions as described in this section or intermediate sanctions as defined in subpart O of this part.

(1) CMS may take compliance actions as described in paragraph (n)(3) of this section if it determines that the Part D plan sponsor has not complied with the terms of a current or prior Part D contract with CMS.

(i) CMS may determine that a Part D plans sponsor is out of compliance with a Part D requirement when the organization fails to meet performance standards articulated in the Part D

statutes, regulations in this chapter, or guidance.

(ii) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that a Part D plan sponsor is out of compliance when its performance in fulfilling Part D requirements represents an outlier relative to the performance of other Part D plan sponsors.

(2) CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the noncompliance, including all of the following:

(i) The nature of the conduct.

(ii) The degree of culpability of the Part D plan sponsor.

(iii) The adverse effect to beneficiaries which resulted or could have resulted from the conduct of the Part D plan sponsor.

(iv) The history of prior offenses by the Part D plan sponsor or its related entities.

(v) Whether the noncompliance was self-reported.

(vi) Other factors which relate to the impact of the underlying noncompliance or the lack of the Part D plan sponsor's oversight of its operations that contributed to the noncompliance.

(3) CMS may take one of three types of compliance actions based on the nature of the noncompliance.

(i) Notice of noncompliance. A notice of noncompliance may be issued for any failure to comply with the requirements of the Part D plan sponsor's current or prior Part D contract with CMS, as described in paragraph (n)(1) of this section.

(ii) Warning letter. A warning letter may be issued for serious and/or continued noncompliance with the requirements of the Part D plan sponsor's current or prior Part D contract with CMS, as described in paragraph (n)(1) of this section and as assessed in accordance with paragraph (n)(2) of this section.

(iii) Corrective action plan. (A) Corrective action plans are issued for particularly serious and/or continued noncompliance with the requirements of the Part D plan sponsors' current or prior Part D contract with CMS, as described in paragraph (n)(1) of this section and as assessed in accordance with paragraph (n)(2) of this section.

(B) CMS issues a corrective action plan if CMS determines that the Part D plan sponsor has repeated or not corrected noncompliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its noncompliance,

and/or must implement a detailed plan to correct the underlying causes of the noncompliance.

* * * * *

■ 32. Section 423.2260 is amended by adding the definition of “Third-party marketing organization (TPMO)” in alphabetical order to read as follows:

§ 423.2260 Definitions.

* * * * *

Third-party marketing organization (TPMO) are 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 a Part D plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § 423.4, but may also be entities that are not FDRs but provide services to a Part D sponsor or a Part D sponsor’s FDR.

■ 33. Section 423.2265 is amended by adding paragraphs (b)(14) and (15) to read as follows:

§ 423.2265 Websites.

* * * * *

(b) * * *

(14) Instructions on how to appoint a representative including a link to the downloadable version of the CMS Appointment of Representative Form (CMS Form-1696).

(15) Enrollment instructions and forms.

* * * * *

■ 34. Section 423.2267 is amended by—

■ a. Redesignating paragraphs (e)(32) through (37) as paragraphs (e)(34) through (39); and

■ b. Adding new paragraphs (e)(32) and (33) and paragraphs (e)(40) and (41).

The additions read as follows:

§ 423.2267 Required materials and content.

* * * * *

(e) * * *

(32) *Member ID card*. The member ID card is a model communications material that plans must provide to enrollees as required under

§ 423.128(d)(2). The member ID card—

(i) Must be provided to new enrollees within 10 calendars days from receipt of CMS confirmation of enrollment or by the last day of month prior to the plan effective date, whichever is later;

(ii) Must include the Part D sponsor’s—

(A) Website address;

(B) Customer service number (the member ID card is excluded from the

hours of operations requirement under § 423.2262(c)(1)(i)); and

(C) Contract/PBP number;

(iii) Must include, if issued for a preferred provider organization (PPO) and PFFS plan, the phrase “Medicare limiting charges apply.”;

(iv) May not use a member’s Social Security number (SSN), in whole or in part;

(v) Must be updated whenever information on a member’s existing card changes; in such cases an updated card must be provided to the member;

(vi) Is excluded from the translation requirement under paragraph (a)(2) of this section; and

(vii) Is excluded from the 12-point font size requirement under paragraph (a)(1) of this section.

(33) *Multi-language insert (MLI)*. This is a standardized communications material which states, “We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who speaks [language] can help you. This is a free service.” in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

(i) Additional languages that meet the 5-percent service area threshold, as required under paragraph (a)(2) of this section, must be added to the MLI used in that service area. A plan may also opt to include in the MLI any additional language that do not meet the 5-percent service area threshold, where it determines that this inclusion would be appropriate.

(ii) The MLI must be provided with all required materials under paragraph (e) of this section.

(iii) The MLI may be included as a part of the required material or as a standalone material in conjunction with the required material.

(iv) When used as a standalone, the MLI may include organization name and logo.

(v) When mailing multiple required materials together, only one MLI is required.

(vi) The MLI may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

* * * * *

(40) *Limited access to preferred cost-sharing pharmacies*. This is standardized content that must—

(i) Be used on all materials mentioning preferred pharmacies when there is limited access to preferred pharmacies; and

(ii) Include the following language:

“<insert organization/plan name>’s pharmacy network includes limited lower-cost, preferred pharmacies in <insert geographic area type(s) and state(s) for which plan is an outlier>. The lower costs advertised in our plan materials for these pharmacies may not be available at the pharmacy you use. For up-to-date information about our network pharmacies, including whether there are any lower-cost preferred pharmacies in your area, please call <insert Member Services phone number and TTY> or consult the online pharmacy directory at <insert website>.”

(41) *Third-party marketing organization disclaimer*. This is standardized content. The disclaimer consists of the 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 Part D sponsor must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 423.2260, that sells plans on behalf of more than one Part D sponsor unless the TPMO sells all commercially available Part D plans in a given service area.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary through email, online chat, or other electronic means of communication.

(iv) Prominently displayed on TPMO websites.

(v) Included in any TPMO marketing materials, including print materials and television advertising.

■ 35. Section 423.2274 is amended by revising the section heading and adding paragraph (g) to read as follows:

§ 423.2274 Agent, broker, and other third-party requirements.

* * * * *

(g) *TPMO oversight*. In addition to any applicable FDR requirements under § 423.505(i), when doing business with a TPMO, either directly or indirectly through a downstream entity, Part D sponsor must implement the following as a part of their oversight of TPMOs:

(1) When TPMOs is not otherwise an FDR, the Part D sponsor is responsible for ensuring that the TPMO adheres to any requirements that apply to the Part D sponsor.

(2) Contracts, written arrangements, and agreements between the TPMO and a Part D plan, or between a TPMO and a Part D plan’s FDR, must ensure the TPMO:

(i) Discloses to the plan any subcontracted relationships used for marketing, lead generation, and enrollment.

(ii) Record all calls with beneficiaries in their entirety, including the enrollment process.

(iii) Report to plans monthly any staff disciplinary actions or violations of any requirements that apply to the Part D sponsor associated with beneficiary interaction to the plan.

(iv) Use the TPMO disclaimer as required under § 423.2267(e)(41).

(3) Ensure that 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 his or her information will be provided to a licensed agent for future contact. This disclosure must be provided:

(A) Verbally when communicating with a beneficiary through telephone;

(B) In writing when communicating with a beneficiary through mail or other paper; and

(C) Electronically when communicating with a beneficiary through email, online chat, or other electronic messaging platform.

(ii) When applicable, disclose to the beneficiary that he or she is being transferred to a licensed agent who can enroll him or her into a new plan.

■ 36. Effective January 1, 2024, § 423.2305 is amended by—

■ a. Revising paragraphs (1) and (2) of the definition of “Negotiated price”; and

■ b. Designating the undesignated paragraph following the definition of “Negotiated price” as paragraph (4).

The revisions read as follows:

§ 423.2305 Definitions.

* * * * *

Negotiated price * * *

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;

(i) Includes all price concessions (as defined in § 423.100) from network pharmacies or other network providers; and

(ii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices;

(2) Is reduced by those discounts, direct or indirect subsidies, rebates, non-pharmacy price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale; and

* * * * *

■ 37. Section 423.2460 is amended by revising paragraphs (a), (b) introductory text, and (d) and adding paragraph (e) to read as follows:

§ 423.2460 Reporting requirements.

(a) Except as provided in paragraph (b) of this section, for each contract year, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, a report that includes the data needed by the Part D sponsor to calculate and verify the medical loss ratio (MLR) and remittance amount, if

any, for each contract under this part, including the amount of incurred claims for prescription drugs, supplemental benefits, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under § 423.2410.

(b) For contract years 2018 through 2022, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, the following information:

* * * * *

(d) Subject to paragraph (e) of this section, the MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

(e) With respect to a Part D sponsor that has already submitted to CMS the MLR report or MLR data required under paragraph (a) or (b) of this section, respectively, for a contract for a contract year, paragraph (d) of this section does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. Such resubmission must be authorized or directed by CMS, and upon receipt and acceptance by CMS, is regarded as the contract’s MLR report or data submission for the contract year for purposes of this subpart.

Dated: April 27, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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