DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS–4192–P]

RIN 0938–AU30

Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Advantage (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 proposed rule would also revise regulations related to dual eligible special needs plans (D–SNPs), other special needs plans, and cost contract plans.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by March 7, 2022.

ADDRESSES: In commenting, please refer to file code CMS–4192–P.

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

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4192–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4192–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

FOR FURTHER INFORMATION CONTACT:

Marna Metcalf Akbar, (410) 786–8251, or Melissa Seeley, (212) 616–2329—General Questions.

Jacqueline Ford, (410) 786–7767—Part C Issues.

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

Marna Metcalf-Akbar, (410) 786–8251—D–SNP Issues.

SUPPLEMENTARY INFORMATION:

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

Acronyms

ACC Automated Criteria Check
ANOC Annual Notice of Change
ARB At-Risk Beneficiaries
BBA Bipartisan Budget Act
CAHPS Consumer Assessment of Healthcare Providers and Systems
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
EOC Evidence of Coverage
FFS Fee-for-Service
FIDE SNP Fully Integrated Dual Eligible Special Needs Plan
HEDIS Healthcare Effectiveness Data and Information Set
HHS Department of Health and Human Services
HIDE SNP Highly Integrated Dual Eligible Special Needs Plan
HOS Health Outcomes Survey
HPMS Health Plan Management System
HSD Health Service Delivery
ICR Information Collection Requirement
I–SNP Institutional Special Needs Plan
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
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
PBP Plan Benefit Package
PDE Prescription Drug Event
PDP Prescription Drug Plan
PHE Public Health Emergency
PRA Paperwork Reduction Act
RFI Request for Information
RFA Regulatory Flexibilities Act
SAE Service Area Expansion
SB Summary of Benefits
SNP Special Needs Plan
SSA Social Security Administration
TPMO Third-Party Marketing Organization

I. Executive Summary

A. Purpose

Over 27 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 24 million individuals receive Part D coverage through standalone Part D plans. The primary purpose of this proposed rule is to implement changes to the MA and Part D programs. The proposed provisions in this rule will reduce out-of-pocket prescription drug costs; improve price transparency and market competition under the Part D program; strengthen consumer protections to ensure MA and Part D beneficiaries have accurate and accessible information about their health plan choices and benefits; strengthen CMS oversight of MA and Part D plans; and improve the integration of Medicare and Medicaid programs for individuals enrolled in dual eligible special needs plans (D–SNPs). The proposed D–SNP provisions build on the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) (Pub. L. 111–148), the

Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123), CMS experience administering the MA and Part D programs, and the experiences of Medicare-Medicaid Plans (MMPs) to better align and integrate benefits for dually eligible beneficiaries.

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] We are proposing to require that any MA organization offering a D–SNP must establish one or more enrollee advisory committees in each State to solicit direct input on enrollee experiences. We also propose 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 believe 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 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.[2] Building on CMS's experience with other programs and model tests, we propose to require that all SNPs include standardized questions on housing stability, food security, and access to transportation as part of their health risk assessments.

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 believe this knowledge would better equip the MA organizations offering these SNPs to meet the needs of their members. Our proposal would also equip MA organizations with person-level information that would help them better connect people to covered services and social service organizations and public programs that can help resolve housing instability, food insecurity, or transportation challenges. Our proposal also would have the benefit of standardizing these data elements collected through HRAs, which we believe would eventually facilitate better data exchange among SNPs (when an individual transitions from one SNP to another) as well as facilitate the care management requirements under section 1859(f)(5) of the Act.

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 propose 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 improve integration.

We propose to require, for 2025 and subsequent years, that all FIDE SNPs have exclusively aligned enrollment, as defined in § 422.2, and cover Medicaid home health, durable medical equipment, and behavioral health services through a capitated contract with the State Medicaid agency. We propose to require 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. Consistent with existing policy outlined in sub-regulatory guidance, we also propose to codify specific limited benefit carve-outs for FIDE SNPs and HIDE SNPs.

We believe these proposals 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. We propose to 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) integrate materials and notices for enrollees. Where States choose to use this opportunity, it would help individuals better understand their coverage. Because Star Ratings are assigned at the contract level, this proposal would also provide the State 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 propose 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 would improve Federal and State oversight of certain D–SNPs (and their affiliated Medicaid managed care plans) through greater information-sharing among government regulators.

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

[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.*

[2] 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.*

increased State payments of Medicare cost-sharing and disadvantages providers serving dually eligible individuals in MA plans. We propose to 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) is 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 because of State limits on the amounts paid for Medicare cost-sharing and dually eligible individuals' exemption from Medicare cost-sharing. The proposal would result in more equitable payment for MA providers serving dually eligible beneficiaries. We project that our proposal would result in increased bid costs for the MOOP for some MA plans. A portion of those higher bid costs would 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 10-year cost estimate for the proposal is $614.8 million.

6. Special Requirements During a Disaster or Emergency (§ 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 limited depending on the type or scope of the disaster or emergency, while other situations, like the current 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. This proposal would clarify the period of time during which MA organizations must comply with the special requirements to ensure access for enrollees to covered services throughout the disaster or emergency period, especially when the end date is unclear and the period renews several times. We also propose to codify an additional condition for triggering the special requirements imposed by § 422.100(m)(1), specifically that there is a disruption in access to health care at the same time as the disaster or emergency.

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

We are proposing 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 would 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 one year ahead of the beginning of the contract as the proposed change for network adequacy rules would require. Therefore, the proposal 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 would no longer apply and MA organizations would need to meet full compliance.

8. Allow CMS To Calculate Star Ratings for Certain Measures for 2023 Given Impacts of the COVID–19 Public Health Emergency (§ 422.166)

Due to the scope and duration of the COVID–19 public health emergency, we codified a change to the 2022 Star Ratings methodology in the interim final rule titled ''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'' (CMS–3401–IFC; 85 FR 54820), published in the **Federal Register** and effective on September 2, 2020, which included a change to our extreme and uncontrollable circumstances policy at 42 CFR 422.166(i)(11) to make it possible for us to calculate 2022 Star Ratings for MA contracts. We propose 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. 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.

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

In the 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 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. We are proposing to 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 and has received feedback from beneficiary advocates and stakeholders concerned about the marketing practices

of third-party marketing organizations (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 are 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 rulemaking, we will address the concerns with TPMOs by means of the following three proposed updates to the communications and marketing requirements under 42 CFR parts 422 and 423, subpart V: (1) We propose to 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 propose to add a new disclaimer that would be required when TPMOs market MA plans/Part D products (§§ 422.2267(e) and 423.2267(e)), and (3) we propose an update to §§ 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 (FDRs).

CMS' January 2021 final rule (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 Patient Protection and Affordable Care Act of 2010 (Affordable Care Act). In the months since the publication of this rule, CMS gained additional insight regarding the void created by the lack of 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, we propose to require MA and Part D plans create a multi-language insert that would inform the reader, in the top fifteen languages used in the U.S., 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. We propose to require the inclusion of 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). Finally, we propose 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 are proposing to 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, we are proposing 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 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)

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 are proposing to eliminate this exception for contingent pharmacy price concessions. We are proposing 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 are proposing to 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). To implement the proposed change at the point of sale, Part D sponsors and their pharmacy benefit managers (PBMs) would load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems that interface with contracted pharmacies. The proposed changes would take effect on January 1, 2023, meaning, if finalized, Part D sponsors would need to account for the changes in the bids that they submit for contract year 2023.

We are also proposing to 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 has not yet been defined in the Part D statute, Part D regulations, or sub-regulatory guidance. We are proposing to define price concession in a broad manner to include all forms of discounts and direct or indirect subsidies or rebates that serve to reduce the costs incurred under Part D plans by Part D sponsors.

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 propose to require that that any MA organization offering a D-SNP must establish one or more enrollee advisory committees in each State to solicit direct input on enrollee experiences.	There is on average an annual impact of $0.9 million for establishing and maintaining these advisory committees with however 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 propose to require that all SNPs include standardized questions on housing stability, food security, and access to transportation as part of their health risk assessments.	For the initial year of implementation, there is an impact on Medicare Advantage special needs plans to update systems. We are unable to reliably estimate the additional burden in subsequent years.
3. Refining Definitions for Fully Integrated and Highly Integrated D-SNPs (§§ 422.2 and 422.107)	We propose to require, for 2025 and subsequent years, that all FIDE SNPs have exclusively aligned enrollment, as defined in § 422.2, and cover Medicaid home health, durable medical equipment, and behavioral health services through a capitated contract with the State Medicaid agency. We propose to require 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. Consistent with existing policy outlined in sub-regulatory guidance, we also propose to codify specific limited benefit carve-outs for FIDE SNPs and HIDE SNPs.	There is a one-time impact to update contracts.
4. Additional Opportunities for Integration through State Medicaid Agency Contracts (§ 422.107)	We propose to codify 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 also propose 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.

Summary of Major Provisions of Rule	Description	Impact
5. Attainment of the Maximum Out-of-Pocket Limit (§§ 422.100 and 422.101)	We propose to specify that the maximum out-of-pocket limit in an MA plan (after which the plan pays 100 percent of MA costs) is 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 because of State limits on the amounts paid for Medicare cost-sharing and dually eligible individuals' exemption from Medicare cost- sharing.	The proposal would 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 (§ 422.100(m))	This proposal would clarify the period of time during which MA organizations must comply with the special requirements to ensure access for enrollees to covered services throughout a disaster or emergency (including PHEs) period, especially when the end date is unclear and the period renews several times. We also propose an additional condition, that there is a disruption in access to health care for enrollees, for triggering the special requirements imposed by § 422.100(m)(1).	None anticipated.
7. Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application (§ 422.116)	We are proposing to amend § 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.	None anticipated.
8. Allow CMS to Calculate Star Ratings for Certain Measures for 2023 Given Impacts of the COVID-19 Public Health Emergency (§ 422.166)	We propose 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.	None anticipated.
9. Past Performance Methodology to Better Hold Plans Accountable for Violating CMS Rules (§§ 422.502 and 422.503)	We are proposing to include Star Ratings, bankruptcy issues, and compliance actions in our methodology going forward.	None anticipated.

Summary of Major Provisions of Rule	Description	Impact
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)	Through rulemaking, we will address the concerns with TPMOs by means of proposed updates to the communications and marketing requirements under 42 CFR parts 422 and 423, subpart V. We propose to require MA and Part D plans to create a multi-language insert that would inform the reader, in the top fifteen languages used in the U.S., that interpreter services are available for free. We propose to require the inclusion of the multi-language insert whenever a Medicare beneficiary is provided a CMS required material as defined under §§ 422.2267(e) and 423.2267(e). Lastly, we propose codifying a number of current sub-regulatory communications and marketing requirements.	There is an annual impact of $0.3 million to print the multi-language insert.
11. Greater Transparency in Medical Loss Ratio Reporting (§§ 422.2460, 422.2490, and 423.2460)	To improve transparency and oversight concerning the use of Trust Fund dollars, we are proposing to reinstate 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 proposing 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.	Medicare Advantage 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.

Summary of Major Provisions of Rule	Description	Impact
12. Pharmacy Price Concessions to Drug Prices at the Point of Sale (§ 423.100)	We are proposing to eliminate the exception for pharmacy price concessions that cannot reasonably be determined at the point of sale. We are also proposing 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 are proposing to 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. Lastly, we are proposing to add a definition of "price concession" at § 423.100.	Requiring pharmacy price concessions in the negotiated price is expected to reduce beneficiary costs by $21.3 billion over 10 years, or approximately 2 percent. In addition, the proposal is estimated to have $40 billion in Part D costs for the government over 10 years due to increases in direct subsidy and low-income premium subsidy payments, which represents a 3 percent increase. Manufacturers would save about $14.6 billion over 10 years. We expect a one-time cost to plan sponsors of $0.1 million to update systems.

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II. Provisions of the Proposed Rule

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.[3]

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

- Maximize person-centered 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.

There is 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. Some States have carefully married MA dual eligible special needs plans (D–SNPs) with Medicaid managed care organizations (MCOs) to create integrated care programs for dually eligible individuals. Researchers have generally found positive results from such integrated care approaches. For example, a study in Minnesota showed that enrollees in fully integrated Medicare-Medicaid managed care plans had greater primary care physician use and lower inpatient hospital and emergency department use in comparison to service delivery when Medicare and Medicaid-funded services were delivered independently. The study also found that home and community-based service use was greater for the fully integrated Medicare-Medicaid managed care plans than the comparison population and nursing

[3] 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.*

facility use was no greater.[4] A study in Oregon found that dually eligible individuals enrolled in plans with aligned financial incentives for Medicare and Medicaid experienced more improvement in their care relative to those enrolled in nonaligned Medicare Advantage and Medicaid managed care plans.[5] Other studies have found that integrated care programs foster high beneficiary satisfaction,[6] perform better than non-integrated plans on certain quality metrics,[7] and provide benefit flexibility needed to allow beneficiaries to continue living in the community.[8] Overall, 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.[9]

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 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.

The Medicare Payment Advisory Commission (MedPAC), Medicaid and CHIP Payment and Access Commission (MACPAC), and a wide array of health policy organizations have long pushed for greater CMS investment in integrated care. Over the last few years, MedPAC and MACPAC have written extensively on opportunities to promote integration through managed care policies.[10]

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, including specific responsibilities. 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.

In two recent MA/Part D rulemakings, CMS has adopted regulations[11] to: (1) Promote better information sharing between States and D–SNPs; (2) unify appeals processes across Medicare and Medicaid for certain D–SNPs that are also capitated for Medicaid benefits; and (3) phase out ''D–SNP look-alike'' plans that enroll a high percentage of dually eligible individuals without meeting the requirements for D–SNPs.[12]

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.

Maximizing the potential of D–SNPs to achieve these goals will require a sustained effort over multiple years, including—

- Partnership with and technical assistance for States;
- Technical assistance and support for providers and health plans, especially among the local not-for-profit plans that disproportionately serve Medicaid beneficiaries;
- Monitoring and oversight that protects beneficiaries and promotes person-centered coordination of care; and
- Federal rulemaking to raise the bar on integration without excessive disruption for enrollees.

We are working to improve and increase options for more integrated care in a variety of ways, including through D–SNPs and Medicare-Medicaid Plans (MMPs).

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 care 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 2021, approximately 3.3 million dually eligible individuals (more than 1 of every 4 dually eligible individuals) were enrolled in 627 D–SNPs.[13]

[4] 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 Planning and Evaluation (ASPE) (March 31, 2016). Retrieved from: *https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis.*

[5] Kim, H., Charlesworth, C.J., McConnell, K.J., Valentine, J.B., and Grabowski, D.C. ''Comparing Care for Dual-Eligibles Across Coverage Models: Empirical Evidence from Oregon'', *Medical Care Research and Review,* (November 15, 2017) 1–17. Retrieved from: *https://journals.sagepub.com/doi/abs/10.1177/1077558717740206.*

[6] Health Management Associates. *Value Assessment of the Senior Care Options (SCO) Program* (July 21, 2015). Retrieved from *https://www.mahp.com/wp-content/uploads/2017/04/SCO-White-Paper-HMA-2015_07_20-Final.pdf.*

[7] Medicare Payment Advisory Committee. ''Chapter 3, Care coordination programs for dual-eligible beneficiaries.'' In June 2012 Report to Congress: Medicare and Health Care Delivery System (June 16, 2012). Retrieved from *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun12_ch03.pdf.**COM028*

[8] Ibid.

[9] CMS Medicare-Medicaid Coordination Office FY 2020 Report to Congress, available at: *https://www.cms.gov/files/document/reporttocongressmmco.pdf.*

[10] Most recently, see MACPAC's June 2021 Report to Congress and MedPAC's June 2019 Report to Congress.

[11] For a discussion of codified requirements for information sharing between States and D–SNPs and unified appeals processes, see the final rule titled ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021,'' (84 FR 15710 through 15717 and 84 FR 15720 through 15744) at: *https://www.federalregister.gov/documents/2019/04/16/2019-06822/medicare-and-medicaid-programs-policy-and-technical-changes-to-the-medicare-advantage-medicare.* For a discussion of codified contract limitations on D–SNP look-alike plans, see the final rule titled ''Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program,'' (85 CFR 33805 through 33820) at: *https://www.federalregister.gov/documents/2020/06/02/2020-11342/medicare-program-contract-year-2021-policy-and-technical-changes-to-the-medicare-advantage-program.*

[12] For a discussion of D–SNP look-alikes, 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 9025) at: *https://www.govinfo.gov/content/pkg/FR-2020-02-18/pdf/2020-02085.pdf.*

[13] Centers for Medicare & Medicaid Services. *SNP Comprehensive Report* (January 2021). Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

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 § 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 § 422.101(f), and contracts with State Medicaid agencies as described in section 1859(f)(3)(D) of the Act and at § 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).[14]

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 (hereinafter referred to as the February 2020 proposed rule).[15]

b. Medicare-Medicaid Plans

To test additional models of integrated care, we established the 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. 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.

Certain elements of the capitated model demonstrations vary by State, but all MMPs include—

- A beneficiary advisory committee or governance board to provide ongoing input on plan operations;
- An integrated set of member materials, including provider directories, beneficiary notices, and a single ID card;
- Person-centered care planning, including HRAs and care plans;
- Care coordination and assistance with care transitions;
- Aligned Medicare and Medicaid plan enrollment and disenrollment effective dates;
- Medicare provider network adequacy standards specific to the dually eligible individual population;
- Integrated grievance and appeal processes at the plan level;
- Joint oversight by CMS and the States through contract management teams;
- Benefit flexibility, an integrated medical loss ratio (MLR), and other financing provisions intended to promote person-centeredness and mitigate incentives for cost-shifting across programs; and
- A set of CMS core and State-specific quality measures, a subset of which are part of performance-based risk through a quality withhold on the payment to the MMP.

CMS and States partnered with MMPs to create a seamless experience for beneficiaries, but MMPs operate as both MA organizations 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 July 2021, there are 39 MMPs in nine States serving approximately 400,000 members.[16]

While an independent evaluation of the FAI is still underway, we have already gleaned several lessons regarding integrated, managed care from the capitated financial alignment model:

- *Enrollee participation in governance helps identify and address barriers to high-quality, coordinated care.* Stakeholder engagement has been an important tenet of the FAI since its inception. We required participating States to work with a variety of stakeholders, including beneficiaries and their advocates, as a condition of demonstration approval and implementation processes. Some have cultivated robust and impactful advisory bodies. For example, Massachusetts developed a One Care Implementation Council,[17] at least half of whose membership is comprised of enrollees and/or their representatives, charged with tracking quality of services, providing support and input to the State, and promoting accountability and transparency. The three-way contracts used in the capitated financial alignment model require MMPs to establish enrollee advisory committees and/or recruit enrollees to governing boards to ensure plans regularly obtain enrollee input on issues of program management. These advisory committees often provide input on enrollee materials, access to covered services, outreach campaigns, and other topics. Not every advisory committee operates at the same level, and many MMPs have had to recalibrate their approaches to ensure robust participation over time, but all have made strides toward seeking out and incorporating enrollee feedback. We believe such mechanisms help MMPs

[14] See *https://www.govinfo.gov/content/pkg/FR-2019-04-16/pdf/2019-06822.pdf.*

[15] See *https://www.govinfo.gov/content/pkg/FR-2020-02-18/pdf/2020-02085.pdf.*

[16] MMP enrollment as of December 2020. See *CMS Monthly Enrollment by Contract Report* (December, 2020). Retrieved from *https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldatamonthly/enrollment-contract-2020-12.*

[17] For more information on the One Care Implementation Council, see the Center for Consumer Engagement in Health Innovation at Community Catalyst & the LeadingAge LTSS Center @UMass Boston. ''The One Care Implementation Council: Stakeholder Engagement Within a Duals Demonstration Initiative.'' (June, 2018). Retrieved from *https://www.healthinnovation.org/resources/publications/body/One-Care-Implementation-Council-Review-June-2018-1.pdf.*

improve the experiences of dually eligible individuals.

• *Assessment processes are a vehicle for identifying and addressing unmet need, particularly those related to social determinants of health.* MMPs are required to offer care coordination services to each beneficiary, including an HRA of the enrollee's physical, psychosocial, and functional status which meet all minimum requirements for MA plans in section 1859(f)(5)(A)(ii) of the Act but often include additional elements to assess social risk factors. As of September 2020, MMPs had performed over 1.3 million HRAs, and in doing so identified significant unmet need among members, particularly related to food insecurity and housing instability.[18] For example, we commonly learn of HRAs identifying people with no regular source of care, untreated chronic conditions, unsafe living conditions, and/or imminent eviction or homelessness. By identifying these unmet needs through the HRA process, MMPs are then able to address them with interventions from care coordinators, connections to community organizations, and by incorporating goals and actions into beneficiary care plans.

• *Medicare-Medicaid integration correlates with high levels of beneficiary satisfaction.* MMP members report high levels of satisfaction with their MMPs through member experience surveys. When asked to rate their health plan on a scale from 0 to 10 (with 0 being the worst possible and 10 being the best possible), 91 percent of respondents rated their health plan and health care a 7 or higher in 2019, the most recent year for which data are available.[19] Sixty-six percent of all respondents rated their MMP a 9 or 10 in 2019, up from 59 percent in 2016.[20] These ratings have improved continuously (by five percentage points per year on average) since the MMPs started reporting such data in 2015 and are on par with ratings in the broader Medicare Advantage program.[21]

• *Carving in Medicaid behavioral health benefits helps promote better coordination of behavioral health and physical health services.* Behavioral health conditions are pervasive among dually eligible individuals. For example, nearly one-third of individuals who are dually eligible for Medicare and Medicaid have been diagnosed with a serious mental illness, such as schizophrenia, bipolar disorder, or major depressive disorder, a rate almost three times higher than for non-dually eligible Medicare beneficiaries.[22] Fragmented physical and behavioral health care, delivered across multiple providers and funding sources, can decrease access to care and lead to poor health status.[23] MMPs in all capitated demonstration States except for California and Michigan include Medicaid behavioral health benefits in their plan benefit package. In California, specialty mental health services and substance use disorder treatment covered by Medicaid are financed and administered by county behavioral health departments, and MMPs are required to coordinate with the counties for members served by both entities. Coordination between the MMPs and the counties has varied by county and has often been difficult; challenges include confusion for plans over county-level variation on which services are covered by the county or the MMP, limited behavioral health provider resources to participate in interdisciplinary care teams, and legal and communication barriers to sharing data between county providers and MMPs.

• *Integrated beneficiary communication materials can enhance the beneficiary experience.* The Medicare and Medicaid programs have different, and sometimes inconsistent, requirements for how plans communicate with individuals. CMS and partnering States, however, require MMPs to provide a single set of integrated member materials designed to meet Federal and State requirements and convey information to members in a more streamlined fashion. CMS tested such materials with beneficiaries to maximize readability and understanding.

• *Effective joint oversight of integrated managed care products is possible.* Through the FAI, we have shown it is possible to create a successful framework for joint State and CMS oversight and contract management. Contract management teams (CMTs) consisting of State Medicaid and CMS staff work hand in hand to assure compliance with the relevant Medicare, Medicaid, and State requirements and MMP three-way contract requirements, and to promote MMP performance in meeting the needs and preferences of beneficiaries. Through each CMT, State and CMS staff coordinate to jointly issue guidance and operational clarification and, as needed, may coordinate to issue joint CMS-State compliance actions. CMTs regularly meet with State ombudsman organizations, State-convened advisory groups, and may also meet with local stakeholders, such as beneficiary advocates, enabling more rapid problem-solving and real-time feedback on plan performance and beneficiary experience.[24] CMS has also developed and refined audit protocols specific to three-way contracts between CMS, the States, and the MMPs, and CMS and State staff coordinate to avoid scheduling conflicting Medicare and Medicaid audits that can cause a plan to split resources between two regulators. Based on feedback from States and MMPs and our own experiences for the last eight years, we believe these joint oversight processes, along with having performance data specific to the local MMPs, have improved communications and driven performance improvement.

• *Integrated care and joint oversight provide a platform for quality improvement.* The capitated model demonstrations have shown it is

[18] MMP reported monitoring measure data. Measure data are provided for informational purposes only and do not constitute official evaluation results. Full measure specifications can be found in the reporting requirements documents, available at: *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPReportingRequirements.html.*

[19] Centers for Medicare & Medicaid Services. *Enrollee Experiences in the Medicare-Medicaid Financial Alignment Initiative: Results through the 2019 CAHPS Surveys.* (October 2020) Retrieved from *https://www.cms.gov/files/document/faicahpsresults.pdf.*

[20] Ibid.

[21] CMS analysis of MMP and Medicare Advantage CAHPS data 2015–2019.

[22] Congressional Budget Office. ''Dual-Eligible Beneficiaries of Medicare and Medicaid: Characteristics, Health Care Spending, and Evolving Policies.'' (June, 2013). Retrieved from: *https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/44308dualeligibles2.pdf.* This report classified Medicare enrollees as having a mental illness if they had a diagnosis from the previous year of schizophrenia; major depressive, bipolar, and paranoid disorders; or other major psychiatric disorders.

[23] Medicaid and CHIP Payment and Access Commission. ''Integration of Behavioral and Physical Health Services in Medicaid.'' (March, 2016). Retrieved from: *https://www.macpac.gov/wp-content/uploads/2016/03/Integration-of-Behavioral-and-Physical-Health-Services-in-Medicaid.pdf.*

[24] RTI International, ''Financial Alignment Initiative Massachusetts Once Care: Third Evaluation Report,'' (April 2019), Retrieved from: *https://innovation.cms.gov/files/reports/fai-ma-thirdevalrpt.pdf;* RTI International, ''Financial Alignment Initiative Michigan MI Health Link First Evaluation Report (Sept 2019), Retrieved from: *https://innovation.cms.gov/files/reports/fai-mi-firstevalrpt.pdf;* RTI International, ''Financial Alignment Initiative MyCare Ohio: First Evaluation Report ''(Nov 15 2018), Retrieved from: *https://innovation.cms.gov/files/reports/fai-oh-firstevalrpt.pdf;* RTI International, ''Financial Alignment Initiative South Carolina Healthy Connections Prime: First Evaluation Report (Sept 2019), Retrieved from: *https://innovation.cms.gov/files/reports/fai-sc-firstevalrpt.pdf.*

possible to effectively incentivize innovation and investment for better serving the dually eligible population. MMPs and CMTs collaborate on continuous performance improvement. Like MA plans, MMPs report quality and performance data such as Consumer Assessment of Healthcare Providers and Systems (CAHPS) and Healthcare Effectiveness Data and Information Set (HEDIS) at the contract level. Because the MMP is the only plan under the three-way contract, CMS and the State have access to performance and quality data specific to each individual MMP. (This is similar to how States generally approach Medicaid managed care contracts and quality reporting. In contrast, a D–SNP may be one of many plan benefit packages under a single MA contract, making it difficult to get a true picture of a particular MA plan's performance.) CMS routinely shares State and national performance data on CAHPS and HEDIS metrics with States and MMPs to identify high and low performing plans. Through the CMTs, State and CMS staff have worked with MMPs to identify specific quality metrics to drive performance improvement and have developed specific quality and performance improvement projects at an MMP and/or demonstration level. These efforts have helped to drive significant year-over-year improvement in CAHPS and HEDIS measures. From 2016 to 2018, MMPs as a group improved performance on measures related to care coordination like Care for Older Adults (by an average of 17 percent across three separate measures) and Medication Reconciliation Post-Discharge (by 54 percent), and on key outcome measures like Controlling High Blood Pressure (by 16 percent) and Plan All-Cause Readmissions (17 percent reduction for beneficiaries age 65 and over).[25] Compared to MA plans as a group, MMPs improved at a higher rate on these measures over the same time period. MA plans as a group improved by an average of 5 percent across the Care for Older Adults measures (although only D–SNPs report those measures) and by 32 percent on the Medication Reconciliation Post-Discharge measure, while the Plan All-Cause Readmissions measure had a 16 percent reduction for beneficiaries age 65 and over.[26] Overall, MA plans saw no change to performance on the Controlling High Blood Pressure measure.[27]

- There is potential for market distortions in areas with multiple options targeting the same population. The MMP experience has shown that we can create a competitive market among MMPs with multiple choices for beneficiaries in the same service area and maintain high expectations for plans around care coordination and cost effectiveness. However, it has also shown the potential for beneficiary confusion and disruption in markets where MMPs are competing with other products targeting dually eligible individuals, including D–SNPs and, more recently, D–SNP look-alikes. For example, fully integrated D–SNPs (FIDE SNPs) served the same population as MMPs that were under New York's Fully Integrated Dual Advantage (FIDA) capitated model demonstration and the FIDE SNPs were offered by the same parent organization as the MMPs, creating confusion among beneficiaries and providers about each program's role.[28] Differences in Medicare capitation payments gave parent organizations a financial incentive to prioritize enrollment in FIDE SNPs over MMPs.[29] In addition to the financial challenges, the MMPs experienced low enrollment spread among a high number of MMPs [30] due to providers not wanting to meet prescriptive care coordination requirements and encouraging patients not to participate. In California, D–SNP look-alikes emerged following the State's decision to limit eligibility for D–SNPs to beneficiaries not otherwise eligible for MMPs.[31] In its June 2018 report to Congress, MedPAC describes broker commissions as another factor incentivizing enrollment in the D–SNP look-alike plans over the MMPs in States like California that prohibit MMPs from using brokers.[32] For a more thorough discussion of market dynamics in New York and California, see MedPAC's June 2018 report to Congress.[33] For a more comprehensive review of D–SNP look-alike plans, see pages 9019–9021 in the February 2020 proposed rule.[34]

- *State investment is critical to successful implementation of integrated care either through MMPs or D–SNPs.* True integration of Medicare and Medicaid requires long-term State participation. However, interest and capacity in pursuing integrated care for dually eligible individuals varies considerably from State to State, and sometimes from year to year. One of the many lessons from the MMP experience has been that standing up a demonstration of this scope requires significant State resources. However, even outside of MMPs, many of the features of integration also require significant State effort. States that have successfully utilized D–SNP contracts to integrate or align Medicare and Medicaid programmatic and administrative elements outside of the FAI have also invested in building State capacity, including establishing dedicated staff or contractors with Medicare knowledge and expertise, building technical capacity to integrate Medicare and Medicaid data, and creating analytic resources to support ongoing program operations and oversight.[35] For example, to maximize integration opportunities, D–SNP members may also enroll in the same organization's Medicaid plan. State investment in establishing enrollment and assignment processes to enable alignment of Medicare and Medicaid enrollment require upfront and ongoing monitoring resources.

[25] CMS analysis of the MMP performance on HEDIS data reported 2017–2019.

[26] CMS analysis of Medicare Advantage performance on HEDIS data reported 2017–2019.

[27] Ibid.

[28] Medicare Payment Advisory Committee. ''Chapter 9, Managed care plans for dual eligible beneficiaries.'' In *June 2018 Report to Congress: Medicare and Health Care Delivery System* (June 15, 2018). Retrieved from *https://www.medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0.*

[29] Ibid.

[30] Per MedPAC's June 2018 report, as of June 2017, 156,000 full-benefit dually eligible individuals were eligible to participate in FIDA, but only 4,708 individuals (3 percent) were enrolled among 14 MMPs.

[31] Pursuant to Welfare and Institutions Code section 14132.277(d), for seven counties, DHCS only offered D–SNP contracts (that is, contracts between the State and the D–SNP that are required under 42 CFR 422.107 for an MA organization to offer a D–SNP) to plans that were approved as of 1/1/13 and new enrollment into those D–SNPs is limited to beneficiaries not otherwise eligible for Medicare-Medicaid plans. The State also did not permit existing D–SNPs to expand service area into the seven counties.

[32] Medicare Payment Advisory Committee. ''Chapter 9, Managed care plans for dual eligible beneficiaries.'' In *June 2018 Report to Congress: Medicare and Health Care Delivery System* (June 15, 2018). Retrieved from *https://www.medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0.*

[33] Ibid.

[34] As finalized in § 422.514 by the ''Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, and Medicare Cost Plan Program'' (85 FR 33796 through 33911) (hereinafter referred as the May 2020 final rule), CMS will no longer enter into a contract with a new D–SNP look-alike beginning in CY 2022 or an existing D–SNP look-alike beginning in CY 2023.

[35] A. Kruse and M. Herman Soper. State Efforts to Integrate Care for Dually Eligible Beneficiaries: 2020 Update. Center for Health Care Strategies, Inc., February 2020. Available at *https://www.chcs.org/media/State-Efforts-to-Integrate-Care-for-Dually-Eligible-Beneficiaries_022720.pdf.*

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. Below we propose 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 that follow would incorporate certain MMP policies into the regulations governing D–SNPs or, in several cases, certain types of D–SNPs. We describe those proposals in greater detail in this section of this proposed rule. Table 1 summarizes how our proposals relate to MMP policies.

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TABLE 1: PROPOSALS THAT WOULD APPLY MMP FEATURES INTO D-SNPs

MMP Characteristic	FIDE SNP	HIDE SNP	Coordination-only D-SNP
Enrollee advisory committee	Propose to require	Propose same as FIDE	Propose same as FIDE
HRA to include social risk factors	Propose to require	Propose same as FIDE	Propose same as FIDE
Exclusively aligned enrollment	Propose to require starting 2025	-	-
Capitation for LTSS and behavioral health	Propose to require starting 2025	-	-
Capitation for Medicare cost-sharing	Propose to specify	-	-
Unified appeals & grievances[1]	Propose to require starting 2025 for all FIDE SNPs	-	Propose to require for certain plans
Continuation of Medicare benefits pending appeal[2]	Propose to require starting 2025 for all FIDE SNPs	-	Propose to require for certain plans
Integrated member materials	Propose to create a new pathway for States to require for certain plans	Propose same as FIDE	Propose same as FIDE
Contract only includes within-State plans limited to dually eligible individuals Quality data/ratings based solely on performance in contracts that only include within-State plans limited to dually eligible individuals[3]	Propose to create a new pathway for States to require for certain plans	Propose same as FIDE	Propose same as FIDE
Mechanisms for joint Federal-State oversight	Propose to establish for States meeting proposed criteria at § 422.107(e)	Propose same as FIDE	Propose same as FIDE
State HPMS access	Propose to establish for States meeting proposed criteria at § 422.107(e)	Propose same as FIDE	Propose same as FIDE

NOTES: HPMS: Health Plan Management System; LTSS: long-term services and supports

[1]The requirement for unified appeals and grievances is currently in place for those FIDE SNPs and HIDE SNPs that qualify as applicable integrated plans, as defined at § 422.561. Our proposal to require exclusively aligned enrollment for FIDE SNPs would mean that all FIDE SNPs would be applicable integrated plans subject to the requirements for unified appeals and grievance systems. In addition, we propose to revise the definition of applicable integrated plans to extend requirements for unified appeals and grievance systems to a subset of coordination-only D-SNPs.

[2]The requirement for continuation of Medicare benefits pending appeal is codified at § 422.632 for those FIDE SNPs and HIDE SNPs that qualify as applicable integrated plans, as defined at § 422.561. Our proposal to require exclusively aligned enrollment for FIDE SNPs would mean that all FIDE SNPs would be applicable integrated plans subject to this requirement of a unified appeals system.

[3]CMS calculates Star Ratings at the contract level. Star Ratings would become specific to plans serving dually eligible individuals where the MA contract is limited to a one or more D-SNPs. We do not propose to change the Star Ratings methods *per se*. (*See* 42 CFR 422.160 through 422.166).

3. Enrollee Participation in Plan Governance (§ 422.107)

CMS believes managed care plans derive significant value from engaging enrollees in defining, designing, participating in, and assessing their care systems.[36] 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.[37] Federal regulations for other programs, such as the Programs of All-Inclusive Care for the Elderly and Medicaid managed care plans that cover long-term services and supports (LTSS) include requirements for stakeholder engagement and committees, including input from beneficiaries. We describe these requirements later in this section.

Stakeholder engagement has been an important tenet of the FAI since its inception. As required by the three-way contracts between CMS, States, and MMPs, all MMPs established enrollee advisory committees. 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. While three-way contract terms differ by State, all three-way contracts require the enrollee advisory committees to meet at least quarterly, be comprised of enrollees, family members, and other caregivers that reflect the diversity of the demonstration population, and provide regular feedback to the MMP's governing board. MMPs have flexibility in conducting these meetings, including determining how to recruit and train enrollees, number of participants,

[36] 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.*

[37] 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_Engagement/Video/Listening_to_Voices_of_Dually_Eligible_Beneficiaries.*

discussion topics, and how feedback is disseminated and used.

CMS's 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.[38] In their work, the Resources for Integrated Care and Community Catalyst identified some practices leading to successful enrollee advisory committees. These include MMP efforts to—

- Recruit enrollees through care coordinator referrals and community outreach events;
- Listen to enrollee feedback;
- Be responsive to enrollee feedback by identifying meaningful changes made because of comments shared and, if the plan is not able to implement a suggestion, providing a rationale;
- Disseminate feedback to appropriate departments across the plan;
- Promote consistent enrollee participation through supports like transportation to the committee meetings, meals, and a stipend; and
- Provide ongoing training to enrollees to help them feel comfortable and empowered to provide feedback.[39]

In late 2018, Federal and State officials led conversations with MMPs to gain a better understanding of the enrollee advisory committees, promising practices, challenges, and how plans are using the feedback received from enrollees and caregivers. A significant number of MMPs reported value from having an advisory committee and that the committee contributes to operational improvements through: (1) Understanding challenges with community resources and potential gaps in services; (2) improving enrollee communications, including printed materials and the website enhancements; (3) identifying barriers to medication adherence and what adherence tools might be most useful to enrollees; and (4) improving delivery of non-emergency transportation, dental, vision, and over-the-counter benefits. A few MMPs reported a neutral value of the advisory committee meetings, citing benefits from enrollee feedback but also challenges in enrollee participation and willingness to engage on issues beyond their personal circumstances. Overall, though, the MMPs reported the committees provided a valuable perspective that shapes the plan's approach to recovery, wellness, and overall access to health care as well as prioritize areas where additional assistance is needed for enrollees.

More recently, MMPs have utilized enrollee advisory committees to gain insight into the effectiveness of specific enrollee materials. For example, some MMPs have shared redacted care plans with enrollee advisory committees for enrollee feedback. Other MMPs have shared draft influenza vaccination outreach materials with their enrollee advisory committees and used the quarterly meetings to discuss influenza prevention. During 2020 and 2021, MMPs have used these committees to discuss ways to educate enrollees about COVID–19 prevention and vaccines. We have had the opportunity to observe some of these meetings and found the dialogue between enrollees and their caregivers and the MMPs to be open and constructive, with all parties interested in sharing information, listening, and identifying solutions. Other programs overseen by CMS include similar committees or mechanisms for beneficiaries to provide feedback and have a role in plan administration.

a. Participant Advisory Committees in PACE Organizations

In addition to MMPs, Programs of All-Inclusive Care for the Elderly (PACE) organizations, per § 460.62(b), must establish participant advisory committees to advise the PACE organization governing body on matters of concern to participants. The majority of the 51,000 PACE participants are dually eligible individuals.[40]

CMS initially required PACE organizations to establish consumer advisory committees as part of the Federal regulations codifying the PACE program in a November 1999 interim final rule with comment period (IFC) for PACE (64 FR 66234). The November 1999 IFC noted that consumer participation through advisory committees is a ''well accepted community organization vehicle to maximize the involvement of consumers in a program designed to serve them'' and that through the use of a consumer advisory committee consumers are also ''likely to feel a greater stake in the operation of the program'' (64 FR 66242). The original regulation, codified at § 460.62, required PACE participants and participant representatives to comprise the majority of committee membership, but there was no Federal requirement relating to how frequently PACE organizations were required to convene the committees.

In a December 2006 final rule (71 FR 71244 through 71337), we made minor revisions to the PACE consumer advisory committee regulation text at § 460.62, including changing the name to participant advisory committee (71 FR 71265). We also clarified in the preamble that the final rule was not specifying the size of the participant advisory committee but that we expected each committee to be representative of the size and population of the PACE organization's participants.

The requirements at § 460.62 allow PACE organizations flexibility in determining the frequency, scope, and participation on these advisory committees. Through its many years of experience overseeing PACE organizations, CMS has learned that PACE organizations value the participant advisory committees as an important way to receive direct feedback from PACE participants to improve program policy and operations. Attendance at participant advisory committees may include PACE organization leadership, including executive directors and PACE center directors. Since PACE participants visit the PACE center at least once per week, feedback provided by PACE participants at the participant advisory committees is generally focused on challenges with transportation between the PACE center and their residences and preferences for meals and activities provided at the PACE center. Per § 460.62(c), PACE organizations must have a participant representative on their governing body. These participant representatives act in part as a liaison of the participant advisory committee to the PACE organization governing body and the participant advisory committee, presenting issues from the participant advisory committee to the governing body. The link between the participant advisory committee and the governing body helps to elevate issues raised by participants to PACE organization leadership.

[38] Resources for Integrated Care and Community Catalyst, ''Member Engagement in Plan Governance Webinar Series'', 2019. Retrieved from: *https://www.resourcesforintegratedcare.com/concepts/member_engagement.*

[39] 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_Engagement/Video/Listening_to_Voices_of_Dually_Eligible_Beneficiaries.*

[40] CMS, Medicare Advantage, Cost, PACE, Demo, and Prescription Drug Plan Contract Report—Monthly Summary Report (Data as of June 2021). Retrieved from: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report.*

b. Member Advisory Committees in Medicaid Managed Care Plans

Medicaid managed care plans that cover long-term services and supports (LTSS) are also required to solicit active member and other stakeholder input through the use of a member advisory committee. Recognizing that stakeholder engagement is an important member protection and is critical to the success of Medicaid managed LTSS programs, CMS requires certain Medicaid managed care plans providing LTSS to establish and maintain a member advisory committee. Per 42 CFR 438.110, as adopted in the ''Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability'' final rule (81 FR 27655 through 27658) (hereinafter referred to as the May 2016 final rule), when LTSS are covered under a risk contract between a State and a Medicaid managed care plan (that is a Medicaid managed care organization (MCO), prepaid inpatient health plan (PIHP), or prepaid ambulatory health plan (PAHP)), each Medicaid managed care plan must establish a member advisory committee. The committee must include at least a reasonably representative sample of the LTSS population, or other individuals representing those members, covered under the contract with the Medicaid managed care plan. CMS designed this requirement in a way that gives managed care plans covering LTSS flexibility to work with their stakeholder communities to establish the most effective member engagement process.

c. Proposal for D–SNP Enrollee Advisory Committees

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 propose 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 propose 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 propose 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 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. Further, this requirement would be consistent with the existing requirement at § 438.110 for Medicaid plans to establish member advisory committees when those Medicaid managed care plans cover LTSS.

While we describe 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 note 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.

We believe that D–SNPs should work with enrollees and their representatives to establish the most effective and efficient process for enrollee engagement. 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 choose not to 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. Further, our proposal includes flexibility for MA organizations in how they structure their enrollee advisory committee(s). 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 practices [41] 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.

First, we propose 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. Under our proposed rule, 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 propose 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. By using the phrase ''representative sample'' in the regulation text, we intend D–SNPs to 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. An MA organization that offers separate D–SNPs in multiple counties in a State could decide to convene one enrollee advisory committee to solicit feedback across the membership of all these D–SNP plans as long as that committee's participants reasonably represent the totality of the D–SNP membership. Alternatively, this MA organization could convene an enrollee advisory committee for each D–SNP in each county where the D–SNP is offered. The MA organization could also choose to implement a combination

[41] Resources for Integrated Care and Community Catalyst, ''Engaging Members in Plan Governance'', 2019. Retrieved from: *https://www.resourcesforintegratedcare.com/node/433#PlanGov.*

of the aforementioned approaches, such as establishing an enrollee advisory committee that solicits enrollees from a D–SNP offered in one county and establishing an enrollee advisory committee with enrollees representing D–SNPs offered in more than one county. For example, a MA organization that offers separate D–SNPs in Broward, Hillsborough, and Orange counties in Florida could establish one enrollee advisory committee that convenes membership representative of these distinct regions of Florida via virtual communications methods, or it could establish separate enrollee advisory committees in each county, or it could implement some combination of these approaches. Similarly, for MA organizations that offer separate D–SNPs serving full-benefit dually eligible individuals and partial-benefit dually eligible individuals in the same State, proposed § 422.107(f) provides flexibility for MA organizations to solicit enrollee input through one or more committees where separate committees might represent specific eligibility groups. Ensuring that the enrollee advisory committee is representative of the covered population of the D–SNP(s) that are served by the committee is key to achieving the goals of requiring an enrollee advisory committee.

Finally, we propose 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). CMS encourages D–SNPs to consider the CMS Office of Minority Health Disparities Impact Statement as a potential tool to improve health equity for underserved populations among their enrollment.[42] Our proposal does not specify other responsibilities or obligations for the committee, but we encourage D–SNPs to solicit input from enrollees on other topics will be part of the committee's responsibilities.

Specifically, we propose the following amendments to § 422.107:

- Revise the section heading from ''Special needs plans and dual eligible: Contract with State Medicaid Agency'' to ''Requirements for dual eligible special needs plans'' to reflect how, as amended, § 422.107 will address D–SNP requirements, such as the enrollee advisory committee, in addition to the State Medicaid agency contracts and their content; and
- Add new paragraph (f) to require that 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, with 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.

An MA organization that offers one or more D–SNPs and offers (or is under a parent organization that offers) one or more Medicaid managed care plans that cover long term services and supports—including the MA organizations associated with all FIDE SNPs and most HIDE SNPs—would be subject to our proposal and § 438.110. In some circumstances, especially among FIDE SNPs and HIDE SNPs, we expect that organizations could meet the requirements in our proposal and § 438.110 through one enrollee advisory committee. Section 438.110(b) requires the member advisory committees to include at least a reasonably representative sample of the LTSS populations covered, but it does not preclude the membership of other enrollees as well. Therefore, an advisory committee could, in some cases, be reasonably representative of both the LTSS population and the D–SNP, even if enrollment in the D–SNP is not limited to LTSS users. Some State Medicaid agency contracts, such as those in Idaho, Massachusetts, Minnesota, New Jersey, and Pennsylvania, already require member advisory committees for FIDE SNPs that operate in those States in compliance with § 438.110, because the MCOs affiliated with those FIDE SNPs cover LTSS. Therefore, based on our review of State Medicaid agency contracts, we expect that a number of FIDE SNPs and HIDE SNPs affiliated with Medicaid managed care plans that cover LTSS already operate enrollee advisory committees that would comply with our proposal and § 438.110. The proposed regulation permits 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 and the State permits this arrangement. In other circumstances, it may not be feasible for an organization to operate a single enrollee advisory committee that meets the requirements of our proposal and § 438.110. Those organizations would need to operate multiple enrollee advisory committees.

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. As a result, we are not proposing specific prescriptive requirements for how D–SNPs must interact with and use these enrollee committees. However, we solicit comments on our proposal, including 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 responsibilities of the enrollee advisory committees, and additional topics for enrollee input, and whether we should limit the enrollee advisory committee proposed at § 422.107(f) to a subset of D–SNPs. We also solicit 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. Consistent with PACE, if our proposal is finalized, we would update the CMS audit protocols for D–SNPs to request documentation of enrollee advisory committee meetings. As we learn about the implementation experiences of these committees, if proposed § 422.107(f) is finalized, we would consider more prescriptive requirements in the future, if needed.

4. Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessment (§ 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 reassessment conducted for each individual enrolled in the plan are addressed in the individual's

[42] CMS Office of Minority Health, Health Equity Technical Assistance. Retrieved from: *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/Health-Equity-Technical-Assistance.*

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.[43] 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 D–SNPs also receiving capitation for Medicaid services may combine their Medicare-required HRA with a State Medicaid-required HRA to reduce assessment burden for enrollees (86 FR 5879). Certain social risk factors can lead to unmet social needs that directly influence an individual's physical, psychosocial, and functional status.[44] This is particularly true for food insecurity, housing instability, and access to transportation. The following are examples of actions that CMS has taken since 2014 to address social risk through the identification and standardization of screening for risk factors:

- *IMPACT Act of 2014.* The Improving Medicare Post-Acute Care Transformation Act of 2014 Section 2(a) (Pub. L. 113–185), hereinafter referred to as the IMPACT Act, amended the Social Security Act (the Act) by adding section 1899B to the Act. Section 1899B(b)(1) of the Act requires, in part, that the Secretary require certain post-acute care (PAC) providers to submit standardized patient assessment data with respect to certain categories of data. CMS finalized several standardized patient assessment data requirements, including on social determinants of health.[45]

- *Accountable Health Communities (AHC) Model.* The AHC Model, which is being tested under section 1115A of the Act, tests whether systematically screening for health-related social needs and referrals to community-based organizations to resolve identified unmet needs will improve healthcare utilization and reduce costs. Over a five-year period, organizations implementing the AHC Model, known as Bridge Organizations, are screening community-dwelling Medicare and Medicaid beneficiaries to identify their health-related social needs and providing navigation assistance to connect those beneficiaries with community services.[46] Some Bridge Organizations are also engaging key stakeholders in community-level continuous quality improvement activities to align the community service capacity with the community's service needs. For purposes of the model, the CMS Innovation Center developed the AHC Health-Related Social Needs (HRSN) Screening Tool. The tool asks 10 standardized questions that identify a patient's HRSNs in five core domains: Housing instability, food insecurity, transportation problems, utility help needs, and interpersonal safety.[47] [48] The first AHC Model evaluation report, assessing model implementation from 2017 to 2020,[49] demonstrated high prevalence of social risk factors among eligible high-need beneficiaries. Food insecurity was the most commonly reported social risk factor.

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.[50] Nonetheless, we have not previously required that SNP HRAs specifically collect information about these issues. We believe requiring SNPs to include standardized questions about social risk factors is 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 will better enable SNPs to design and implement effective models of care.

We propose 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. These questions will help SNPs gather the necessary information in order to conduct a comprehensive risk assessment of each individual's physical, psychosocial, and functional needs as required at § 422.101(f)(1)(i) and will inform the development and implementation of each enrollee's comprehensive individualized plan of care as required at § 422.101(f)(1)(ii). Rather than include the specific questions in regulation text, we propose 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 intend to provide ample notice to MA organizations of any changes in the questions over time. Should we finalize our proposal, SNPs would comply with the new requirement added to § 422.101(f) by

[43] 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.

[44] 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/.*

[45] 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 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.

[46] CMS Innovation Center, ''Findings at a Glance: Accountable Health Communities: Evaluation of Performance Years 1–3 (2017–2020).'' Retrieved from: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt-fg.*

[47] CMS Innovation Center, ''The Accountable Health Communities Health-Related Social Needs Screening Tool.'' Retrieved from: *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

[48] There are now Logical Observation Identifiers Names and Codes (LOINC) terms available for the AHC HRSN Screening Tool, as of June 2021. For more information, see: *https://loinc.org/loinc/96777-8/.*

[49] RTI International, ''Accountable Health Communities (AHC) Model Evaluation First Evaluation Report,'' Dec 2020. Retrieved from: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[50] 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.*

including in their HRAs the standardized questions on these topics that we would specify in sub-regulatory guidance. At a minimum, we intend to align selected questions with the Social Determinants of Health (SDOH) Assessment data element [51] established as part of the USCDI v2, when finalized and where applicable.

While we are proposing that the regulation text specify that the wording of individual questions would be established through sub-regulatory guidance, we provide here examples 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 include the transportation question in the post-acute care patient/resident instruments and the housing and food insecurity questions from the AHC Model HRSN Screening Tool: [52]

Housing. What is your living situation today? [53]

- I have a steady place to live
- I have a place to live today, but I am worried about losing it in the future
- I do not have a steady place to live (I am temporarily staying with others, in a hotel, in a shelter, living outside on the street, on a beach, in a car, abandoned building, bus or train station, or in a park)

Food. Some people have made the following statements about their food situation. Please answer whether the statements were OFTEN, SOMETIMES, or NEVER true for you and your household in the last 12 months. Within the past 12 months, you worried that your food would run out before you got money to buy more.[54]

- Often true
- Sometimes true
- Never true

Within the past 12 months, the food you bought just didn't last and you didn't have money to get more.

- Often true
- Sometimes true
- Never true

Transportation. Has lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living? [55]

- Yes, it has kept me from medical appointments or from getting my medications
- Yes, it has kept me from non-medical meetings, appointments, work, or from getting things that I need
- No

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 HRA. Having knowledge of this information for each enrollee would better equip MA organizations to develop an effective plan of care for 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 (for example, non-emergency medical transportation, when capitated by Medicaid or covered as a supplemental benefit) 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 are not explicitly proposing 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. Results of the HRAs do 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. A SNP could demonstrate this in several ways, consistent with its MOC. For example, a SNP may make a referral to an appropriate community partner, consistent with the individual's goals and preferences, to assist in meeting these needs. The SNP may also adapt communication methods to fit the individual's circumstances and take steps to maximize access to covered services that may meet the individual's needs and preferences, especially for supplemental benefits that may help with housing instability, food insecurity, or transportation.

SNPs currently report to CMS the number of completed HRAs, and, as part of the Medicare Part C Program Audit Protocols for SNP Care Coordination, we currently review a sample of HRAs and ICPs.[56] However, we do not currently collect specific data elements from HRAs for all SNP enrollees, in part because the data elements vary from plan to plan. 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 HRA to the State or its designee.) 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 information, in multiple HRAs. We believe that the benefit gained by all SNPs having standardized information about these social risk factors outweighs this potential risk. These questions build on other work across CMS. Where States are interested in requiring

[51] For more information, see: *https://www.healthit.gov/isa/taxonomy/term/1801/uscdi-v2.*

[52] 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.

[53] Adapted from National Association of Community Health Centers and partners, National Association of Community Health Centers, Association of Asian Pacific Community Health Organizations, Association OPC, Institute for Alternative Futures. (2017). PRAPARE. *http://www.nachc.org/research-and-data/prapare/.*

[54] Adapted from Hager, E.R., Quigg, A.M., Black, M.M., Coleman, S.M., Heeren, T., Rose-Jacobs, R., Cook, J.T., Ettinger de Cuba, S.E., Casey, P.H., Chilton, M., Cutts, D.B., Meyers A.F., Frank, D.A. (2010). Development and Validity of a 2-Item Screen to Identify Families at Risk for Food Insecurity. Pediatrics, 126(1), 26–32. doi:10.1542/peds.2009–3146.

[55] National Association of Community Health Centers and partners, National Association of Community Health Centers, Association of Asian Pacific Community Health Organizations, Association OPC, Institute for Alternative Futures. (2017). PRAPARE. *http://www.nachc.org/research-and-data/prapare/.*

[56] For more information, see: *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.*

assessment questions, we recommend that States consider conforming to the standardized questions we implement for use under this proposed rule and, for integrated care programs, ensuring that plans do not need to ask the same enrollees similar or redundant questions. However, we also seek 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.

We are considering several alternatives to our proposal. We are considering requiring fewer or more assessment questions on additional topics related to social risk factors or different combinations of questions from the post-acute care patient/resident assessment instruments and AHC Model HRSN Screening Tool. For example, we are considering requiring that SNPs use the post-acute care patient/resident assessment instruments questions on health literacy (''How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?'') and social isolation (''How often do you feel lonely or isolated from those around you?''). We believe these would provide valuable insight but are not proposing to require HRAs to include standardized questions in these areas out of parsimony. We focused on the proposed areas since there is a large evidence base suggesting they have a particularly significant influence on the physical, psychosocial, and functional needs of the enrollees.[57] For example, our experience with the FAI demonstrations has shown that lack of transportation can have a large impact in securing needed health care services. Our proposal would not preclude SNPs from asking additional questions related to these areas as long as the minimum standardized questions (specified in CMS sub-regulatory guidance pursuant to the regulation) are included as part of the HRA.

We considered soliciting comment in this preamble on different examples of questions on housing, food, and transportation other than the examples included above, such as the housing-related questions from the U.S. Department of Veteran Affairs' Homelessness Screening Clinical Reminder[58] or the housing-, food-, and transportation-related questions from the Medicare Current Beneficiary Survey.[59] We also considered simply proposing that all HRAs address certain domains (for example, housing), without authorizing CMS to specify the standardized questions to be used. However, we believe the benefit of flexibility for SNPs is outweighed by the challenges posed by use of multiple different questions used by different SNPs across the country. Having different questions that touch on the same topics in different ways would pose difficulties for interoperability, comparability, and reporting on these risk factors. We are considering specifying that the new questions only apply to certain enrollees and not others. For example, we are considering whether the questions on housing insecurity would be relevant for enrollees in congregate housing. However, because people may move between settings, including from an institutional placement to the community, we believe that such a proposal would add complexity without obvious benefit.

Finally, due to the processes associated with developing HRA tools, approval of MOCs, and MOC implementation, we would not enforce this requirement until contract year 2024. However, we are also considering 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 welcome comments on our proposal and these potential alternatives including adding questions regarding health literacy, social isolation, or other areas. We also welcome comments on when CMS would need to issue sub-regulatory guidance providing the specific questions to be included in the HRA to ensure that MA organizations would have sufficient time to incorporate the required 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, including Original Medicare with a standalone prescription drug plan, non-SNP MA plans, multiple types of SNPs, and Programs of All-inclusive Care for the Elderly. Those choices can be complex and, for some, overwhelming. An average Medicare beneficiary will have access to 54 MA plans in 2022, excluding MMPs and PACE, compared to 39 MA plans in 2020.[60] In one extreme example, dually eligible individuals in Los Angeles have over 85 choices for Medicare coverage for 2022, including 70 MA plans, nine D–SNPs, two FIDE SNPs, and five MMPs—more Medicare options to choose from than Medicare-only beneficiaries.[61]

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 propose several 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. Our proposals would lay the groundwork for potential future improvements to Medicare Plan Finder and other communications to help beneficiaries better understand their options for integrated coverage of Medicare and Medicaid benefits.

a. Exclusively Aligned Enrollment for FIDE SNPs

Section 422.2 defines the term ''fully integrated dual eligible special needs plan,'' most recently updated in the May 2020 final rule. 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 managed care organization (MCO) contract under section 1903(m) of the Act with a State Medicaid agency, (ii) under the capitated Medicaid managed care 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

[57] See Kushel MB, Gupta R, Gee L, Haas JS. 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.

[58] For more information, see the U.S. Department of Veteran Affairs, VA National Center of Homelessness Among Veterans March 2014 Research Brief ''Using a Universal Screener to Identify Veterans Experiencing Housing Instability'' at *https://www.va.gov/HOMELESS/Universal_Screener_to_Identify_Veterans_Experiencing_Housing_Instability_2014.pdf.*

[59] For more information, see *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS.*

[60] Information from 2022 Landscape Source Files. Retrieved from *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn.* Excludes EGWPs.

[61] Ibid.

(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. One benefit of FIDE SNP designation for the MA organization is that the MA plan 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); FIDE SNPs with a similar average level of frailty (as determined by the Secretary) as the PACE program may qualify for the frailty adjustment, which may result in increased aggregate payment from CMS.

Section 422.2 also defines the term ''aligned enrollment'' as referring to when a full-benefit dually eligible individual is an enrollee of a D–SNP and receives 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. It facilitates the use of integrated beneficiary communication materials (because all beneficiaries in the D–SNP are also in the companion Medicaid MCO), clarifies overall accountability for outcomes and coordination of care, and makes feasible the requirement (effective January 1, 2021) that the plan use unified grievance and appeals procedures for both Medicare and Medicaid benefits.

All MMPs operate with exclusively aligned enrollment, and several States require exclusively aligned enrollment for FIDE SNPs that operate in the State by including this requirement in the State Medicaid agency contract that is required for D–SNPs by § 422.107(b). However, 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.

In 2021, there are 69 FIDE SNPs in 12 States, enrolling 264,146 beneficiaries as of January 2021.[62] Fifty-seven of those 69 FIDE SNPs have exclusively aligned enrollment. Only Arizona, Pennsylvania, and Virginia currently contract with FIDE SNPs without requiring exclusively aligned enrollment.

We propose to amend the definition of ''fully integrated dual eligible special needs plan'' at § 422.2 with a new paragraph (5) that requires, for 2025 and subsequent years, that all FIDE SNPs have exclusively aligned enrollment. Our proposed change would move FIDE SNPs toward greater integration in the provision of Medicare and Medicaid benefits for dually eligible individuals and make the options available to these beneficiaries simpler to understand. Requiring all FIDE SNPs to have exclusively aligned enrollment would simplify the ways we, States, and benefit counselors communicate about FIDE SNPs by eliminating some of the confusing scenarios related to unaligned enrollment that our current definition permits. It would allow all enrollees to have their Medicare and Medicaid benefits explained under the FIDE SNP clearly, which is made more difficult when some enrollees are, but others are not, also enrolled in the affiliated Medicaid MCO. Our proposed change promotes higher levels of Medicare-Medicaid integration by ensuring that 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 members do not receive the Medicaid benefits from the same organization.

Under our proposed definition, all FIDE SNPs would (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. Ultimately, we believe this change in the definition of a FIDE SNP will help simplify options and provide a better plan experience for dually eligible beneficiaries, as they will be able to receive all their covered Medicare and Medicaid benefits through one organization.

In the absence of a State Medicaid policy change (to require or facilitate exclusively aligned enrollment) in Arizona, Pennsylvania, or Virginia, our proposal would result in 12 plans 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. (A HIDE SNP is another type of D–SNP defined at § 422.2 which we describe in more detail in section II.A.5.d. of this proposed rule.) A consequence of this would be that these plans would not qualify for the frailty adjustment, as described in § 422.308(c)(4); however, only six of the 12 potentially-affected FIDE SNPs qualify for the frailty adjustment in 2021 because only those six plans have a similar average level of frailty (as determined by the Secretary) as the PACE program. States may also choose to require, through their State Medicaid agency contracts under § 422.107, that MA organizations create separate 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 are proposing in section II.A.6.a. to redesignate from § 422.530(c)(4), for such enrollment transitions.

Finally, because the definition of aligned enrollment is specific to full-benefit dually eligible individuals, our proposal would newly preclude partial-benefit dually eligible individuals from enrolling in FIDE SNPs. Like with unaligned enrollees, enrollment of partial-benefit dually eligible individuals, who receive no Medicaid benefits other than coverage of Medicare premiums and—in some cases—Medicare cost-sharing, precludes a D–SNP from clearly communicating the Medicaid benefits available through the FIDE SNP or using unified appeals and grievance procedures for adjudication of both Medicare and Medicaid benefits. For CY 2021, however, no FIDE SNPs

[62] CY 2021 data is from CMS review of CY 2021 State Medicaid agency contracts submitted by FIDE SNPs. 2016 data is from Verdier, J., A. Kruse, R. Lester, et al. 2016. *State contracting with Medicare Advantage dual eligible special needs plans: Issues and options.* Washington, DC: Integrated Care Resource Center. Retrieved from *https://www.integratedcareresourcecenter.com/sites/default/files/ICRC_DSNP_Issues__Options.pdf.*

enroll partial-benefit dually eligible individuals. As such, we do not believe this would have any meaningful impact for plans currently operating as FIDE SNPs. Moving forward, we believe that the benefits to be achieved with FIDE SNPs having exclusively aligned enrollment for Medicare beneficiaries eligible for full Medicaid benefits, as proposed here, and the associated greater levels of integration in the provision and coverage of benefits and plan administration outweigh the potential negative effects for partial-benefit dually eligible individuals, who would be limited to enrollment in HIDE SNPs, coordination-only D–SNPs, other MA plans, or the original Medicare FFS program.

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

Section 1902(a)(10)(E) of the Act directs States to pay providers for Medicare coinsurance and deductibles for dually eligible individuals in the Qualified Medicare Beneficiary (QMB) program. Under section 1905(p)(3) of the Act, ''Medicare cost-sharing'' includes costs incurred with respect to a dually eligible individual in the QMB program,[63] ''without regard to whether the costs incurred were for items and services for which medical assistance [Medicaid] is otherwise available under the plan.'' For QMBs, Medicare cost-sharing amounts include Medicare Parts A and B premiums, coinsurance, and deductibles, and at State option, Medicare Advantage (MA) premiums. Section 1902(n)(2) of the Act permits the State to limit payment for Medicare cost-sharing 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.[64] About 8.8 million dually eligible individuals are enrolled in the QMB program.[65] Some States also elect to cover all Medicare cost-sharing for Medicare beneficiaries eligible for full Medicaid benefits who are not QMBs. This election means the State pays Medicare cost-sharing for a non-QMB full-benefit dually eligible individual even if the Medicare service is not covered under the Medicaid State plan. Absent such an election by the State, the State would pay the Medicare cost-sharing for non-QMB full-benefit dually eligible individual only if the Medicare service, such as inpatient hospitalization, is also covered under the Medicaid State plan. [66] Typically, States allow FIDE SNP enrollment of both QMB and non-QMB full-benefit dually eligible individuals.

CMS automatically forwards claims under the original Medicare FFS program to State Medicaid agencies and other secondary payers to adjudicate the claims for payment of any Medicare cost-sharing.[67] This automatic claims crossover process greatly reduces provider burden by eliminating the need for providers to submit separate claims to both Medicare and the State Medicaid agency, or a Medicaid managed care plan, such as a Medicaid MCO, prepaid inpatient health plan (PIHP), or prepaid ambulatory health plan (PAHP), as defined at § 438.2, for payment of Medicare cost-sharing when it is covered by Medicaid. For providers serving dually eligible individuals enrolled in MA plans, including FIDE SNPs, HIDE SNPs, and other D–SNPs, there is no guarantee of an automated crossover process to State Medicaid agencies or Medicaid managed care plans to process Medicaid payment of Medicare cost-sharing. This means the providers must submit claims to the MA plan, then determine the responsible State Medicaid agency or Medicaid managed care plan, and then submit another claim to the State Medicaid agency or Medicaid managed care plan for adjudication of the claims for Medicare cost-sharing.

One way to alleviate provider burden and streamline claims processing is for the State Medicaid agency to make a capitated payment for Medicaid coverage of Medicare cost-sharing to the MA plan in which a dually eligible individual (specifically, a QMB or other dually eligible individual for which the State covers Medicare cost-sharing) is enrolled. When the State contract with the MA plan includes capitated payment for Medicaid coverage of Medicare cost-sharing, the provider submits one claim to the MA plan, and the MA plan adjudicates the claim for Medicare coverage of services and for Medicaid payment of Medicare cost-sharing without the provider submitting separate claims to the MA plan and the proper Medicaid entity (that is, State Medicaid agency or Medicaid managed care plan). Additionally, this arrangement reduces other potential obstacles, including determining the proper Medicaid entity to bill for Medicare cost-sharing, determining a beneficiary's applicable coverage of Medicare cost-sharing (for example, in States that pay Medicare cost-sharing for Medicare beneficiaries eligible for full Medicaid benefits who are not QMBs), and the potential for improper QMB billing.

We propose 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 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. We intend this revision to encompass all cost-sharing, whether it is in the form of coinsurance, copayments, or deductibles, for Medicare Part A and Part B benefits covered by the D–SNP. The current definition of a FIDE SNP at § 422.2 requires a FIDE SNP's capitated contract with the State Medicaid agency to provide coverage, consistent with State policy, of specified primary care, acute care, behavioral health, and LTSS, and provide coverage of nursing facility services for a period of at least 180 days during the plan year. Medicare covers most primary care and acute care services and Medicare is always the primary payer for any Medicare-covered services with Medicaid covering any Medicare cost-sharing in such cases.

[63] Under 1905(p)(1) of the Act, a QMB is an individual who is entitled to hospital insurance benefits under Part A of Medicare, with income not exceeding 100 percent of the Federal poverty level, and resources not exceeding three times the SSI limit, adjusted annually by the Consumer Price Index. For more information about QMB eligibility and benefits, see chapter 1, section 1.6.2.1 and Appendices 1.A and 1.B of the Manual for the State Payment of Medicare Premiums, found here: *https://www.cms.gov/files/document/chapter-1-program-overview-and-policy.pdf.*

[64] 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. This is often referred to as the ''lesser of'' policy. Under the ''lesser of'' policy, a State caps its payment of Medicare cost-sharing at the Medicaid rate for a particular service.

[65] CMS Medicare-Medicaid Coordination Office, ''Data Analysis Brief: Medicare-Medicaid Dual Eligible Enrollment: 2006–2019''. Retrieved from: *https://www.cms.gov/files/document/medicaremedicaiddualenrollmenteverenrolledtrendsdatabrief.pdf.*

[66] 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.*

[67] State Medicaid agencies and Medicaid managed care plans enter into a Coordination of Benefits Agreement (COBA) for the purpose of coordinating health insurance benefits and facilitating the proper payment of claims for beneficiaries enrolled in the original Medicare FFS program. Within the COBA, State Medicaid agencies and Medicaid managed care plans elect which COBA claims for CMS to transfer. For more information, see: *https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/COBA-Trading-Partners/Coordination-of-Benefits-Agreements/Coordination-of-Benefits-Agreement-page.*

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. In plan year 2021, all 69 FIDE SNPs include Medicare cost-sharing in their capitated contracts with the State Medicaid agency.[68] Therefore, we do not expect our proposal to have any impact on existing FIDE SNPs.

We chose to propose this change only for FIDE SNPs because FIDE SNPs are the only type of D–SNP that must cover 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 proposed in section II.A.5.a. of this proposed 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. In this way, the proposed additions 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. This proposal furthers the level of integration required for FIDE SNPs in a way that we believe would achieve those improved experiences. In other types of D–SNPs, such as HIDE SNPs, members may participate in the HIDE SNP for their Medicare benefits and an unaffiliated Medicaid managed care plan or the State Medicaid FFS program for their Medicaid acute and primary care benefits. When Medicare and Medicaid plan enrollment is unaligned, as it is in many HIDE SNPs, a provider serving a dually eligible individual enrolled in a HIDE SNP would submit a claim to the HIDE SNP for Medicare payment of the service, then submit a second claim to the Medicaid managed care plan or the State Medicaid program for Medicaid payment of the covered benefit.

Our proposal does not include Medicare Parts A and B premiums in the requirement for FIDE SNPs to cover Medicare cost-sharing. We do not believe that it is necessary to require FIDE SNPs (or other D–SNPs) to pay premiums as there is a loss of efficiency and no additional integration of benefits to be achieved by having a State pay a capitation rate to an MA organization for the MA organization to cover Medicare premiums. The State Medicaid agency will 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. Therefore, we propose to specifically exclude payment of Medicare premiums as a coverage requirement for dually eligible beneficiaries enrolled in FIDE SNPs.

In addition to our proposal for FIDE SNPs, we encourage States to include Medicaid coverage of Medicare Part A and Part B cost-sharing (other than Medicare premiums) for dually eligible individuals in their capitated contracts with all D–SNPs as a method of reducing provider burden and improving access. We considered proposing a requirement that *all* D–SNPs have a contract with States for capitation for Medicare cost-sharing. Unlike FIDE SNPs with our proposed requirement for exclusively aligned enrollment, applying a requirement to other D–SNPs raises a number of complicating, but we believe solvable, problems. In States that have capitated payment arrangements with Medicaid managed care plans to cover Medicaid primary and acute services and behavioral health, such coverage typically requires the Medicaid managed care plan to cover Medicare cost-sharing when Medicare covers the service. That means, when enrollment is not aligned between a D–SNP and the Medicaid managed care plan, the result is not a streamlined payment process for the provider. A contract with the D–SNP for capitated coverage of Medicare cost-sharing—and a carve-out of Medicare cost-sharing coverage from the Medicaid managed care contract—can put Medicare coverage of services and Medicaid coverage of Medicare cost-sharing under a single entity, but could be a complicated process for States to implement. For States without Medicaid managed care programs for dually eligible individuals, contracting (with capitation payments) with D–SNPs for coverage of Medicare cost-sharing can be a more straightforward process. We solicit feedback on the feasibility, implementation, estimated time to enact, and impact of requiring capitated Medicare cost-sharing for all D–SNPs to inform future rulemaking.

In the CY 2020 Medicare Parts C and D Draft Call Letter, we requested comments on the ways to extend the benefits of the automatic claims crossover process for services provided to dually eligible individuals in MA plans and discussed those comments in the CY 2020 Medicare Parts C and D Final Call Letter.[69] Commenters described the need for MA plans to have real-time Medicaid eligibility and enrollment data to facilitate better coordination of care and Medicare cost-sharing payment across MA plans and Medicaid MCOs. Therefore, we also considered proposing a requirement for States 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. We chose not to propose a requirement at this time to allow more time for us to consider the operational challenges for States. We solicit 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.

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

[68] CMS Special Needs Plan Comprehensive Report, January 2021: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data#:~:text=Special%20Needs%20Plan%20%28SNP%29%20Data%20%20%20,%20202021-03%20%206%20more%20rows%20.*

[69] CMS, Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 1, 2019. Retrieved from: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

benefits and services, consistent with State policy. We explained then that the term ''consistent with State policy'' recognizes the variability in the degree and extent to which Medicaid services are covered from one State to the next (76 FR 21444). Section 1859(f)(3)(D) of the Act, as added by section 164(c)(3)(D) of MIPPA, uses the phrase ''consistent with State policy'' to describe the Medicaid long-term care services that the D–SNP may include in its contract with the State Medicaid agency. As used in the definition of FIDE SNP, the term ''specifies'' acknowledges that States vary in the degree in which Medicaid services are covered by the State under its Medicaid program (encompassing the Medicaid State plan and any waivers) by only requiring the FIDE SNP to cover those services specified by the State Medicaid agency as covered in its Medicaid program. Further, in the April 2011 final rule (76 FR 21444), we explained that the FIDE SNP definition at § 422.2 requires the plan to provide all Medicaid-covered primary, acute, and long-term care services and supports (LTSS) to beneficiaries, and not some combination thereof.

Despite this discussion in the 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. CMS 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.

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, which was the goal of the April 2011 final rule. We propose 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 proposed requirements 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), includes flexibility for approval of some limited carve-outs of LTSS and behavioral health services.

(2) Requiring FIDE SNPs To Cover All 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 propose revisions to the FIDE SNP definition in paragraph (2)(i) of § 422.2 to limit the FIDE SNP designation to D–SNPs that cover all 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. Our proposal here means that all primary and acute care services, including the Medicare cost-sharing covered by the State Medicaid program (as discussed earlier in section II.A.5.b. of this proposed 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 seek comment on whether we should allow for specific carve-outs of some of these benefits and services. We welcome 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 request that comments include the reason for the existing and proposed future carve-outs.

We are clarifying here 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 recognize that Medicaid NEMT is a critical service for dually eligible individuals to access primary and acute care services. However, we do not consider NEMT coverage to be required for FIDE SNPs under the current or proposed definition. We note that States are able to contract with their D–SNPs, or the affiliated Medicaid managed care plans, to cover NEMT. Such contracting might provide these plans with useful tools to facilitate access to care for their members and make it easier for States to coordinate Medicaid NEMT with overlapping services provided by D–SNPs as Medicare supplemental benefits.

(3) Requiring FIDE SNPs To Cover Medicaid Home Health and Durable Medical Equipment

We propose 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. Those benefits we are proposing to add are home health services, as defined in § 440.70, and durable medical equipment (DME) services, as defined in § 440.70(b)(3). We believe that FIDE SNPs should be required to cover the Medicaid home health and DME benefits because home health and DME 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 DME, so we do not expect this proposal to impact any existing FIDE SNPs. However, we propose that this change in the scope of required coverage by FIDE SNPs would not apply until 2025 in case there are other circumstances of which we are not aware that would necessitate additional time to adapt to our proposal.

As such, we propose to add a new paragraph (2)(iv) of the FIDE SNP definition at § 422.2 related to scope of services to clarify that a FIDE SNP's capitated contract with the State Medicaid agency must include all Medicaid home health services as defined at § 440.70. Also, we propose to add a new paragraph (2)(v) of the FIDE SNP definition at § 422.2 related to scope of services to clarify that a FIDE SNP's capitated contract with the State Medicaid agency must include all Medicaid DME as defined at § 440.70(b)(3).

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

Behavioral health needs are extensive among dually eligible individuals. Nearly one-third of individuals who are dually eligible for Medicare and Medicaid have been diagnosed with a serious mental illness, such as schizophrenia, bipolar disorder, or major depressive disorder, a rate almost three times higher than for non-dually eligible Medicare beneficiaries.[70] Full-benefit dually eligible individuals experience higher rates of bipolar disorder and are more likely to use at least one Medicare or Medicaid community mental health service than partial benefit dually eligible individuals.[71] Fragmented physical and behavioral health care, delivered across multiple providers and funding sources, can decrease access to care and lead to poor health status.[72] Some studies, such as the ''Improving Mood—Promoting Access to Collaborative Treatment for Late-Life Depression'' study, provide evidence that coordinated medical and behavioral health care lead to better behavioral health outcomes.[73]

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 15706–15707). We believe that a revision to that policy is appropriate and propose 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 propose the 2025 date to allow time for MA organizations and States to adapt to our proposal.

Restricting FIDE SNP designation to plans capitated for Medicaid behavioral health services, as well as other benefits, 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. Absent coverage of Medicaid behavioral health services, a FIDE SNP would be less able to effectively coordinate overlapping behavioral health services covered by Medicare and Medicaid and would have an incentive to steer beneficiaries toward Medicaid-covered services for which it is not financially responsible. 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.[74] 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.

Since codifying the definition of HIDE SNP in the April 2019 final rule, we have received many questions from MA organizations and other stakeholders about the difference between a FIDE SNP and HIDE SNP, and we attempted to further explain the distinction in a January 17, 2020 Health Plan Management System memorandum titled, ''Additional Guidance on CY 2021 Medicare-Medicaid Integration Requirements for Dual Eligible Special Needs Plans'' (January 2020 memorandum).[75] Requiring a FIDE SNP to include Medicaid behavioral health services, with the exception of limited carve-outs as proposed at § 422.107(h) and described in section II.A.5.e., would make the coordination continuum from HIDE SNP to FIDE SNP easier to explain and understand since HIDE SNP designation would allow for a carve-out in full or in part of either Medicaid behavioral health services or LTSS while FIDE SNP designation would allow for only limited carve-outs of Medicaid behavioral health services (or, as discussed in section II.A.5.e., of LTSS). As proposed, § 422.107(h) would permit limited exclusions from coverage of Medicaid behavioral health services by both FIDE SNPs and HIDE SNPs while treating those plans as providing coverage of the category of benefits. Under the proposal, the permissible carve-outs would be limited to a minority of beneficiaries eligible to enroll in the D–SNP and use Medicaid behavioral health services or constitute a small part of the total scope of behavioral health services for which Medicaid is generally the primary payer. Thus, under our proposal, FIDE SNPs would cover the vast majority of Medicaid behavioral health benefits *and* Medicaid LTSS benefits, and HIDE SNPs would cover the vast majority of Medicaid behavioral health benefits *or* Medicaid LTSS benefits (or potentially both categories of benefits).

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. Our review of State Medicaid agency contracts for FIDE SNPs in CY 2021 indicates that States include full coverage of Medicaid behavioral health services for 45 of the 69 FIDE SNPs.[76] The FIDE SNPs with contracts that carve

[70] Congressional Budget Office. ''Dual-Eligible Beneficiaries of Medicare and Medicaid: Characteristics, Health Care Spending, and Evolving Policies.'' (June 2013). Retrieved from: *https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/44308dualeligibles2.pdf.* This report classified Medicare enrollees as having a mental illness if they had a diagnosis from the previous year of schizophrenia; major depressive, bipolar, and paranoid disorders; or other major psychiatric disorders.

[71] Integrated Care Resources Center, Working With Medicare Webinar, *https://www.integratedcareresourcecenter.com/sites/default/files/4.15.20%20WWM%20BH%20Slide%20Deck_for%20508%20Review.pdf.*

[72] 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.*

[73] Unutzer, et al., Journal of the American Medical Association, ''Collaborative Care Management of Late-life Depression in the Primary Care Setting: A Randomized Controlled Trial'', December 11, 2002. Available at: *https://aims.uw.edu/resource-library/collaborative-care-management-late-life-depression-primary-care-setting-randomized.*

[74] Unutzer, et al., Journal of the American Medical Association, ''Collaborative Care Management of Late-life Depression in the Primary Care Setting: A Randomized Controlled Trial'', December 11, 2002. Available at: *https://aims.uw.edu/resource-library/collaborative-care-management-late-life-depression-primary-care-setting-randomized.*

[75] 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/httpsedit cmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memo-5.*

[76] CMS review of CY 2021 State Medicaid agency contracts for FIDE SNPs.

out Medicaid behavioral health include two FIDE SNPs in California, 17 FIDE SNPs in New York, and five FIDE SNPs in Pennsylvania.[77] 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.[78] If the remaining FIDE SNPs in California and Pennsylvania do not meet the proposed FIDE SNP definition at § 422.2, they may still meet the HIDE SNP definition proposed 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 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 discussed earlier in this section, 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.

Specifically, we propose the following changes at paragraph (2) of the FIDE SNP definition at § 422.2 related to scope of services:

- Strike the words ''provides coverage consistent with State policy of'' and replace them with ''requires coverage of the following benefits, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a FIDE SNP in the State, except as approved by CMS under § 422.107(g) and (h)'' to clarify the services the FIDE SNP must include in its capitated contract with the State Medicaid agency;
- Redesignate to a new paragraph (2)(i) the requirement that a FIDE SNP's capitated contract with the State Medicaid agency must include all primary care and acute care covered under the State Medicaid program, and newly specify that these contracts must include 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;
- Redesignate to a new paragraph (2)(ii) the requirement that a FIDE SNP's capitated contract with the State Medicaid agency include all LTSS covered under State Medicaid policy, including coverage of nursing facility services for a period of at least 180 days during the plan year;
- Add new paragraph (2)(iii) to require that a FIDE SNP's capitated contract with the State Medicaid agency must include Medicaid behavioral health services for plan year 2025 and subsequent years;
- Add new paragraph (2)(iv) to require that a FIDE SNP's capitated contract with the State Medicaid agency must include all Medicaid home health services as defined at § 440.70 for plan year 2025 and subsequent years; and
- Add new paragraph (2)(v) to require that a FIDE SNP's capitated contract with the State Medicaid agency must include all Medicaid DME as defined at § 440.70(b)(3) for plan year 2025 and subsequent years.

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 propose to update 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 proposed 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 propose 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. Specifically, we propose the following at paragraph (2) of the HIDE SNP definition at § 422.2:

- Strike the words ''consistent with State policy, of long-term services and supports, behavioral health services, or both'' and instead require a HIDE SNP to have a capitated contract with the State Medicaid agency that requires the HIDE SNP to cover, at a minimum, Medicaid long-term services and supports or Medicaid behavioral health services;
- Reorganize paragraphs (1) and (2) into paragraphs (1)(i) and (ii) to outline that the capitated contract is between the State Medicaid agency and the MA organization or between the State Medicaid agency and the MA organization's parent organization, or another entity that is owned and controlled by its parent organization;
- Redesignate paragraph (2) into paragraphs (2)(i) and (ii) to state that the capitated contract requires coverage of LTSS, including community-based LTSS and some days of coverage of nursing facility services during the plan year, or behavioral health services to the extent Medicaid coverage of such services is available to individuals eligible to enroll in a HIDE SNP in the State; and
- To redesignated paragraph (2), add the words ''except as approved by CMS under § 422.107(g) or (h)'' such that the HIDE SNP ''requires coverage of the following benefits, to the extent Medicaid coverage of such benefits is

[77] See *https://www.cms.gov/files/document/smacdsnpintegrationstatusesdata.xlsx.*

[78] New York State Department of Health, New York State Office of Mental Health, and New York State Office of Alcoholism and Substance Abuse Services, ''Duals Integration: Adding Behavioral Health Services into Medicaid Advantage Plus,'' December 2020.

available to individuals eligible to enroll in a HIDE SNP in the State, except as approved by CMS under § 422.107(g) or (h),'' to clarify that the HIDE SNP must cover under its capitated Medicaid contract the full scope of the Medicaid benefit for the specified LTSS or Medicaid behavioral health services, except for limited carve-outs that CMS permits under proposed § 422.107(g) or (h); and

• Add new paragraph (3) to require that the capitated Medicaid contract applies in the entire service area of the D–SNP for plan year 2025 and subsequent plan years.

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

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

As discussed earlier, we propose 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. In both definitions, we propose 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 propose 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 proposed 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 would improve transparency for stakeholders and allow us to better enforce our policies to limit benefit carve-outs.

Our proposal is consistent with the policy described in a memorandum CMS issued in January 2020,[79] 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 is 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 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. The Medicaid contract may be between the State and either the legal entity providing the D–SNP, the parent organization of the D–SNP, or a subsidiary owned or controlled by the parent organization of the D–SNP. As discussed in the April 2019 final rule (84 FR 15705), the breadth of Medicaid LTSS coverage under a HIDE SNP does not have to be as broad as the coverage of Medicaid benefits provided by a FIDE SNP. For example, a HIDE SNP is not required to provide at least 180 days of nursing facility coverage during the plan year. If the HIDE SNP designation is based on coverage of Medicaid LTSS, such capitated coverage must include both of the following: Community-based LTSS, subject to permissible carve-outs, and institutional LTSS. Institutional LTSS must include coverage of nursing facility services with some days for which Medicaid coverage is primary but, in contrast to a FIDE SNP, may be less than 180 days each plan year. However, if a HIDE SNP designation is based on coverage of Medicaid behavioral health services, the HIDE SNP can cover some community-based and/or institutional LTSS or no LTSS.

We currently grant FIDE SNP status despite Medicaid LTSS carve-outs of limited scope if such carved-out services (1) apply to a minority of the full-benefit dually eligible LTSS users eligible to enroll in the 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 the FIDE SNP who use Medicaid LTSS. Examples of permissible LTSS carve-outs for FIDE SNPs that apply to a minority of full-benefit dually eligible LTSS users may include services specifically limited to individuals with intellectual or developmental disabilities, individuals with traumatic brain injury, or children. Carve-outs of specific Medicaid LTSS would be permissible if the carved-out services would typically only be a small component of the broad array of LTSS provided to the majority of Medicaid LTSS users eligible to enroll in the FIDE SNP. We would not, however, expect to approve carve-outs for LTSS services for a specific population—for example, individuals with intellectual or developmental disabilities—if enrollment in the FIDE SNP was limited to individuals with those disabilities. For example, personal emergency response systems or home modifications may be important supports for participants in a Medicaid home and community-based waiver program. However, those specific services would rarely constitute the preponderance of an enrolled dually eligible individual's care plan because most individuals receiving such services also receive other types of in-home supports, such as personal care services. In contrast, we would not expect to approve carve-outs of in-home personal care or related services provided to older adults or people with disabilities even if such services were limited to individuals meeting a nursing home level of care.

D–SNPs can currently obtain the HIDE SNP designation with limited carve-outs of Medicaid behavioral health services from their capitated contracts. A behavioral health services carve-out would be of limited scope if such service: (1) Applies primarily to a minority of the full-benefit dually eligible users of behavioral health services eligible to enroll in the HIDE 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 the HIDE SNP. We specify 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 Medicaid programs provide to individuals with severe and moderate

[79] 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/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memo-5.*

mental illness are covered through the D–SNP or the affiliated Medicaid managed care plan. We believe that level of integrated coverage is a minimum standard for a D–SNP to be considered highly or fully integrated. It would be insufficient for a HIDE SNP or FIDE SNP to solely cover the counseling services where Medicare is primary. Examples of permissible carve-outs that apply to primarily a minority of full-benefit dually eligible users of such services who are eligible to enroll in the HIDE SNP include school-based services for individuals under 21 years of age and court-mandated services. Examples of permissible carve-outs that constitute a small part of the total scope of Medicaid behavioral health services include inpatient psychiatric facilities and other residential services, such as payment of Medicare cost-sharing or coverage of days not covered by Medicare; substance abuse treatment, such as payment of Medicare cost-sharing or coverage of services not covered by Medicare; services provided by a Federal Qualified Health Center or Rural Health Clinic; and Medicaid-covered prescription drugs for treatment of behavioral health conditions. We believe such carve-outs would still allow FIDE SNPs and HIDE SNPs to meaningfully integrate Medicaid behavioral health coverage for their enrollees. We seek comment on whether we have struck the right balance in permitting such carve-outs, including for the examples cited previously.

Specifically, we propose the following language at § 422.107:

- Add new paragraph (g) to describe that a D–SNP may meet the FIDE SNP or HIDE SNP definition at § 422.2 even if the contract between the State and the plan carves out some Medicaid LTSS, as long as the carve-out, as approved by CMS, applies primarily to a minority of beneficiaries eligible to enroll in the D–SNP who use long-term services and supports or constitutes a small part of the total scope of Medicaid LTSS provided to the majority of beneficiaries eligible to enroll in the D–SNP;
- Add new paragraph (h) to describe that a D–SNP may meet the FIDE SNP or HIDE SNP definition at § 422.2 even if the contract between the State and the plan carves out some Medicaid behavioral health services, as long as the carve-out, as approved by CMS, applies primarily to a minority of beneficiaries eligible to enroll in the D–SNP who use behavioral health services or constitutes a small part of the total scope of behavioral health services provided to the majority of beneficiaries eligible to enroll in the D–SNP; and
- Redesignate paragraph (e) ''Date of Compliance'' as new paragraph (i) due to the proposed new paragraphs (e) through (h).

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

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 members 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 and is codified at § 422.2.

Currently, under § 422.2, a D–SNP can meet the requirements to be designated as a FIDE SNP and 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.[80] For FIDE SNP and HIDE SNP members outside the companion Medicaid plan's service area, this lack of alignment does little to integrate Medicare and Medicaid benefits as the D–SNP member does not have the option to join the companion Medicaid plan. In its June 2019 report to Congress, MedPAC illustrated service area misalignment between D–SNPs and companion Medicaid managed LTSS plans, finding a significant number of D–SNP members not in the same service area as the D–SNP sponsor's Medicaid managed LTSS offering.[81] In its June 2021 report to Congress, MACPAC recommended States use the State Medicaid agency contracts (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.[82] 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 minimum criteria for Medicare and Medicaid integration, we are proposing to amend the definitions of FIDE SNP and HIDE SNP at § 422.2. We propose to amend 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. Requiring the service area of the Medicaid capitated contract to include at least the service area of the D–SNP contract allows all FIDE SNP and HIDE SNP enrollees to access both Medicare and Medicaid benefits from a single parent organization. These proposed changes to § 422.2 are in addition to the other edits proposed to the definitions of FIDE SNP and HIDE SNP at § 422.2 as described in this proposed rule.

Our proposal addresses an unintended loophole to the minimum D–SNP integration criteria we have 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 members in the same service area as the companion Medicaid plan. Where the overlap in the service areas for the separate MA D–SNP contract and the Medicaid capitated contract is small, the opportunity for Medicare-Medicaid integration is similarly limited as only enrollees in that overlapping area have the potential to receive benefits from an integrated plan with both MA and Medicaid managed care plan contracts under a single parent organization. In such a FIDE SNP or HIDE SNP, the members without access to the companion Medicaid plan might not benefit even from the improved care coordination possible under the notification requirement at § 422.107(d) required for a D–SNP that is not a FIDE SNP or HIDE SNP if the State has not imposed that requirement. We do not believe that is consistent with the goals and purposes

[80] 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.*

[81] Medicare Payment Advisory Commission, ''Report to the Congress: Medicare and the Health Care Delivery System,'' June 2019. Retrieved from: *https://medpac.gov/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf.*

[82] 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.*

of increasing 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.

The proposal is not intended 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. Our proposal would not 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 have other policy objectives better met with larger service areas in their Medicaid managed care programs.

In plan year 2021, all FIDE SNPs meet the service area requirement being proposed. Most, but not all, HIDE SNPs also meet the proposed requirement. As of June 2021, there were 1,302,505 HIDE SNP members across 16 States in 186 HIDE SNP plan benefit packages and 89 contracts.[83] In four States, 20 HIDE SNPs have service area gaps with their affiliated MCOs, leaving 97,004 members in 174 counties with no corresponding Medicaid plan.[84] Approximately half the D–SNPs with unaligned service area have over 50 percent of their enrollment in the unaligned service area, and the vast majority of HIDE SNP members and counties with unaligned service areas are concentrated in one State and one parent organization. Therefore, we believe some HIDE SNPs have only met the D–SNP integration requirements for a fraction of their enrollment due to the unintended gap in integration that is created by a lack of service area alignment.

If finalized, an MA organization impacted by our proposal would have several options. First, the organization can work with the State to expand their companion Medicaid plan service area to the full D–SNP service area, thus increasing the opportunity for integrated care and qualifying as a HIDE SNP under our proposal. Second, the MA organization can request to crosswalk enrollees (using the crosswalk exception currently at § 422.530(c)(4), which we are proposing to redesignate as § 422.530(c)(4)(i) in section II.A.6.a.) from the existing D–SNP that includes the service area outside of the companion Medicaid plan service area into a new D–SNP; the end result is two separate D–SNPs, one which qualifies as a HIDE SNP (because it has the overlapping service area with the companion Medicaid plan and meets other requirements) and another D–SNP that, because it is neither a FIDE SNP nor a HIDE SNP, would need to meet the notification requirement at § 422.107(d). Third, the MA organization can keep the existing service area for the existing D–SNP and contract with the State as a non-HIDE D–SNP by meeting the notification requirement at § 422.107(d).

These options all require the MA organization to collaborate with the State Medicaid agency. We believe that a State currently engaged with MA organizations to integrate care through a HIDE SNP would likely be willing to work with the MA organization to come into compliance with the proposed rule. However, if the State was unwilling to engage with the MA organization, the MA organization would need to end the HIDE SNP plan benefit package in the unaligned service area. We seek comment on whether this proposal would likely result in additional, unintended disruption for current HIDE SNP membership, particularly if such unintended disruption is for more than the initial year of transition. We generally believe that the additional integration—and the benefits from higher integration—outweigh the limited disruption potentially caused by realignment of FIDE SNP and HIDE SNP service areas to meet this proposed requirement by 2025.

We are 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. That is, a D–SNP would qualify as a FIDE SNP or HIDE SNP if a minimum percentage of the D–SNP enrollment resides in the companion Medicaid plan (or plans) service area or if a minimum percentage of the D–SNP service area overlaps with the companion Medicaid plan (or plans). We are 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 are not proposing either of these alternative approaches because we believe these alternatives 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. We seek comment on these alternatives, including input on what an appropriate percentage threshold of overlap in the services areas should be, whether an attestation process would provide the necessary level of oversight, and whether the status quo, with a clarification in the regulation text, creates a sufficient level of integration for FIDE SNPs and HIDE SNPs. We are interested in comments on whether the alternatives create sufficient improvements in coordination of the Medicare and Medicaid benefits compared to current practice or if the alternatives would adequately address the policy goals outlined in this proposal.

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 to require greater integration of Medicare and Medicaid benefits from the D–SNPs that operate in the State. For example, to develop products that integrate Medicare and Medicaid coverage, several states—

[83] CMS, SNP Comprehensive report, June 2021. Retrieved at: *https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldataspecial-needs/snp-comprehensive-report-2021-06.*

[84] 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/smacdsnpintegrationstatusesdata.xlsx;* and service area information from State Medicaid agency websites.

including Arizona, Hawaii, Idaho, Massachusetts, Minnesota, New Jersey, Pennsylvania, and Tennessee—operate Medicaid managed care programs for dually eligible individuals in which the State requires that the Medicaid MCOs serving dually eligible individuals offer a companion D–SNP product. These States also require specific care coordination or data sharing activities in their contracts with D–SNPs.[85]

Even among States that have used the State Medicaid agency contract at § 422.107 to promote integration, we believe there are additional opportunities to improve beneficiary experiences and health plan oversight. We propose addressing such opportunities in this section of this proposed rule.

We propose 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. Proposed paragraph (e)(1) provides that CMS will take the steps described in proposed paragraphs (e)(2) and (3) when a State Medicaid agency's contracts with D–SNPs require exclusively alignment enrollment and require the D–SNPs to request MA contracts that only include one or more State-specific D–SNPs and that such D–SNPs use integrated member materials. We do not believe that proposed paragraph (e)(1), in and of itself, creates or limits opportunities already available to States to contract with D–SNPs. The primary purpose of proposed paragraph (e)(1) is to establish a pathway for States with parameters for how CMS will work with the State when the State wishes to require D–SNPs with exclusively aligned enrollment in that State to operate under D–SNP-only MA contracts and use specific integrated enrollee materials. 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) describe steps CMS would take when the conditions of proposed paragraph (e)(1) are met.

a. Limiting Certain MA Contracts to D–SNPs

Special needs plans, including D–SNPs, are currently included as separate 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. MA organizations may offer multiple PBPs under the same contract number, and the plans under these contracts may have service areas in multiple States or regions. PBPs under one contract number may have very different benefit packages and serve different populations. MA organizations report medical loss ratios and certain quality measures—including many Star Ratings measures—at the contract level, which does not allow for differentiation of PBPs that are D–SNPs. While we capture some measures 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 (for example, CAHPS, HEDIS,[86] Medicare Health Outcomes Survey (HOS), Star Ratings) of the D–SNP distinguished from other PBPs in the contract. Combining data from all PBPs offered under a contract, however, ensures that there is generally a large enough sample to administer CAHPS surveys and calculate HEDIS measures; CMS has discussed the possibility of collecting data and assigning Star Ratings at the plan level in the past, such as in the April 2018 final rule (83 FR 16526 through 16528). Currently, §§ 422.162(b) and 423.182(b) provide for Star Ratings to be assigned at a contract level.

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, RPPO, etc.) it seeks to offer for all PBPs for the totality of the States.[87] Under CMS's administration of the MA program, SNPs and non-SNPs may be PBPs in the same contract(s) so long as they are the same product type (for example, SNP HMO and non-SNP HMO PBPs can be in the same contract, but a SNP HMO and non-SNP PPO would not be). Except under our existing authority in § 422.550 where there is a change in ownership or for purposes of model tests under Section 1115A that utilized D–SNPs, CMS has not previously permitted MA organizations to create separate D–SNP contracts. If necessary, under §§ 422.504(k) and 423.504(e), CMS does have authority to sever specific PBPs from a contract and to deem a separate contract is in place for the severed PBP(s).

The majority of D–SNPs are in contracts that include other non-SNP MA plans. Of the 276 D–SNP PBPs offered in CY 2021, only 88 (32 percent) are in D–SNP-only contracts.[88] 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. Throughout our work with MMPs, we and our State partners benefited from having performance data that was specific to the MMP.

Therefore, we are proposing to codify a pathway where if a State requires an MA organization to establish a contract that only includes one or more D–SNPs with exclusively aligned enrollment within a State, the MA organization may apply for such a contract using the existing MA application process. We do not anticipate this proposal would create a large volume of new contracts, because most States do not meet the prerequisite of requiring exclusively aligned enrollment, and—among those that do—some D–SNPs are already in D–SNP-only contracts. The proposed language at § 422.107(e)(1)(i) would give States the flexibility to require an MA organization to establish one or more D–SNP-only contracts, which would provide more transparency in D–SNP plan performance within States. For example, the Florida State Medicaid agency could allow an MA organization serving South Florida and the Florida Panhandle to establish one D–SNP-only contract for South Florida and a separate D–SNP-only contract for the Florida Panhandle.[89]

[85] Verdier, J., Kruse, A., Sweetland Lester, R., Philip, A.M., and Chelminsky, D. *State Contracting with Medicare Advantage Dual Eligible Special Needs Plans: Issues and Options* (November 2016). Retrieved from *https://www.integratedcareresourcecenter.com/sites/default/files/ICRC_DSNP_Issues__Options.pdf;* 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 from *https://www.macpac.gov/wp-content/uploads/2021/06/June-2021-Report-to-Congress-on-Medicaid-and-CHIP.pdf.*

[86] Certain HEDIS measures are reported by SNPs at the PBP level and are available in public use files that can be used to review and assess D–SNP performance outside of CMS's Quality Star Rating program. These PBP-level measures are used to calculate the Care for Older Adults measures in Star Ratings, but they are not used to calculate Star Ratings to compare performance across MA plans. The public use files are available at: *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata?redirect=/mcradvpartdenroldata.*

[87] The following memo outlines the policy for CY2020, 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-partcpartd-mmp.pdf.*

[88] CMS, Contract Management Reports 2020, SNP Type and Subtype Report, August 7, 2020.

[89] Due to smaller enrollment compared to broader MA contracts, D–SNP-only contracts may experience sample size issues, such that certain

Where States choose to use this opportunity, it would have several benefits. First, it would provide the State and the public with greater transparency on the quality ratings for the D–SNP, reflecting outcomes and experiences specific to dually eligible individuals in the State.[90] This can help CMS and States better identify disparities between dually eligible and other beneficiaries and target interventions accordingly where the population covered by the D–SNP-only contract is of sufficient size to reliably report performance on quality measures and surveys. Second, it would improve transparency on financial experiences related to furnishing Medicare and Medicaid benefits because the contract's medical loss ratio would reflect Medicare financial experience specific to dually eligible individuals in the State that are enrolled in a companion Medicaid MCO as well as the D–SNP because this proposal is limited to D–SNPs with exclusively aligned enrollment. Exclusively aligned enrollment, as defined in § 422.2, means the Medicaid MCO that furnishes Medicaid benefits is the same as the D–SNP, the D–SNP's parent organization, or owned and controlled by the D–SNP's parent organization. Third, it would allow a D–SNP to create a MOC that is specific to the State, which would facilitate review by the State and provide opportunities for greater customization of the MOC to the State's Medicaid-related policies and priorities. Fourth, it would enable CMS to review and evaluate the provider network specific to the D–SNPs offered under that D–SNP-only contract.

We describe 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. We will provide States with additional information on timelines and procedures in sub-regulatory guidance; we may also address our recommendations for best practices and identify considerations for States that are considering this. We would expect the following steps—which are consistent with current timeframes and procedures for submission of applications, bids and other required materials to CMS—to be taken if a State sought to include these requirements for the 2025 plan year:

- Consistent with CMS recommendations, the State consults with CMS, MA organizations, and other stakeholders beginning in early 2023 on whether to add the requirements at § 422.107(e)(1) to its State Medicaid agency contract.
- Upon reaching a decision to proceed, the State would notify CMS (by letter) and the affected MA organizations by August 2023 to enable the MA organization and CMS to start the necessary steps.
- Following existing timelines and procedures for applications, bids, and other annual submissions, and consistent with § 422.501(b), the impacted MA organizations would submit a Notification of Intent to CMS to apply for a new D–SNP-only contract in November of 2023 and an application for a new D–SNP-only contract (beginning January 2025) in February of 2024.
- CMS and the State would develop integrated SB, Formulary, and combined Provider and Pharmacy Directory model materials from January through June 2024.
- The impacted MA organizations would submit a bid for the D–SNP PBP in the new D–SNP-only contract per § 422.254 by the first Monday in June 2024.
- The impacted MA organizations would not submit a bid in June 2024 for the D–SNP PBP that had been included in the non-D–SNP-only MA contract, indicating it is non-renewing the existing PBP.
- The affected D–SNPs would submit their State Medicaid agency contracts, including the provisions described at § 422.107(e)(1), in July of 2024 and the D–SNP's request to use the proposed crosswalk exception at § 422.530(c)(4)(ii) in June of 2024 to move enrollees from the non-renewing D–SNP to the new D–SNP offered under the D–SNP-only contract.
- Subject to compliance with all Part C and Part D requirements, CMS would approve the new D–SNP PBP and its bid in the D–SNP-only contract for CY 2025 in September 2024.
- Dually eligible beneficiaries enrolled in non-renewing D–SNP PBPs could be crosswalked to the new D–SNP PBP in October 2024 for a January 1, 2025 effective date if the MA organization requests the crosswalk exception proposed at § 422.530(c)(4)(ii) and it is approved by CMS.
- The new D–SNP PBP into which individuals are crosswalked describes changes to the MA–PD benefits and provides information about the D–SNP PBP in the Annual Notice of Change, which must be sent consistent with § 422.111(a), (d), and (e) for beneficiary receipt in early October 2024.

Establishing D–SNP-specific contracts creates some new challenges. CMS would have added administrative burden to oversee a larger number of contracts. MA organizations would similarly experience new burdens, such as additional reporting to CMS, calculation of HEDIS measures, and administration of HOS and CAHPS surveys. We believe these costs are modest relative to the benefits. We solicit comments on other consequences that would flow from our proposal, both in terms of benefits for the MA organizations, States, and dually eligible individuals and potential unforeseen difficulties for these stakeholders.

Finally, to avoid any significant beneficiary disruption, we propose a new crosswalk exception to allow MA sponsors to seamlessly move D–SNP members into any 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). It would allow transition to a D–SNP under a contract subject to proposed § 422.107(e) from a D–SNP that is non-renewing, has enrollees residing in the portion of the current service area impacted by the service area reduction, or has its eligible population newly restricted by a State contract. To add this new crosswalk exception, we propose redesignating the existing paragraph (c)(4) into new paragraphs (c)(4)(i) and (ii) in § 422.530. Under this proposal, the processes used for other crosswalk exceptions (for example, the notice to CMS and CMS' review and approval of the crosswalk exception) would apply to this new crosswalk exception.

We seek comment on this new proposed crosswalk exception and whether any additional beneficiary protections should apply.

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quality measures (for example, HEDIS and CAHPS) may not have sufficient data to reliably report performance. States may want to consider this implication when contemplating whether to establish D–SNP-only contracts, particularly if a State wishes to further limit D–SNP-only contracts based on regions within the State.

[90] Star Ratings for the new D–SNP-only contracts would be calculated in accordance with § 422.166. As described at § 422.166(d)(2)(vi), new D–SNP-only contracts that do not have sufficient data to calculate and assign ratings and do not meet the definition of low enrollment or new MA plans at § 422.252 would be assigned Quality Bonus Payment ratings based on the enrollment-weighted average highest rating (as defined at § 422.162) of the parent organization's other MA contract(s).

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.[91] 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 in more detail later in this section, so we are proposing 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. Under this proposal, the applicable Medicaid managed care and MA requirements and standards would continue to apply to the integrated materials. As background, we discuss in this section some of the requirements for mandatory communications materials in the MA and Medicaid programs.

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. Standardized 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 3 years.[92] While MA organizations and Part D sponsors must use *standardized* materials and content in the form and manner CMS provides, CMS *model* materials and 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 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). However, CMS does not create standardized or model materials for use by Medicaid managed care plans. States may create such required materials and have primary responsibility for ensuring that Medicaid managed care plans comply with the minimum information requirements in § 438.10 and any additional requirements imposed by the State. Among the materials that Medicaid managed care plans must distribute are enrollee handbooks, provider directories, and formularies.

To allow MA organizations and Part D sponsors sufficient time to populate required materials with plan-specific information; submit them through the CMS Health Plan Management System (HPMS) for submission, or submission and approval, as applicable; translate them into any non-English language that is the primary language of at least 5 percent of the individuals in the service area; and make them available to beneficiaries by the required dates indicated later in this section, CMS aims to issue required materials and instructions annually by the end of May for the following plan year.

Among 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, are—

- Evidence of Coverage (EOC), which is a standardized communications material that tells members how to get plan-covered health care services and prescription drugs and explains member rights and responsibilities. To comply with § 422.111(b)(2)(iii), CMS expects D–SNPs to modify language in the standardized EOC, as applicable, to address and include Medicaid benefits for which enrollees are eligible, and CMS permits D–SNPs to use further modifications to explain Medicaid benefits the D–SNP furnishes to its enrollees. Plans must send the EOC, or a notice informing enrollees how to access it electronically, to current enrollees by October 15 of each year and to new enrollees within 10 days of CMS's confirmation of enrollment or the last day of the month prior to the enrollment effective date (whichever is later). The EOC is similar to the model enrollee handbook that States are required to develop for Medicaid MCOs to send under § 438.10(c)(4)(ii).
- Annual Notice of Changes (ANOC), which is a standardized marketing material that provides information to current members about changes for the upcoming contract year. It identifies any changes to the plan's health care services, prescription drugs, cost-sharing for MA benefits (including Part A and Part B benefits and supplemental benefits), and administrative items such as contract number or grievance and appeal procedures. D–SNPs may also modify language in the ANOC, as applicable, to address and include Medicaid changes. Plans must send the ANOC to current enrollees for receipt no later than September 30 of each year, except that enrollees with an October 1, November 1, or December 1 enrollment effective date must receive the ANOC within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.
- Summary of Benefits (SB), which is a model marketing material that provides prospective members a description of health care services and prescription drugs the plan will cover in the upcoming contract year. It helps individuals determine which plans best meet their needs. D–SNPs must describe or identify their Medicaid benefits, and FIDE SNPs and HIDE SNPs may display integrated benefits where applicable. Plans are not required to send SBs to all prospective members but, in our experience, many do and make the SB available by October 15 of each year. CMS permits distribution of marketing materials as early as October 1 of each year.
- Formulary, which is a model communications material that includes the list of Medicare Part D drugs the plan covers when the drugs are medically necessary and filled at one of the plan's network pharmacies. The formulary also includes information about plan-covered over-the-counter (OTC) drugs and non-drug OTC products, any mail-order procedures, and utilization management procedures such as prior authorizations, step therapy, or quantity limits that the plan requires.[93] Plans must send the Formulary, or a notice informing how to

[91] 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.

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

[93] Refer to *www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Materials.*

access it electronically, for current enrollees, for receipt by October 15 of each year, and to new enrollees within 10 days of CMS's confirmation of enrollment or the last day of the month prior to the enrollment effective date (whichever is later).

- Provider Directory, which is a model communications material that lists the number, types, and addresses for the plan's network providers and rules about access to providers, such as authorization and referral requirements. D–SNPs using this model may identify Medicare providers who also accept Medicaid.[94] Plans must send the Provider Directory, or a notice informing how to access it electronically, for current enrollees, for receipt by October 15 of each year, and to new enrollees within 10 days of CMS's confirmation of enrollment or the last day of the month prior to the enrollment effective date (whichever is later).
- Pharmacy Directory, which is a model communications material that contains a list of the plan's network pharmacies and contact information, including all retail, mail-order, home infusion, and long-term care options.[95] Plans must send the Pharmacy Directory, or a notice informing how to access it electronically, for current enrollees for receipt by October 15 of each year, and to new enrollees within 10 days of CMS's confirmation of enrollment or the last day of the month prior to the enrollment effective date (whichever is later).

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, can 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.

CMS conducts studies to improve the effectiveness of the model and standardized beneficiary materials and content that we provide to MA and Part D plans for their use in communicating with enrollees and potential enrollees. To test materials, we conduct 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. For example, a 2017 study focused on beneficiary assessment of the Provider and Pharmacy Directory. Beneficiaries consistently described the CMS model directory as ''clear,'' ''simple,'' and ''easy to read.'' Beneficiaries also noted that the integrated version of the directory with the combined information on Medicare and Medicaid providers/pharmacies was comparatively better than separate Medicare and Medicaid directories they received from their current or previous insurance plans. We received similarly positive feedback from individuals with disabilities and from Spanish-speaking beneficiaries who tested a translated version.

MMPs participating in the capitated financial alignment model and the Minnesota Senior Health Options (MSHO) plans in the Demonstration to Align Administrative Functions for Improvements in Beneficiary Experience use integrated versions of these required materials. In addition, since 2019, CMS has worked with Massachusetts, New Jersey, and the FIDE SNPs in each State to develop and annually update certain integrated materials that the States require and issue to these plans. For contract years 2020 and 2021, we provided high-level assistance to New York as the State developed select integrated materials that its Medicaid Advantage Plus (MAP) plans could use. We are also working with California for contract year 2023 to develop integrated materials for those D–SNPs with exclusively aligned enrollment receiving Cal MediConnect members at the end of the California capitated FAI demonstration in 2022.

For the D–SNPs we have worked with, CMS typically begins development of integrated national templates and State-specific models with the SB; a Formulary that contains Medicare Part D, Medicaid, and OTC drugs as well as non-drug OTC products; and one combined Medicare and Medicaid Provider and Pharmacy Directory. Starting with these materials has several advantages. First, these materials integrate key Medicare and Medicaid information, which dually eligible individuals can use to make more knowledgeable decisions about their health care choices. Second, the SB, Formulary, and Provider and Pharmacy Directory are required materials but are not standardized and, therefore, are not subject to the PRA clearance process, which often takes nine months or more to complete. In contrast, D–SNPs must use standardized materials, as discussed earlier, without modification to the language, content, format, or order of information except in a few, specific instances per § 422.2267. Third, the SB, Formulary, and Provider and Pharmacy Directory 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 can contribute to increased understanding of and satisfaction with the coverage both programs provide.

To provide a more coordinated beneficiary experience, we propose at § 422.107(e) 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 SB, Formulary, and combined Provider and Pharmacy Directory (which would have to comply with §§ 422.111, 422.2267(e)(11), 423.128, 423.2267(e), and 438.10(h)). Proposed § 422.107(e)(1) establishes 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 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 and State law, 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. Therefore, proposed 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

[94] Refer to *www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Marketng ModelsStandardDocumentsand EducationalMaterial.*

[95] Refer to *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual.*

integrated materials and apply for a D–SNP-only contract. We intend 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.

We do not intend through this proposal to significantly change timelines for plans to prepare materials nor do we intend to require any State to mandate that D–SNPs use integrated materials. We intend for this proposal 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).

We are considering including the EOC and ANOC as part of the minimum scope of integrated materials identified in proposed § 422.107(e)(1)(ii). However, without yet navigating the PRA process for creating integrated versions of these materials, it may be better to re-assess integration of these materials at a later date. We welcome comments on this alternative and whether including these additional materials as part of the minimum scope of integration addressed in proposed § 422.107(e)(1)(ii) would better further our goals or better suit the needs of States that may use the pathway we are proposing at § 422.107(e) to achieve more integration for certain D–SNPs. Either way, our proposal would not preclude CMS and States from collaborating on other integrated materials, including an integrated EOC or ANOC. As proposed, § 422.107(e) applies only when a State requires 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 have 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 under this proposal. Further, we do not intend to prohibit or foreclose the possibility that CMS will work with States on other potential integration efforts that are not within the scope of § 422.107(e)(1).

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, including requirements imposed at the State level that are not identical to Federal minimum standards for Medicaid managed care plans in part 438. CMS and States have built separate infrastructure to monitor compliance with each set of requirements. This has three drawbacks related to integrated care approaches for dually eligible individuals. First, State regulators may be unaware of important compliance or performance problems related to the delivery of Medicare services or imposed on D–SNPs (or MA plans generally), and CMS may be unaware of important compliance or performance problems related to the delivery of Medicaid services, even when both parties are monitoring the same organization's coverage of services to the same people. Second, State and CMS officials may pursue different performance improvement priorities applicable to the plan(s) that cover dually eligible individuals, even when the plan(s) are under the same parent organization and serving the same enrollees. Third, uncoordinated oversight by CMS and the States can create inefficiencies for health plans where regulators seek duplicative information or initiate Medicare and Medicaid audits at the same time. We propose 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).

(1) State Access to the Health Plan Management System

We propose in paragraph (e)(3)(i) a mechanism to address access by States to the CMS Health Plan Management System (HPMS) (or a successor system) to better coordinate State and CMS monitoring and oversight of D–SNPs that operate under the conditions described at proposed paragraph (e)(1). 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. Our experience granting State access to HPMS through the FAI and a related demonstration in Minnesota suggest that HPMS access is a useful tool and that State access is without known problematic unintended consequences. Therefore, we propose that CMS would grant State access to HPMS, or any successor system, 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).

Under our proposal, approved State Medicaid officials would be able to use HPMS to conduct a number of information sharing and oversight activities for these D–SNPs including, but not limited to, reviewing marketing materials, and viewing models of care, member complaints, plan benefits, formulary, network, and other basic contract management information. This access would 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 because the State users would be able to review the same data and information available to CMS. MA organizations offering D–SNPs with exclusively aligned enrollment may benefit when it reduces the need for States to separately obtain the same information that is already available in HPMS.

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. Based on the current architecture of HPMS, approved State officials would only have access specific to information related to the MA contract(s) described in proposed paragraph (e)(1)(i). This proposal would not limit CMS's discretion to make HPMS accessible in other circumstances not described in our proposal but would authorize State access, which 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 seek 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 proposed rule.

(2) State-CMS Coordination on Program Audits

Proposed paragraph (e)(3)(ii) establishes that CMS would coordinate with State Medicaid officials on program audits. This coordination

would include sharing major audit findings for State awareness related to D–SNPs subject to proposed paragraph (e)(1).

CMS conducts audits of MA plans periodically to assess compliance with Federal requirements, including D–SNP-specific care coordination requirements. We believe that there are benefits for CMS, the State, and the MA organization to increasing coordination in connection with such audits. For example, providing State officials the opportunity to join the entrance and exit conference, as we have in the FAI and related demonstrations, has afforded greater transparency for State Medicaid officials into the Medicare-focused auditing process. Similarly, we would offer to work with States to attempt to avoid scheduling simultaneous State and Federal audits. For example, if State officials share a schedule of their planned Medicaid audits for MA organizations with contracts subject to proposed paragraph (e)(1) before CMS finalizes its audit schedule in October preceding the audit year, CMS may be able to adjust its program audit schedule to avoid overlapping audits. If a State official shares a schedule of planned audits with CMS after October, CMS could alternatively alert the State Medicaid agency if any of the State's planned audits are scheduled to overlap with a CMS program audit. This process would reduce the risk 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. We currently have the ability to coordinate with State Medicaid agencies on audits, but we are proposing to codify how CMS would commit to coordination in situations where § 422.107(e) applies. This would help in setting expectations for and provide clarity to stakeholders, especially State Medicaid agencies. While these activities are provided as examples, we do 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).

(3) State Input on Provider Network Exceptions

As part of implementing the proposed policy to coordinate on program audits and providing access to HPMS, CMS expects to use existing authority and flexibility as it pertains to the review of medical provider networks, particularly the 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.[96] As indicated in the Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance,[97] MA organizations are required to demonstrate network adequacy by submitting data for specific contracted provider and facility specialty types via the Network Management Module (NMM) of HPMS. To the extent an MA organization offers one or more D–SNPs, State Medicaid officials may be uniquely positioned to provide relevant information to CMS during our adjudication of certain network adequacy decisions, specifically when an MA organization seeks an exception to our network adequacy standards in § 422.116. We are not proposing 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, our proposal here outlines how we expect this type of collaboration to work.

When an MA plan fails to meet the specific network adequacy standards in § 422.116(b) through (e), the MA plan may request an exception to these network adequacy criteria. 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 the data CMS uses to evaluate network adequacy; whether there are factors present, as identified in § 422.112(a)(10), that demonstrate that network access is consistent with or better than the original Medicare pattern of care; and whether approval of the exception is in the best interests of beneficiaries. State Medicaid agencies may have information and insight about such other factors that might be relevant in setting a standard for an acceptable health care delivery network in a particular service area. For example, State Medicaid agencies could provide information about the number and scope of providers enrolled and screened by the State Medicaid agency, local practice patterns, geographic barriers, or transportation dynamics.

In this proposed rule, CMS is proposing 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 proposed rule). In addition, CMS intends to reach out to States when a 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). In those instances, CMS may collaborate 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 piloted a similar approach in the Financial Alignment Initiative and a related demonstration in Minnesota where States provided input to inform the exception review process.

Collectively, our proposed paragraph (e)(3) at § 422.107 would improve Federal and State oversight of certain D–SNPs (and their affiliated Medicaid managed care plans) through greater information-sharing among government regulators. We have successfully tested these approaches in other circumstances and believe applying them under the conditions described in proposed paragraph (e)(1) would provide greater transparency to the regulated industry while assuring States that CMS will be a willing partner. We welcome comments on our proposals.

d. Comment Solicitation on Financing Issues

In Medicare and Medicaid, benefits funded by one payer (for example, behavioral health treatment funded by Medicaid) may generate savings for the other payer (for example, reduced emergency room and inpatient admissions funded by Medicare). For dually eligible beneficiaries, each payer has an incentive to provide benefits and focus spending in a manner that promotes its own cost saving, which may not be consistent with meeting beneficiaries' overall needs. In the Financial Alignment Initiative, we tried

[96] 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).

[97] *https://www.cms.gov/files/document/medicareadvantageandsection1876costplannetworkadequacyguidance6-17-2020.pdf.*

to solve for this financial misalignment through integrated financial approaches, including blending Medicare and Medicaid capitation payments [98] and evaluating integrated Medicare-Medicaid medical loss ratios (MLRs).[99] Based on this experience, we are assessing whether there are ways to take two elements of MMP financial methodology and apply to D–SNPs: (1) Integrated MLRs; and (2) consideration of the expected impact of benefits provided by MA organizations on Medicaid cost and utilization in the evaluation of Medicaid managed care capitation rates for actuarial soundness. We describe each in this section.

MA organizations, including those offering FIDE SNPs and other integrated plans with both MA and Medicaid managed care plan contracts, separately report medical loss ratio (MLR) results for their Medicare experience (per subpart X of part 422) and, where applicable, their Medicaid experience (per § 438.8). MA organizations submit MLR reports in a timeframe and manner specified by CMS. As required by section 1857(e) of the Act, CMS collects remittances for MLRs below a minimum threshold of 85 percent; additionally, enrollment sanctions apply for MA contracts that fail to meet minimum MLR thresholds for three consecutive years, while contracts are terminated for those MA organizations that fail to meet these thresholds for 5 consecutive years. Medicaid managed care plans calculate and report their MLR experience for each contract year (per § 438.8), with actuarially sound rates set to achieve an MLR of at least 85 percent (per § 438.4(b)(9)). Additional Medicaid MLR requirements vary at States' discretion, including the option to impose remittance requirements.

While the MA and Medicaid managed care MLR requirements are similar, they are not identical. Areas of difference include treatment of fraud reduction expenses, credibility adjustments, the level of detail reported, and use of MLR results in ratesetting. While these differences serve program purposes in the separate Medicare Advantage and Medicaid managed care programs, they can make it challenging to compare MLRs across programs and to evaluate the performance of a plan that integrates Medicare and Medicaid benefits. For example, an integrated plan may show a low MLR for Medicare Advantage and a high MLR for Medicaid managed care if it successfully delivers more community behavioral health treatment that results in fewer emergency room visits and hospitalizations. In this example, however, even if the aggregate payment amount across Medicare and Medicaid generally matches the combined cost of furnishing covered benefits to enrollees, both Medicare and Medicaid would potentially make adjustments. For example, if the Medicare MLR was below 85 percent, CMS would recoup funds from the plan. If the Medicaid MLR exceeds a reasonable maximum threshold that would account for reasonable administrative costs, the State would evaluate that when setting future capitation rates, the result of which may be to increase the Medicaid capitation rates in subsequent years. Further, as MA plans report MLR results at the contract level (not the plan level), MLR data specific to a particular FIDE SNP is not necessarily available. In contrast, MMPs report a combined Medicare and Medicaid MLR to CMS and States, with such reporting building off MA requirements, meeting Medicaid requirements, and offering a more complete picture of these integrated plans' performance.[100]

In the rulemaking to implement the statutory requirement for an MLR for MA plans, CMS received comments requesting we allow the MLR for D–SNPs and FIDE SNPs to include Medicare and Medicaid costs and revenue, to better evaluate such plans' performance and spending. [101] While we do not believe we have the statutory authority to include Medicaid experience as part of the Medicare MLR requirement, States may require additional data to be reported, including combined Medicare-Medicaid MLRs, in addition to the MLR reporting required by § 438.8. Such reporting would be in addition to, and not a substitute for, the required MA MLR under §§ 422.2400 through 422.2490 and Medicaid managed care MLR under § 438.8.

As described in section II.A.6.a., we propose 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. While such D–SNPs would still have to calculate and report separate Medicare and Medicaid MLRs under the applicable program requirements (absent a waiver), having a separate contract for certain D–SNPs would better equip States to evaluate MLRs and financial performance specific to that D–SNP product. Combining MA MLR information with corresponding Medicaid MLR data could potentially provide a more complete picture of plan financial performance in an integrated environment, as compared to what may be available currently.

We are seeking feedback on the extent to which this approach would better allow States to evaluate the performance of integrated plans. We are also interested in feedback from stakeholders—including States, health plans, actuaries, and advocates—on the impact of separate Medicare and Medicaid MLR requirements on meeting integration goals, administrative burden for plans and others through separate MLR standards, and whether the current approach provides sufficient data for State decision making and policy development.

Integrated plans serving dually eligible beneficiaries receive Medicaid capitation payments from States for coverage of Medicaid-covered services. These Medicaid managed care capitation rates are subject to actuarial soundness requirements under § 438.4. Several States limit enrollment in D–SNPs to achieve exclusively aligned enrollment in which all D–SNP enrollees are also in an affiliated Medicaid managed care plan, for which these 42 CFR part 438 actuarial soundness requirements apply.

[98] For more information on the ratesetting methodology for the FAI capitated model, see *Joint Rate-Setting Process for the Financial Alignment Initiative's Capitated Model,* available at: *https://www.cms.gov/files/document/capitatedmodelratesettingprocess03192019.pdf.*

[99] Unless waived by CMS, MMPs are required to comply with Medicaid managed care requirements under 42 CFR part 438 and with MA requirements in Part C and Part D of Title XVIII of the Act and 42 CFR parts 422 and 423. While (unlike MA plans) MMPs do not submit bids, the existing payment policies for each program generally apply to MMPs, including requirements related to actuarial soundness of Medicaid capitation rates and the MLR reporting required in both the Medicare and Medicaid programs.

[100] In the FAI capitated model, CMS waived section 1857(e) of the Act, which requires MA MLR remittances, insofar as such provisions were inconsistent with the methodology for determining MLRs for the demonstration. For more information, see the signed memoranda of understanding for capitated model demonstrations available at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/ApprovedDemonstrationsSignedMOUs.* The MLR approach varies across capitated model demonstrations, with most demonstrations requiring remittances for MLRs below thresholds of 85 to 87 percent, while the remaining demonstrations include other risk mitigation approaches, such as risk corridors, that provide the opportunity for recoupment of MMPs' gains above specified thresholds. More information on such arrangements may be found in the MMP three-way contracts available at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/CapitatedModel.*

[101] Summaries of the comments and CMS's responses may be found in the 2013 *Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs* final rule (78 FR 31283).

In the FAI capitated model, CMS developed an approach to Medicaid actuarial soundness within the model to take into account the effects of Medicare payment for Medicare covered benefits, for which Medicaid is a secondary payer, as well as the opportunities for efficiencies in an integrated program, when developing the Medicaid capitation rates paid in the FAI model.[102] Since we developed this approach, CMS has expanded options for MA plans to offer a broader array of supplemental benefits than available 10 years ago.[103] This change also expands the potential that MA supplemental benefits have an impact on lowering Medicaid costs because the MA supplemental benefit must be used first to pay for any items and services that are covered by both the MA plan and Medicaid. In some cases, MA plans may offer the types of community supports or LTSS that previously were only available through Medicaid. As a result, the MA supplemental benefit may replace or be used before using the Medicaid benefit, which would lower utilization and overall costs to cover Medicaid benefits when an integrated plan covers both Medicare and Medicaid services for the same enrollees.

With this context and our FAI model experience, we believe that Medicaid managed care capitation rates can be actuarially sound as required by § 438.4 when those rates are developed in a way that considers the impact of MA supplemental benefits and any State-specific requirements in the State Medicaid agency contract, D–SNP MOC, or MMP contract on the costs and utilization of the Medicaid benefits covered by the Medicaid managed care capitation rates. MA supplemental benefits and State-specific D–SNP requirements may impact Medicaid-related costs and utilization, and Medicaid rate setting could consider the impact on both: (1) Replacing costs that would otherwise be a Medicaid responsibility, as a primary impact; and (2) affecting expenditures on other Medicaid benefits, as a secondary impact. For example, intensive care coordination, covered by MA plans through supplemental benefits or as administrative expenses, could reasonably be expected to impact Medicaid costs by (a) reducing Medicaid care coordination costs directly; and (b) indirectly reducing Medicaid expenditures through lower Medicare cost-sharing as a result of preventing avoidable hospitalizations. We seek feedback on this interpretation, including from States, health plans, and actuaries, on the extent to which consideration of the impact of Medicare-covered benefits on costs and utilization of Medicaid services as described here advances integration goals and is consistent with actuarial standards of practice. We also request input on what information States, actuaries, and others would need to evaluate actuarial soundness under this approach. Finally, we solicit feedback on other options related to financing for integrated plans CMS should evaluate and consider for future rulemaking or sub-regulatory clarification.

7. Definition of Applicable Integrated Plan Subject to Unified Appeals and Grievances Procedures (§ 422.561)

In § 422.561, we propose 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 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 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 and, therefore, we should require the unified process. 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. 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. We believe that unified grievance and appeals procedures are feasible for the additional D–SNPs. Accordingly, we propose, effective January 1, 2023, to expand the definition of the term applicable integrated plan to include an additional type of D–SNP subject to the rule.

We propose 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. Under our proposal, the definition of ''applicable integrated plan'' will include (1) a D–SNP that has, by State policy, fully aligned enrollment with an affiliated Medicaid plan owned by the same parent organization, where

[102] As described in the signed memoranda of understanding for capitated model demonstrations available at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/ApprovedDemonstrationsSignedMOUs,* ''Assessment of actuarial soundness under 42 CFR 438.6, in the context of this Demonstration, should consider both Medicare and Medicaid contributions and the opportunities for efficiencies unique to an integrated care program. CMS considers the Medicaid actuarial soundness requirements to be flexible enough to consider efficiencies and savings that may be associated with Medicare. Therefore, CMS does not believe that a waiver of Medicaid actuarial soundness principles is necessary in the context of this Demonstration.''

[103] The BBA of 2018 (Pub. L. 115–123) amended section 1852(a) of the Act to expand the types of supplemental benefits that may be offered by MA plans to chronically ill enrollees as of plan year 2020, to specifically allow those ''supplemental benefits that, with respect to a chronically ill enrollee, have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee and may not be limited to being primarily health related benefits.'' In addition, 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'' which appeared in the **Federal Register** on June 2, 2020 (June 2020 final rule) finalized provisions to allow for plans to target other chronic conditions included in the Medicare Managed Care Manual. In the January 2021 final rule, CMS codified existing policy on supplemental benefits, including the criteria for a supplemental benefit, the expanded definition of ''primarily health related,'' and the reinterpreted uniformity requirements.

the affiliated Medicaid plan has a capitated contract with a Medicaid MCO to provide all of the beneficiary's Medicaid managed care benefits (2) and its affiliated Medicaid plan. 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, Medicaid durable medical equipment, or Medicaid nursing facility services.

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 believe such plans integrate a sufficiently broad range of Medicaid benefits so as to make unifying their grievance and appeals processes worthwhile. Our proposal would not change grievance and appeals processes for any Medicaid services not covered by the Medicaid managed care plan that is affiliated with the D–SNP where the three conditions are met. We anticipate our proposal would newly require unified appeals and grievances processes in a number of plans in California following the end of the California capitated financial alignment model demonstration.

We propose 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) will become paragraphs (2)(i)(A) and (B) and apply before January 1, 2023. Proposed new paragraph (2) of the definition will apply beginning January 1, 2023, and will include paragraphs (2)(i) and (ii). Proposed new paragraphs (2)(i)(A) and (B) include the current definition, and proposed new paragraph (2)(ii) includes the new category of D–SNPs and affiliated Medicaid managed care plans that would qualify as an applicable integrated plan. New proposed paragraph (2)(ii)(A) addresses enrollment requirements for the D–SNP, and new proposed paragraph (2)(ii)(B) addresses what types of contracting must be in place, and new proposed paragraph (2)(ii)(C) the minimum Medicaid benefits that must be covered by the capitated contract with the State Medicaid agency or contract with Medicaid MCO. Under our proposal, the definition of ''applicable integrated plan'' remains unchanged from the current definition for the period before January 1, 2023, and would include additional types of D–SNPs and affiliated Medicaid plans on and after January 1, 2023.

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 the health maintenance organization (HMO) or competitive medical plan (CMP) on a reasonable cost basis. Cost contracts arrange for Medicare services and provide members several flexibilities not offered to MA plan members, 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 network of providers through original Medicare. As of January 2021, approximately 173,250 beneficiaries were enrolled in seven cost contracts offered in nine States.[104]

Federal statute and regulation restrict cost contracts in several ways. First, as provided in section 1876(h)(5)(A) of the Act and § 417.402(b), CMS no longer enters into cost contracts. Second, CMS established a requirement, originally at § 422.501(b)(4), that an entity seeking to contract as an MA organization must not accept new members under a cost contract plan in any area in which it seeks to offer an MA plan when implementing the original Part C requirements in the interim final rule titled ''Medicare Program; Establishment of the Medicare+Choice Program'' (HCFA–1030–IFC) (63 FR 35014 through 35015; 35100) (hereinafter referred to as the June 1998 final rule). CMS later moved this requirement to § 422.503(b)(5). The June 1998 final rule stated that CMS established this prohibition to eliminate the potential for an organization to encourage higher cost members to enroll under its cost contract plan while healthy members were enrolled in its risk-based MA plan. Manipulating enrollment in this way would shift costs to the government away from the entity.

Third, MIPPA and the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (hereinafter referred to as MACRA) amended section 1876(h)(5)(C) of the Act by specifying that cost contract plans operating in service areas or portions of service areas with two MA plans meeting minimum enrollment requirements would be non-renewed. Implementing regulations are codified at § 417.402(c) and went into effect at the end of CY 2018, leading to a significant decrease in cost contract enrollment.[105]

The prohibition on an entity accepting new enrollees in a cost contract plan while offering an MA plan in the same service area was amended in ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (CMS–4159–F) (hereinafter referred to as the May 2014 final rule) to apply to: (1) A parent organization owning a controlling interest in a separate legal entity accepting new members under a cost contract plan, and (2) another separate legal entity owned by the same parent organization as the legal entity accepting new members under a cost contract plan (79 FR 29850; 29959). An error in the amendment in the May 2014 final rule prevented this change from being correctly codified in the CFR. This error was corrected in the January 2021 final rule (86 FR 6099).

As stated in the May 2014 final rule, CMS did not exempt entities with both cost contract plans and D–SNPs from the regulatory provision at § 422.503(b)(5) because we did not believe that the Medicare premium and cost-sharing differences in cost contract plans and MA plans, including D–SNPs, necessarily reduced the incentives an organization may have for moving an individual from one of its plans to another. We also stated that D–SNPs, which frequently serve members with greater frailty and morbidity than the general Medicare population, may have an even greater incentive to move members to a cost contract plan.

Since CMS finalized the policy in the 2014 final rule, 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.[106] Three of the seven MA

[104] Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report.html.*

[105] Ibid.

[106] See *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-*

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 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.[107]

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 members to cost contract plans offered under the same parent organization. The Minnesota demonstration, which is focused on alignment of administrative procedures, did not change the incentives for shifting of members that was the rationale for § 422.503(b)(5). In the demonstration, we required that each of the affected D–SNPs report annually the number of D–SNP members who switched to the entity's cost contract plan. If two percent or more of a D–SNP's enrollment switched to the cost contract plan, CMS would further investigate enrollment patterns, potentially require corrective actions, and rescind the waiver.

The results of this reporting have been instructive. In no year since the waiver was established has the number of D–SNP members switching to the affiliated cost contract plan approached the 2 percent threshold. The two remaining D–SNPs with cost contract plans under the same parent organization [108] which had a combined December 2020 D–SNP enrollment of 19,168, reported a total of 10 members switched to the affiliated cost contract plans during the 2020 plan year. The enrollment patterns for prior reporting periods are similar: only a small number of individuals switched from a D–SNP to a cost contract plan affiliated with the same entity.

In addition to this reporting, we reviewed current enrollment data on all cost contract plans to see if the two parent organizations offering both a cost contract plan and a D–SNP in the demonstration have a higher enrollment of dually eligible individuals than in the cost contract plans without such affiliated D–SNPs. The average enrollment of dually eligible individuals across all cost contracts in December 2020 was 3.6 percent, and ranged from 1.62 percent to 12.2 percent. In comparison, about 20 percent of Medicare Advantage enrollees are dually eligible individuals.[109] The two cost contracts operating in Minnesota that had affiliated D–SNPs were consistently on the low end of that range, with average enrollments of dually eligible individuals of 1.6 percent and 3.5 percent respectively. These averages suggest that the availability of a D–SNP that shares a parent organization with a cost contract plan may decrease such likelihood of dually eligible individuals enrolling in a cost contract plan.

The data from the Minnesota demonstration shows allowing both a D–SNP and a cost contract plan under the same parent organization has not resulted in a substantial number of members moving from the D–SNP to the cost contract plan. We believe that the number of such plan switches is likely minimal for the reasons outlined by the commenters in the May 2014 final rule: the premiums charged by cost plans are unattractive to low-income dually eligible individuals who have access to a D–SNP that charges no premium.

We also note that the cost contract plans outside of the demonstration that had more than 5 percent dually eligible enrollment included cost contract plan options with zero-dollar premiums. This indicates that the typical cost contract plan premium functions as a deterrent to enrollment by full-benefit dually eligible individuals.

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 will not undermine the policy goals that underlie § 422.503(b)(5)—that is, prohibiting entities from steering high-cost members to their cost contract plans and lower cost members 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. Without a D–SNP, States have few options to integrate Medicare and Medicaid services and improve the experience of care for dually eligible individuals. In particular, removing this barrier would allow entities offering cost contract plans in rural markets in the nine States [110] where cost contract plans are currently offered, including markets without multiple MA plan alternatives, to work with those States to offer new D–SNPs, which could further State goals for integrating Medicare and Medicaid services. We anticipate that this flexibility would provide dually eligible individuals in those States new choices for integrated coverage. Therefore, we propose 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.

Should we finalize this proposal, we would monitor patterns of enrollment and disenrollment. To the extent we see any pattern that suggests that sponsors are persuading D–SNP members to

Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Minnesota.html.

[107] 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 Planning and Evaluation (ASPE) (March 31, 2016). Retrieved from *https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis.*

[108] One of the three entities offer a D–SNP and cost contract plan ceased offering a cost contract plan in the same market as its D–SNP in January 2019.

[109] CMS, ''Data Analysis Brief: Managed Care Enrollment Trends among Dually Eligible and Medicare-only Beneficiaries, 2006 through 2019''. March 2021. Retrieved from *https://www.cms.gov/files/document/managedcareenrollmenttrendsdatabrief.pdf.*

[110] For CY 2021, cost contract plans were offered in Colorado, Iowa, Illinois, Kansas, Minnesota, Nebraska, North Dakota, South Dakota, Wisconsin.

move into the cost plan, we would investigate and pursue corrective actions or additional rulemaking, potentially including the future rulemaking to remove or restrict the exemption proposed here. We seek comment on the proposed exception for D–SNPs and our process for monitoring for unintended consequences.

We are considering more limited exceptions to the requirements at § 422.503(b)(5) that may more closely fit our policy goals of removing regulatory obstacles to the availability of D–SNPs that could further Medicare-Medicaid integration. We are also considering whether additional limitations could guard against entities steering less healthy, higher cost enrollees toward their cost contract plans. Specifically, we are considering limiting the exception to:

- D–SNPs designated as highly integrated D–SNPs (HIDE SNPs), as defined at § 422.2, which are capitated for Medicaid behavioral health or Medicaid long-term services and supports, or both; and to fully integrated D–SNPs (FIDE SNPs), as defined at § 422.2, which are capitated for a comprehensive set of Medicaid long-term services and supports;
- D–SNPs that only enroll full-benefit dually eligible individuals, who qualify for full Medicaid benefits, rather than D–SNPs that also enroll partial-benefit dually eligible individuals, who are only eligible for Medicaid coverage of Medicare premiums or cost-sharing;
- 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 are concerned that these alternatives would add complexity to the regulation that we do not believe is necessary to achieve our primary aim of removing regulatory barriers that impede the availability of new D–SNPs to integrate Medicare and Medicaid services and improve care for dually eligible individuals. However, we seek 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.

9. Requirements To Unify Appeals and Grievances for Applicable Integrated Plans (§§ 422.629, 422.631, 422.633, and 422.634)

In the final rule ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021,'' which appeared in the **Federal Register** on April 16, 2019, we established procedures for unified appeals and grievances and require certain D–SNPs and Medicaid MCOs to use them beginning in 2021 (84 FR 15680). 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 defined at § 422.561 as FIDE SNPs and HIDE SNPs with exclusively aligned enrollment. We propose an amendment to the definition of applicable integrated plan in section II.A.7. of this proposed rule. These rules took effect for the 2021 plan year. Based on our initial implementation experience and feedback from stakeholders, we are proposing several adjustments, clarifications, and corrections to these regulations at §§ 422.629 through 422.634. We do not intend for these proposals to substantially change current policy.

a. Providing Enrollees Information on Presenting Evidence and Testimony (§ 422.629(d))

We propose adding additional language to § 422.629(d) to codify in regulation a provision from existing sub-regulatory guidance.[111] We propose 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. While we believe this requirement is within the scope of the current requirement that applicable integrated plans inform enrollees of the limited timeframe for presenting evidence as stated in § 422.629(d) and otherwise provide enrollees with reasonable assistance in taking procedural steps related to grievances and appeals as required at §§ 422.562(a)(5) (applicable to D–SNPs) and 438.406(a) (applicable to Medicaid managed care plans), revision of the regulation text will clarify this. We believe that this proposed addition will ensure that enrollees better understand the process for submitting evidence and testimony to the plan so that their information is timely considered with their appeal. In addition, our proposal would reorganize § 422.629(d) to improve the readability of the provision.

b. Technical Correction (§ 422.629(k))

We propose technical changes to § 422.629(k)(4)(ii) to correct a minor error from the April 2019 final rule. This paragraph references the integrated organization determination decision, however, the requirements in paragraph (k)(4) relate to integrated reconsideration determinations. Therefore, we are proposing to replace the word ''organization'' with ''reconsideration'' and remove the word ''decision'' from the end of the sentence in § 422.629(k)(4)(ii).

c. Accommodate State Medicaid Representation Rules (§ 422.629(l))

At § 422.629(l)(1), we propose adding additional language to codify in regulation current sub-regulatory guidance [112] regarding the appointment of a representative. The Medicare Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, Section 20.2, lists several elements that should be included in an appointment of representation form. A State, in its Medicaid program, may have developed other forms or requirements for appointment of representation forms that are accepted in appeals cases. We propose to amend § 422.629(l)(1) to ensure that we are not restricting the means that an enrollee would otherwise have, outside of the integrated appeals process, to appoint a representative. We propose to add language to clarify that an enrollee's representative includes any person authorized under State law. We propose to reorganize paragraph (l)(1) as part of this amendment. Specifically, we propose 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 propose to move the content of current paragraph (l)(1)(ii) that deals with rights of assignees to a new

[111] 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.*

[112] 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.*

§ 422.629(l)(4) as discussed in section II.A.9.d. of this proposed rule.

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. In so doing, we inadvertently created confusion, particularly pertaining to the rights of non-contracted providers. Like contracted providers, non-contracted providers can request an initial integrated organization determination on behalf of an enrollee if they treat or intend to treat the enrollee; this is reflected in § 422.629(l)(1)(iv) and (l)(3) and is consistent with MA rules at § 422.566(c)(1)(ii). However, our policy is that assignees (for example, a non-contracted provider to whom an enrollee has assigned their appeal rights) and other providers with appealable interests can only file an integrated reconsideration; assignees cannot file a grievance, and until the initial organization determination is completed, there is no enrollee interest to assign or other appealable interest at stake. This policy is also consistent with the MA rules which do not specifically allow anyone other than an enrollee to file a grievance (§ 422.564), and which require a provider to waive any right to payment from the enrollee for the service to be an assignee and a party to the organization determination (§ 422.574(b)) who is then able to file a request for a reconsideration under § 422.578. We are therefore proposing 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 proposed rule, we propose 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 propose 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. At proposed paragraph (l)(4)(i), we would 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. At proposed paragraph (l)(4)(ii), we would 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.

e. Timelines for Processing Payment Requests (§ 422.631)

In the April 2019 final rule, we neglected to specify explicitly how the MA ''prompt payment'' rules at § 422.520 governing payment of claims apply to applicable integrated plans. The MA organization determination timeline rules at § 422.568(c) state that the prompt payment rules at § 422.520 govern the timeline for requests for payment. However, as finalized, § 422.631 establishes the timelines for integrated reconsiderations in lieu of the timelines at § 422.568 but does not include a specific reference to the prompt payment rules at § 422.520 and does not include (in lieu of the rule in § 422.520(c) that is applicable to all MA plans) a different rule for applicable integrated plans. As a result, we have received several questions from applicable integrated plans requesting that we clarify what timeline applies to processing payment requests.

Accordingly, at § 422.631(d), we propose 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 will mirror the current provision at § 422.568(c). We believe these prompt payment provisions are generally consistent with Medicaid prompt payment standards and therefore will not create any inconsistencies with State Medicaid policies in this area. We welcome comments on this issue.

f. Clarifying Integrated Reconsideration Request (§ 422.633(e) and (f))

We are proposing 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. In the preamble to the April 2019 final rule, we noted that there may be rare circumstances in which a dually eligible enrollee's financial need is so pressing that an enrollee's reimbursement request meets the standard for expediting a post-service integrated reconsideration request. This was a departure from the MA rule at § 422.584(a), and we intended to limit this option to requests filed by enrollees. As finalized, however, § 422.633(e) does not distinguish between pre-service and post-service expedited requests filed by the enrollee and those filed by a provider on the enrollee's behalf.

During implementation of these new unified procedures, we received several comments pointing out that § 422.633(e), as finalized, permits a provider to request an expedited post-service integrated reconsideration on behalf of an enrollee. This was not our intent, because a post-service case can only meet the expedited standard if the enrollee has already paid a provider and urgently needs reimbursement from the applicable integrated plan. We believe that a provider should not deliver a service, accept the enrollee's payment, and then argue on the enrollee's behalf that the enrollee needs an expedited decision on reimbursement. We also did not intend to place the burden on plans to accept such requests and assess whether the standard for expedited treatment is met when these post-service appeals are filed by providers. We are therefore proposing 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. This proposed change aligns provider appeal rights with MA regulations which do not allow expedited integrated reconsideration determinations in cases where services or items have already been furnished (see § 422.584(a)).

During implementation, we also received several questions from plans regarding the timeframe, at § 422.633(f), 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. In the April 2019 final rule, we required all integrated reconsiderations, including those involving requests for payment, be resolved within 30 days, which is consistent with Medicaid rules at § 438.408(b)(2) but shorter than the 60 days permitted under § 422.590(b)(1). In response to the sub-regulatory guidance issued subsequent to the April 2019 rule but before the effective date of the regulation, several plans commented that meeting a 30-day timeframe for all requests for payment would be difficult. We believe that the shorter 30-day timeframe is appropriate for beneficiary requests and consistent with Medicaid

rules. However, we seek 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 also seek 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, in response to several questions we have received since the regulation became effective regarding the availability of extensions for standard and expedited integrated reconsiderations, we are proposing 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. In our proposal at § 422.633(f)(3) we would exclude integrated reconsiderations about Part B drugs from the authority for extensions. This is 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.

g. Timeframes for Service Authorization After a Favorable Decision (§ 422.634(d))

We are proposing changes to § 422.634(d) to clarify the requirements for how quickly an applicable integrated plan must authorize or provide a service after a favorable decision for an enrollee upon appeal. The current regulatory text includes timeframes for how quickly services must be put in place for an enrollee after receipt of a favorable decision on an integrated reconsideration or State fair hearing. The current regulation refers to timeframes specified in §§ 422.618 and 422.619 for implementing decisions made by the IRE and additional entities on the Medicare side. In reviewing feedback received from applicable integrated plans, we believe that these requirements should more clearly describe timeframes for authorizing services in all situations where an applicable integrated plan's decision is reversed.

We propose reorganizing § 422.634(d) to more explicitly address each scenario that an applicable integrated plan will face when effectuating a reversal. In proposed paragraph (d)(1), we propose 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 propose 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.

This would be a slight change from the current requirements, which require applicable integrated plans to authorize or provide the service as expeditiously as the enrollee's condition requires but not later than 72 hours from the date of the reversed decision. The current 72-hour rule is adopted from the Medicaid managed care rule at § 438.424(a). However, as applied in § 422.634(d), there is the possibility that in some cases an enrollee could wait longer for a determination to be effectuated by an applicable integrated plan than the enrollee would have to wait under the current MA regulation (§ 422.618(a)(1) and (3)), which requires effectuation no later than 30 calendar days after the MA plan receives the reconsideration request, or 7 calendar days for Part B drugs. If, for example, the applicable integrated plan reversed its decision on the 29th day after receiving the reconsideration request (for a request that is not a Part B drug), as allowed under § 422.633(f)(1), under the current text of § 422.634(d) it would still have another 72 hours to effectuate the determination. We also propose 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 for these drugs; 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. We believe our proposal better reflects the directive in section 1859(f)(8)(B)(ii) of the Act to adopt requirements that are most protective for enrollees.

In proposed paragraph (d)(2), for the sake of clarity we propose 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 propose no changes to this effectuation timeline.

Lastly, we propose to add a new paragraph (d)(3) to require the same timelines for an applicable integrated plan to effectuate reversals by the Medicare independent review entity, 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 request 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.

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 propose to strike the reference to Medicare in paragraph (c)(6). 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.[113] 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. Functionally, our proposal would have no impact on the responsibilities of a plan to verify eligibility. However, it would remove a detail from the State Medicaid agency contract minimum requirements, thus simplifying our review of the contracts.

11. Compliance With Notification Requirements for D–SNPs That Exclusively Serve Partial-Benefit Dually Eligible Beneficiaries (§ 422.107(d))

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 and coordination of the delivery of Medicare and Medicaid benefits. We codified these minimum integration requirements in the April 2019 final rule 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) as required for its contract with the State Medicaid agency. When it applies,

[113] See *https://www.cms.gov/medicare/health-plans/healthplansgeninfo/downloads/mc86c02.pdf.*

§ 422.107(d) 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. We direct readers to the April 2019 final rule for a more detailed explanation of our intent and rationale for this approach (84 FR 15710 through 15717).

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. Providing separate PBPs for full-benefit dually eligible individuals enables MA organizations to more clearly explain and coordinate the Medicaid benefits that those enrollees are entitled to receive. In addition, HIDE SNPs or FIDE SNPs that limit enrollment to full-benefit dually eligible individuals qualify to unify Medicare and Medicaid appeals and grievance processes under §§ 422.629 through 422.634. MA organizations that have D–SNPs with a combination of full-benefit and partial-benefit dually eligible enrollees can choose to ''split'' the D–SNP into two plans to take advantage of these opportunities. We codified a crosswalk exception to facilitate this process at § 422.530(c)(4) in the January 2021 final rule. (In section II.A.6.a., we are proposing to redesignate this crosswalk to § 422.530(c)(4)(i) in this proposed rule.)

However, D–SNPs that only enroll 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).

In lieu of requiring inclusion of this notification requirement in the State Medicaid agency contract for partial-benefit-only D–SNPs during the initial CY 2021 implementation of the D–SNP integration requirements, CMS issued guidance permitting an alternative in January 2020.[114] The MAO offering the partial-benefit-only D–SNP would be considered as meeting the integration requirements in connection with the partial-benefit-only D–SNP provided that the MAO also offers a full-benefit-only D–SNP in the same State and under the same contract and that full-benefit-only D–SNP meets the integration requirements in the definition of a D–SNP at § 422.2.

We are proposing to codify this policy with the additional requirement that the service areas of the full-benefit-only D–SNP covers the entire service area of the partial-benefit-only D–SNP. That is, we propose 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. We propose to add this by reorganizing paragraph (d). The current provision in paragraph (d) would be redesignated as new paragraph (d)(1) and amended to reference exceptions listed in proposed paragraph (d)(2). Proposed paragraph (d)(2) provides that paragraph (d)(1) does not apply to any D–SNP that, under the terms of its contract with the State Medicaid agency, only enrolls beneficiaries that are not entitled to full medical assistance under a State plan under title XIX if the SNP operates under the same parent organization and in the same service area as a D–SNP limited only to full-benefit dually eligible individuals that meets the requirements at (d)(1).

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 PBP including 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 do not anticipate any negative impact for beneficiaries or partial-benefit-only D–SNPs as a result of this proposed rule. For CY 2021, nine partial-dual-only D–SNP PBPs operate under the same MA contract and same service area as a full-benefit-only D–SNP. All nine operate in either Florida or Virginia. In CY 2021, one other Virginia D–SNP enrolled partial-benefit dually eligible individuals with a corresponding D–SNP for full-benefit dually eligible individuals under the same parent organization. The proposed changes to § 422.107(d) would allow these partial-benefit-only D–SNPs to continue as they are currently operating.

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 limit on in-network and out-of-pocket expenses for enrollees in Regional Preferred Provider Organization (RPPO) MA plans. In addition, MA Local PPO (LPPO) 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 called 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 the 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 to the enrollee's progress toward the plan MOOP limit. This

[114] 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/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memo-5.*

approach also applies to D–SNPs. Thus, for any D–SNP enrollee, MA plans had 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.[115] 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 may negatively affect access to Medicare providers for dually eligible enrollees.

We propose 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 are proposing to amend the regulations by adding § 422.100(f)(4)(i) and (f)(5)(iii) 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 are proposing 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 effect 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 is not intended to and will 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 that first adopted in the April 2011 final rule. We note that the specific regulatory amendments may change if CMS publishes a final rule that addresses the MOOP limit provision 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) (hereinafter referred to as the February 2020 proposed rule).

We believe that this amendment is appropriate and necessary for several reasons. First, we believe this amendment will result in equal treatment under the MOOP limit for dually eligible MA enrollees compared to how Medicare-only enrollees are treated. Medicare-only MA enrollees receive the protection afforded by the MOOP limit after they have accrued cost-sharing under the MA plan benefit whether they have paid this cost-sharing or still owe their providers for some or all of the cost-sharing. 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. Under our proposed amendment, dually eligible MA enrollees with unpaid cost-sharing due to limits on Medicaid payment of Medicare cost-sharing under State lesser-of policies would similarly receive 100 percent coverage of Parts A and B services under their MA plan after the MOOP limit was attained. In addition, dually eligible beneficiaries with Medicaid coverage that is secondary to Medicare would receive the same benefits from the MOOP as MA enrollees with employer or commercial insurance that is secondary to Medicare; in both cases, the Medicare cost-sharing counting towards the MOOP limit would be based on the out-of-pocket costs accrued under the MA plan benefit without regard to whether secondary coverage pays parts or all of the Medicare cost-sharing for Parts A and B services used before attainment of the MOOP.

Second, we believe this amendment will ensure that the providers serving dually eligible enrollees in MA plans receive the same benefit from the MOOP limit that providers receive when they serve Medicare-only MA enrollees, based on our understanding of how some MA plans pay providers after the MOOP limit is reached. Absent the revision we have proposed, a provider serving a dually eligible MA enrollee in a State that paid less than the full Medicare cost-sharing under the lesser-of policy (the vast majority of States) would continue to receive less than the full MA rate negotiated between the MA organization and the provider for a Part A or Part B service even after cost-sharing adds up to more than the MOOP limit during the course of the plan year. Medicare cost-sharing protections for certain dually eligible individuals prohibit providers from billing any of that unpaid Medicare cost-sharing to the beneficiary. For a Medicare-only enrollee with similarly high medical expenses, the provider can, for example, work out a payment plan for unpaid Medicare cost-sharing accumulated before attainment of the MOOP with the assurance that the MOOP amount would

[115] 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.*

limit providers' liability for unpaid Medicare cost-sharing. If the out-of-pocket costs that counts towards the MOOP limit are calculated similarly for dually eligible enrollees with Medicare cost-sharing protections, the providers would similarly know that there was a limit on the liability for unpaid Medicare cost-sharing that they must assume. We believe this proposal to revise the method 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. As a result, the proposal 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.

Third, our proposed amendments to §§ 422.100(f)(4) and (5) and 422.101(d)(4) are consistent with the statutory requirement at section 1902(a)(25)(G) of the Act that the State plan under title XIX must provide that the State prohibits any health insurer (including a group health plan, as defined in section 607(1) of the Employee Retirement Income Security Act of 1974, a self-insured plan, a service benefit plan, and a health maintenance organization), in enrolling an individual or in making any payments for benefits to the individual or on the individual's behalf, from taking into account that the individual is eligible for or is provided medical assistance under Medicaid. The current method for calculating attainment of the MOOP explicitly takes into account the provision of medical assistance—specifically the payment of Medicare cost-sharing—by Medicaid in determining at what point the MA plan will begin paying 100 percent of costs for Medicare Parts A and B services. Our proposed amendments would ensure that the provision of Medicare cost-sharing assistance by the State is no longer considered in calculating attainment of the MOOP limit. In particular, this will ensure that D–SNPs that contract with State Medicaid agencies calculate attainment of the MOOP limit consistent with the Medicaid State plan requirements under the Act.

Fourth, our investigations show that D–SNPs offered by MA organizations currently differ in how they determine if the MOOP limit has been attained. Some D–SNPs calculate attainment of the MOOP as we propose, by adding up all cost-sharing accrued under the plan benefit until the MOOP limit is attained and, for the remainder of the year, paying 100 percent of the costs of covered services. Other D–SNPs do not seem to count any cost-sharing accrued under the benefit toward the MOOP for dually eligible individuals with Medicare cost-sharing protections—the D–SNPs do not count any cost-sharing amounts paid by the State and apparently assume that all cost sharing that is not paid by the State is not billed to the dually eligible enrollee because of the cost-sharing protections these beneficiaries receive. As a result, the MOOP is never attained. Our proposed amendments would bring consistency to how MA organizations determine if the MOOP limit has been attained, since it is based entirely on the claims adjudicated by the MA organization regardless of the enrollee's dual eligibility status. We believe this provides MA organizations with a straightforward method of determining when the MOOP limit has been attained based on claims data that the MA organization has in its possession.

For illustrative purposes, we provide below an example of how our proposal would change payment for services delivered after attainment of the MOOP limit in a D–SNP with cost-sharing that mirrors Original Medicare cost-sharing and where all benefits received by the enrollee are from in-network providers.

A D–SNP enrollee with unmanaged diabetes enters the hospital and has both legs amputated. After a lengthy hospital stay, followed by admission into a skilled nursing facility (SNF), the enrollee is discharged to her home with a power wheelchair. The enrollee also requires substantial follow-up care, including frequent visits with primary care and specialist physicians, physical and occupational therapy, wound care, and wheelchair modifications. The cost-sharing—inpatient charges, SNF per day charges, and the 20 percent coinsurance for the power wheelchair and follow-up care—has accrued to $7,550, the D–SNP's MOOP limit, by June. Under the lesser-of policy, the State Medicaid payment policy caps total payment at the Medicaid rate for specific services, which resulted in payment of some of the hospital cost-sharing but none of the SNF per-day charges or the 20 percent coinsurance for the power wheelchair or follow-up services. As such, providers did not receive payment for the cost-sharing amounts from the MA plan, Medicaid, or the enrollee for the SNF, power wheelchair, or other follow-up services.

Under our proposal, all of the cost-sharing, whether paid by Medicaid or unpaid, moves the beneficiary toward the $7,550 MOOP limit under the D–SNP's benefit design, after which the D–SNP would pay 100 percent of its rate for all Medicare Part A and B services provided to the enrollee for the remainder of the year. Absent the implementation of our proposal, the enrollee would not have reached the MOOP limit in June, because the D–SNP did not count either the Medicaid payments of the cost-sharing amounts or unpaid cost-sharing (which providers are prohibited from collecting from the enrollee under Medicare rules) toward attainment of the MOOP limit. Therefore, the D–SNP would continue to deduct cost-sharing amounts from payment to providers and, due to the lesser-of policy, some providers would continue to not receive payment for the cost-sharing amount at all when furnishing services to the dually eligible enrollee. In our example, assuming the enrollee only receives Part B services after June, the providers of these services would receive only 80 percent of the total payment rate for the furnished services from the D–SNP, compared with the 100 percent providers would receive under our proposal.

For the reasons described in this section, we propose 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 the enrollee and must alert enrollees and contracted providers when the MOOP limit is reached. For purposes of this amendment, the term accrued includes Medicare cost-sharing obligations regardless of whether the enrollee or another party or entity pays and regardless whether the provider is permitted to collect the Medicare cost-sharing from the enrollee.

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. State Medicaid agencies may include provisions related to the MA supplemental benefits the D–SNP offers, how the MA organization shares information about those benefits, and processes for coordinating benefits across Medicare and Medicaid programs.

In this proposed rule, we describe a number of ways that State Medicaid agencies can use their D–SNP contracts under § 422.107 to coordinate D–SNP supplemental benefits, including

reductions in Medicare cost-sharing, with Medicaid benefits. How this coordination works varies based on whether or not the D–SNP, or an affiliated Medicaid MCO, is capitated by the State Medicaid agency to deliver Medicaid benefits, or whether those benefits are delivered through the Medicaid FFS program or an unaffiliated Medicaid MCO. We seek comments on the following examples [116] of potential coordination of Medicaid and MA supplemental benefits:

- In some States, D–SNPs offer Medicare supplemental benefits that overlap with Medicaid benefits that the State covers on an FFS basis. Under section 1902(a)(25) of the Act, State Medicaid agencies that deliver these benefits must coordinate benefits with the D–SNP to ensure that Medicaid does not pay for benefits that are covered by the D–SNP as MA supplemental benefits. For example, a State could ensure that dually eligible enrollees use up the number of non-emergency medical transportation trips provided by the D–SNP (as supplemental benefits) before using the overlapping Medicaid transportation benefits. State Medicaid agencies can also use their contracts with D–SNPs to require these plans to take specific actions, such as instructing its network providers to bill the D–SNP before billing the Medicaid program or providing information on benefits or service use to the State or its Medicaid providers, to enable successful and more seamless coordination of benefits.
- A D–SNP that is capitated by the State Medicaid agency to provide Medicaid benefits, such as dental services, can also provide dental services as a MA supplemental benefit, as long as the D–SNP (or its Medicaid MCO affiliate) is not paid twice, once by Medicare and once by Medicaid, for coverage of the identical benefit for the same enrollees in the same contract year. As noted previously, under section 1902(a)(25) of the Act, Medicaid should not pay for a benefit that Medicare or an MA plan (or a third party) covers to the same extent for the same individual. This principle applies whether the benefits are paid for on an FFS or capitation basis.

We also seek 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.

State Medicaid agencies can use their contracts with D–SNPs under § 422.107 to meet these requirements and ensure Medicaid funds provided to the D–SNP only pay for Medicaid benefits. These State contracts with D–SNPs, in combination with State Medicaid benefit design, can help create benefits that are in addition to Medicare benefits and complementary across programs. For example, a D–SNP that also has a Medicaid managed care contract could use both Medicare and Medicaid dollars to provide a benefit that, on an actuarial basis, equals the value of the benefit from the combination of both funding streams. The plan must be able to clearly identify, for Medicaid managed care rate setting purposes, claims that are payable under the Medicaid program after exhaustion of the Medicare benefit. In addition, § 422.254 requires the MA organization to comply with actuarial standards in developing and submitting bids, including bids for supplemental benefits.

In all cases, the capitation rate for the Medicaid benefit must be actuarially sound and based on the cost of furnishing only the Medicaid-covered benefits (§§ 438.3(c) and (e); 438.4 through 438.7). Similarly, the rebate allocated for the MA supplemental benefits must reflect the organization's estimate of the revenue required to furnish the MA supplemental benefits only and provide the actuarial basis for the bid (§§ 422.252 through 422.256; 422.266).

Coordination of overlapping benefits works differently if the State Medicaid agency has a capitated contract with a different legal entity, such as a specialty dental plan or transportation vendor for services that overlap with the D–SNP's supplemental benefits. As noted previously, Medicare or the MA plan is the primary payer whenever Medicare and Medicaid cover the same services. As such, the State Medicaid agency and its capitated vendor should take the steps necessary to avoid duplication of services or duplicate payment for services delivered as MA supplemental benefits. For example, the State can make an adjustment to the base data used for Medicaid rate development to address coordination of benefits, such as when both Medicare (or an MA plan) and Medicaid cover a benefit, to ensure Medicaid rate development appropriately accounts for Medicaid being the payer of last resort.[117] One more advantage of integrated care—capitating the same organization for all services—over fragmentated care is elimination of the administrative burden of coordinating benefits and identifying the correct payments for the secondary coverage with each service and each processed claim.

State Medicaid agencies have flexibility to determine whether a D–SNP supplemental benefit covered with Medicare funds substitutes for an identical Medicaid benefit, given that Medicare coverage is primary to Medicaid, with the Medicaid benefit not provided, or to coordinate the D–SNP benefit and Medicaid benefit to provide D–SNP enrollees with an enhanced benefit. For example, a State Medicaid agency can determine that the use of the D–SNP supplemental benefit covered with Medicare funds, such as coverage of two dental cleanings per year, will be provided first, with the same Medicaid benefit provided after the Medicare benefit has been exhausted, resulting in coverage of up to four cleanings a year, which is recommended in some cases. A State Medicaid agency may determine that provision of the Medicaid benefit in addition to the same benefit covered as a D–SNP supplemental benefit is not medically necessary or cost-effective, or coordinate the two benefits as in the example above if the State believes the additional benefits would improve the care and support received by dually eligible individuals through the two programs. The contract between the D–SNP and the State Medicaid agency required under § 422.107 can be used to document the above types of determinations, and instruct the D–SNP for how to coordinate Medicare Part A and B benefits, MA supplemental benefits, and Medicaid benefits, consistent with applicable law.

A State Medicaid agency may use the agreement required by § 422.107 between the State and the D–SNP to require a FIDE SNP to offer MA supplemental benefits that expand coverage of LTSS that are also covered under Medicaid (with the Medicaid coverage furnished by the FIDE SNP or its affiliated Medicaid MCO). For example, the State Medicaid agency may require the FIDE SNP to have coverage of an item or service that is only covered under Medicaid for certain beneficiaries by offering an MA supplemental benefit that—

- Covers the item or service as a supplemental benefit (provided the requirements for supplemental benefits are met per section 1854(c) of the Act and 42 CFR 422.2 (definition of MA plan), 422.100(d), and other regulations) for enrollees who are not eligible to receive the item or benefit under Medicaid; or

[116] These examples also appeared in a May 27, 2021 FAQ document at: *https://www.cms.gov/files/document/dsnpmedicaremedicaidcoordbenefitsfaqs.pdf.*

[117] See 42 CFR 438.5 regarding rate development standards for Medicaid managed care capitation rates.

• Fills in gaps or provides coverage that exceeds the amount, duration, or scope of the Medicaid coverage of the item or service.

All MA plans, including D–SNPs, must comply with uniformity requirements in designing and offering supplemental benefits under section 1854(c) of the Act and §§ 422.2, 422.100(d), and other regulations. CMS will consider the 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 are 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. We welcome comments on that issue.

For example, a State can require, via the State's contract with a FIDE SNP, that the FIDE SNP offer an MA supplemental benefit that covers home and community-based services for certain, but not all, enrollees, such as enrollees who either: (1) Meet the State Medicaid criteria to receive Medicaid home and community-based services but are on waiting lists (and therefore ineligible *at the time* to receive the Medicaid services); or (2) are not eligible for the Medicaid benefits, such as because the enrollees do not receive full Medicaid benefits (that is, partial-benefit dually eligible individuals) or do not meet State Medicaid criteria to receive home and community-based services. In this case, enrollees have access to medically necessary home and community-based services when their needs are similar, even though some may be funded as an MA supplemental benefit and others through Medicaid.

Alternatively, a State Medicaid agency could contract with a FIDE SNP to use Medicare rebate dollars to pay for a supplemental benefit that the State wants the FIDE SNP to provide in addition to the Medicaid-funded benefit the FIDE SNP provides under its Medicaid managed care contract. For example, depending on the State Medicaid agency's contracting and benefit design, a D–SNP could provide its enrollees with 2 total weeks of respite care even though the Medicaid benefit is limited to 1 week, by providing an MA supplemental benefit for respite care. The FIDE SNP would provide the first week of respite care—as an MA supplemental benefit—and the second week of respite care in its role as a Medicaid managed care plan (where Medicaid is the secondary payer).

(a) Using the D–SNP MOC To Coordinate Medicaid Services

Although not a supplemental benefit, 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 SDoH. 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 § 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.

(b) Coordinating Coverage of Medicare Cost-Sharing

In general, 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. For example, if a D–SNP does not impose the Part B deductible but otherwise uses Part B cost-sharing for its coverage of Part B Medicare benefits, it would have the following effects:

• It would reduce to $0 the amount the State Medicaid FFS program pays providers serving QMBs and other full-benefit dually eligible enrollees in the D–SNP for the Part B deductible.

• If the State pays the D–SNP (or its affiliate) for coverage of MA cost-sharing otherwise payable by the State, it would eliminate any cost for coverage of the Part B deductible from those payments to the plan. D–SNPs cannot receive duplicate payments for coverage of the Part B deductible—once, in the form of the capitated payments from the State for Medicaid coverage and again by including the cost of eliminating the Part B deductible in the supplemental benefits that are paid by the Medicare beneficiary rebate under section 1854(b) of the Act.

Most States pay less than the full MA cost-sharing amount due to the application of a ''lesser-of'' [118] payment method for MA cost-sharing, and some of these States capitate D–SNPs in their States to pay this ''lesser-of'' amount to the provider. D–SNPs in these States can combine Medicaid capitated payments and Medicare rebate dollars to more fully cover MA cost-sharing—that is, the amount a dually eligible individual would pay if not subject to Medicare cost-sharing protections [119]—provided that the State Medicaid capitation payment and MA bid do not both pay for the same costs. The amount paid using MA rebates must be based on the actuarial value of the reduction in Medicare cost-sharing that is part of the MA plan benefit design, and the State Medicaid capitation payment must be based on the actuarial value of Medicare cost-sharing paid for Medicare Parts A and B services under the ''lesser-of'' payment method. The overall reduction in Medicare cost-sharing must be actuarially equivalent to the Medicare cost-sharing paid for by the Medicaid capitated payment plus the Medicare rebate dollars allocated to additional reductions in Medicare cost-sharing compared to the actuarial value of Medicare cost-sharing in the original Medicare FFS program.

We seek 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

[118] Under the ''lesser of'' policy, a State caps its payment of Medicare cost-sharing at the Medicaid rate for a particular service. 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.

[119] Qualified Medicare Beneficiaries and full benefit Medicare beneficiaries have protections from being charged Medicare cost-sharing for Medicare Parts A and B services. See *https://www.cms.gov/files/document/medicaremedicaidenrolleecategories.pdf* for the protections that apply to different categories of dually eligible individuals.

to accessing services among dually eligible beneficiaries.

14. 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, effective 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.[120] These factors, in combination with the proposals discussed earlier in this proposed rule, offer the opportunity to implement integrated care at a much broader scale than existed when MMPs were first created. As a result, should we finalize the proposals in this rule that facilitate or require greater integration, we would 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.

The process for converting MMPs to integrated D–SNPs would depend in part on each State's circumstances. States may choose to use the opportunities under our proposed § 422.107(e) to structure the integrated D–SNP products to replicate key features of MMPs. Interested States, in consultation with local stakeholders, could submit letters as described at proposed § 422.107(e)(2) indicating intent to include contract requirements under § 422.107(e)(1) and take steps toward including those new terms in their contracts with D–SNPs. Concurrently, the interested States would also notify the MMP sponsors via the transition plan required in the three-way contracts. The organizations offering the MMPs would submit a notice of intent to apply and corresponding application for an MA contract, along with the D–SNP application specific to the integrated product as part of the annual MA application process, as described in section II.A.6.a. of this proposed rule. These States would work together with CMS to take the administrative steps necessary to maintain several of the integrated processes developed as part of the capitated model demonstrations, as discussed in the previous proposals (for example, integrated materials, unified appeals and grievances, enrollment processes to support exclusively aligned enrollment, etc.). States would develop new or revise existing State Medicaid agency contracts with integrated D–SNP sponsors to reflect State-specific Medicaid-related policies and priorities. Concurrently, States may need to attain appropriate Medicaid authorities to preserve integration through Medicaid managed care plans or may need to use existing Medicaid authorities to restructure Medicaid managed care contracts.

Incorporating successful elements from MMPs into D–SNPs, using the processes and new requirements proposed in this rule, while phasing out MMPs as separate managed care products, would streamline and strengthen integrated care options for dually eligible individuals. It would allow CMS, States, and plan sponsors to concentrate quality improvement resources on a smaller number of products focused on dually eligible individuals. Now that Congress has permanently authorized SNPs, it would offer greater stability to States and sponsors and signal a longer term commitment to integration to stakeholders, including advocates, providers, and plans, than we could offer under time-limited model tests. It would also alleviate States and plans of the additional administrative burden associated with a demonstration, potentially freeing up additional resources that could be reinvested in refining and enhancing integrated care. 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.

Converting MMPs into integrated D–SNPs would not be without downsides. While the aforementioned proposals, if finalized, would create mechanisms and new requirements to replicate much of the programmatic or administrative integration found in MMPs, other aspects of integration would be lost, including financing provisions (such as integrated risk mitigation and medical loss ratio calculations) and the ability to conduct passive enrollment at scale. States may also no longer have access to the same funding we provide to support ombudsman and options counseling as part of the current model tests. It may also be challenging to replicate the integrated enrollment processes utilized for MMPs if States no longer process all enrollments, and it is possible that we would lose some integration in beneficiary communications materials, particularly enrollment notices, in the process. In addition, converting MMPs to integrated D–SNPs also means transitioning the over 400,000 individuals currently being served by MMPs, and there is risk for beneficiary confusion and disruption of services and care coordination during 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. To that end, we are considering use of our authority under section 1115A of the Act to facilitate the transition of MMP enrollees to D–SNPs operated by the same parent organization, subject to State approval, unless enrollees choose otherwise. This will minimize disruption of services and ensure continuity of care to the greatest extent possible. We already have experience with similar transitions at the end of the Virginia [121] and New York MMP demonstrations [122] 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.[123] We seek comment on this contemplated approach to working with States to convert MMPs to integrated D–SNPs.

[120] ATI Advisory. *New, Non-Medical Supplemental Benefits in Medicare Advantage in 2021.* May 2021. *https://atiadvisory.com/wp-content/uploads/2021/06/2021-Special-Supplemental-Benefits-for-the-Chronically-Ill.pdf.*

[121] 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.*

[122] 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.*

[123] 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.*

B. Special Requirements During a Disaster or Emergency (§ 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 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 are proposing 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 to codify our previous guidance. Specifically, we are proposing 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 propose 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 propose 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 propose 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)–(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 they 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 they 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 plans' 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 plan, 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 safer 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 safer location without being able to access out-of-network care. We request 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 propose 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 emergency [124] 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, 2017 [125] and a Public Health Emergency declaration by the Secretary as of September 17, 2017.[126] 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.

Under this proposal, we propose 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 closely 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 an affected area to comply with § 422.100(m), but 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 in order for the MA organization to know when compliance 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

[124] *https://governor.hawaii.gov/wp-content/uploads/2016/02/160212_EmergencyProclamation_Dengue.pdf.*

[125] *https://www.govinfo.gov/content/pkg/FR-2017-10-06/pdf/2017-21649.pdf.*

[126] *https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Puerto-Rico-and-US-Virgin-Islands-PHE-Determination.pdf.*

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 we have seen during the COVID–19 PHE, CMS expects that there will be situations where there is a disruption of access to health care 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 later time period during the same 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 are also proposing 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 are proposing 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 Act. Second, we are proposing 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 are proposing 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 propose to update the language throughout to reference disasters and emergencies with the aim of being consistent in that we refer to the various types of declarations listed at § 422.100(m)(2).

Lastly, we are proposing 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 are proposing 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 are also proposing 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. 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 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 the return to normal operations. We therefore propose 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 propose 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 are proposing 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 are also proposing.

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 propose 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 propose 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 are not proposing specific time periods but are proposing 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 propose 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 subregulatory 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 propose 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)–(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 to the end of the applicability of the special requirements rather than to 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).

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 codified, with some modifications, our network adequacy criteria and access standards (previously outlined in sub-regulatory guidance) under a new regulation at § 422.116. Section 1852(d)(1) of the Act permits an MA organization to limit the providers from which an enrollee may receive covered benefits provided that the MA organization, among other standards, makes such benefits available and accessible in the service area with reasonable promptness. Using our authority under the statute to implement, interpret and enforce these requirements, we finalized § 422.116 setting forth specific requirements. The provisions at § 422.116 outline standards for measuring network adequacy and access under a contracted provider network in accordance with requirements and standards in section 1852(d)(1) of the Act and in §§ 422.112(a) and 422.114(a)(1) of our regulations. In addition, the regulation codified our then-existing policy, that CMS does not deny an application based on the evaluation of the applicant's network for a new or expanding service area. Under our policy at the time of 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.

We are proposing to amend § 422.116(a)(1)(ii) 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. As discussed in the June 2020 final rule, we removed network adequacy reviews from the application process beginning in 2018 for contract year 2019. 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 as discussed further in this section, and are therefore proposing to improve our oversight and effectiveness of network adequacy reviews for initial applicants and services area expansion (SAE) applicants by requiring provider network reviews at the time of such MA applications.

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 bid submission 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 meet network adequacy, 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. Requiring the submission of networks for review as part of the application will mitigate this issue, as the application review 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 we are monitoring networks and requiring organizations to provide sufficient access to providers and facilities without placing undue burden on enrollees seeking covered services. 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 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 removing 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. 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, will account for, or whether they are failures that the organization cannot cure. Establishing and maintaining an adequate provider network 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 a MA contract due to previous failures associated with access to services or network adequacy 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 are proposing, to 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 are proposing to broaden our ability to safeguard the MA program by permitting evaluations of network adequacy in connection with 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 have found that the current timing of the network adequacy reviews impact 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''.[127] 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 Announcements [128]) 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 proposing 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 are also proposing to add new regulation text at § 422.116(d)(7) to 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 42 CFR 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'' [129]) 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 propose 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 available to enrollees have adequate networks for furnishing covered benefits.

Under our proposal, initial and service area expansion applicants starting with the contract year 2024 application cycle would be required to submit their proposed contracted networks during the application process. Applicants would upload their HSD tables to the NMM by the application deadline, and CMS would generally follow the current operational processes for network reviews, which includes 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 service area during the application process, and their existing network service areas separately, during the triennial review in mid-June.

For these reasons, we propose the following changes to § 422.116:

- Revise § 422.116(a)(1)(ii) 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

[127] *https://www.cms.gov/files/document/medicareadvantageandsection1876costplannetworkadequacyguidance6-17-2020.pdf.*

[128] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.*

[129] *https://www.cms.gov/files/document/cy-2022-medicare-part-c-application-updated-1-12-2021.pdf.*

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, this credit no longer applies and if the application is approved, the MA organization must be in full compliance with the section.

D. Part C and Part D Quality Rating System

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.

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 Health Outcomes Survey (HOS), Star Ratings are based on performance up to 3 calendar years prior to the Star Ratings year. For example, the HOS survey administered in 2021 asks 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 are used for the 2023 Star Ratings.

In the interim final rule titled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 19230) published in the **Federal Register** on April 6, 2020 with a March 31, 2020 effective date (hereafter referred to as the ''March 31st COVID–19 IFC''), 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 to adapt their current practices in light of the PHE for COVID–19 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. (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 impact of the PHE for COVID–19 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 final rule ''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,'' published in the **Federal Register** in April 2019 (84 FR 15680), hereafter referred to as 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 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 does not apply to the calculation of cut points for CAHPS measures because those measures do not use the clustering methodology; thus, CAHPS measures were not impacted by this issue. 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). 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 begins [130] during the 2020 measurement period results in a disaster adjustment for the 2022 Star Ratings). For Part C measures derived from the HOS survey, the disaster adjustment is delayed an additional year due to the timing of the survey and 1 year recall period. In the April 2019 final rule (84 FR 15772 through 15773), we specifically gave the example of how HOS and HEDIS–HOS measures [131] for the 2023 Star Ratings would be adjusted for contracts affected by an extreme and uncontrollable circumstances in 2020. We explained how the delay for HOS measures due to the follow-up component of HOS and the adjustment for an extreme and uncontrollable circumstance would be to the Star Ratings for the year after the completion of the follow-up HOS survey (that is administered 2 years after the baseline HOS survey).

Due to the unique circumstances surrounding the PHE for COVID–19 in which all contracts operational in 2020 qualified for the extreme and uncontrollable circumstance

[130] 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.

[131] The HEDIS measures derived from the HOS include *Monitoring Physical Activity, Reducing the Risk of Falling,* and *Improving Bladder Control.*

adjustments, we created special rules for the 2022 Star Ratings to be able to calculate non-CAHPS measure-level cut points and codified these special rules at §§ 422.166(i)(11) and 423.186(i)(9). Although the CAHPS surveys and HEDIS data collection were not completed in 2020 (we did conduct the HOS survey in 2020 on a later schedule than usual), CAHPS surveys and HEDIS data collection completed in 2021 would reflect performance by plans in 2020 during the COVID–19 PHE and would be used in the 2022 Star Ratings. In the interim final rule titled ''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'' (85 FR 54820), published in the **Federal Register** and effective on September 2, 2020 (hereinafter referred to as the ''September 2nd COVID–19 IFC''), 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). The September 2nd COVID–19 IFC also modified the calculation of the performance summary and variance thresholds for the reward factor so as not to 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 from the determination of the performance summary and variance thresholds. 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 ultimately calculate 2022 overall and summary Star Ratings.

We intend to address the changes and comments we received in response to the March 31st COVID–19 IFC and the September 2nd COVID–19 IFC in a future final rule. We are proposing here a specific provision for 2023 Star Ratings for measures derived from the HOS data collection administered in 2020.

2. Measures Calculated From the HOS Survey

In response to the September 2nd COVID–19 IFC, some commenters asked for clarification about the measures that come from the HOS survey 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 asked, 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 asked for clarification since the September 2nd COVID–19 IFC adopted a regulatory change to the 60 percent rule for only the 2022 Star Ratings. We are proposing here to address the HOS measures used in the 2023 Star Ratings.

As described in the 2019 final Part C and D rule (CMS–4185–F) (84 FR 15772 through 15773), for measures derived from the HOS survey, 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 survey for 2020 extreme and uncontrollable circumstances. (85 FR 15772 through 15773) Based on the comments received and the timing of the HOS administration, we propose to amend § 422.166(i) to specifically address the 2023 Star Ratings, for measures derived from the 2021 HOS survey 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 measures derived from the HOS survey 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 survey, 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 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 survey as described at § 422.166(i)(3)(iv).

As a reminder, in a Health Plan Management System memorandum issued on August 5, 2021 (''Medicare Health Outcomes Survey (HOS) Outcome Measures Moved to Display for 2022 and 2023 Star Ratings''), we explained that due to the pervasive way in which COVID–19 has undermined and continues to undermine the validity of the two HOS outcome measures for the 2020 and 2021 follow-up measurement periods, CMS will calculate the 2022 and 2023 Star Ratings without the use of the two measures, Improving or Maintaining Physical Health and Improving or Maintaining Mental Health. This decision was made applying the standard in § 422.164(b).

E. Past Performance (§§ 422.502, 422.504, 423.503, and 423.505)

CMS has an obligation to ensure the organizations in which we contract with will be able to provide health care services to beneficiaries in a high-quality manner. We do not want organizations entering into or expanding in MA that have shown to be poor performers. Currently, if an organization meets all of the requirements in CMS' 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 Part C and Part D 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 Part D contract, including for a service area expansion, if that organization has failed to comply with the requirements of a previous MA or Part D 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% of beneficiaries currently having access to an MA plan. In addition, 97.7 of eligible beneficiaries will have access to ten or more plans for 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 Part D 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 Part D business to the responsible organization would pose a high risk to the success and stability of the MA and Part D 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 this proposed rule, CMS seeks to expand the bases for application denial to include Star Ratings history, bankruptcy proceedings, and certain CMS compliance actions. CMS also proposes to codify the types of compliance notices which will 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 propose to codify 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 also propose to codify CMS' compliance actions which are NONCs, WLs, and CAPs in §§ 422.504(m) and 423.505(n). We are not proposing to add a recent history of Civil Money Penalties (CMPs) as a basis for a past performance application denial at this time, but we will consider it in future rulemaking. Therefore, we are soliciting comments on how best to incorporate CMPs into CMS' methodology used to deny applications based on prior contract performance.

We are also proposing to correct a few technical issues identified since the final rule was published in January 2021. Specifically, we are proposing 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. Section 423.503(b)(1)(i)(A) already provides for the denial of an application if the organization failed to meet MLR requirements and was prohibited from enrolling new members pursuant to § 423.2410(c). The technical correction would revise § 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). The new § 422.502(b)(1)(i)(A) would read as follows, ''. . . 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 pursuant to § 422.2410(c), with the exception of a sanction imposed under § 422.752(d).'' Secondly, we are proposing to correct a minor technical error in § 423.503(b)(1)(i)(A) to remove the word ''to'' when referencing subpart O. The revised sentence would read ''. . . 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 pursuant to § 423.2410(c).'' Finally, we are proposing 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. Our current review for past performance does not view incomplete CAPs as a sole basis for denying an application. Nor does CMS intend to deny an application on the sole basis of an incomplete CAP. Therefore, we propose to remove the references in §§ 422.502(b)(1) and 423.503(b)(1).

As stated previously, we propose 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. Currently, we have the authority to deny an application for organizations that fail to maintain a fiscally sound operation during the performance period. 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 Part D 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 are also seeking 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 are proposing 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. We previously proposed that low Star Ratings would be the basis for an application denial but decided not to finalize that proposal in the January 2021 final rule. In responses to comments to the January 2021 final rule,

we stated that a history of 3 consecutive years of low Star Ratings permits CMS to terminate an organization's contract, so we previously concluded it was not necessary to include one year of low ratings as a basis for a past performance application denial. However, we have re-evaluated our position, as discussed below, and believe that a history of one year of low Star Ratings merits an application denial.

CMS' Star Ratings are provided to beneficiaries to help them make informed health care choices. Moreover, MA organizations and Part D sponsors are required by §§ 422.504(b)(17) and 423.505(b)(26) to maintain summary MA 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 three consecutive years in a row for Part C summary ratings or for having less than 3 Stars for three consecutive years in a row for Part D summary ratings. Such a termination carries with it an exclusion from future MA or Part D 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 proposed rule. We have concluded that providing for an application denial based on a 1-year history of low Star Ratings is consistent with CMS' current practice of graduated enforcement. Furthermore, CMS does not want to provide an organization at risk of being terminated in 2 years, based on its Star Ratings history, with an opportunity to expand. Expansion would put more beneficiaries at risk of losing their health care coverage if an organization cannot improve its Star Ratings. As a note, terminating contracts based on Star Ratings rarely occurs, with the last termination being prior to 2016. Based on this, CMS is seeking to include one year of low Star Ratings as a reason to deny new applications or applications for service area expansions.

Finally, we are proposing to codify our practice of issuing compliance notices in §§ 422.504(m) and 423.505(n). CMS is also proposing, 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. In §§ 422.504(m) and 423.505(n), we are codifying NONCs, WLs, and CAPs as types of CMS compliance actions. CMS has been issuing compliance notices for more than 10 years. Based on our experience, we have decided that Warning Letters with Business Plans are no longer necessary. NONCs, WL, and CAPs are sufficient to record non-compliance that does not yet warrant stronger enforcement action. Based on this, we will not codify Warning Letters with Business Plans as a type of compliance action.

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 Part D 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 propose 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 organization, and those who are at or above a specified threshold may have applications for new contracts or service area expansions denied on the basis of past performance.

CMS is proposing a threshold of 13 compliance action points. CMS would have the right to deny applications from any organization who scored 13 or more compliance action points. This would be the equivalent of just over two CAPs. We believe any organization whose performance is such that two CAPs and a NONC are issued or a combination of compliance actions that add up to 13 points should not be permitted to expand. In determining this threshold, we reviewed 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% of plans based on compliance action points to accrue 13 compliance action points. We solicit comments on alternative methodologies for considering compliance notices, such as calculating outlier performance based on percentages.

For these reasons, we propose to revise §§ 422.502(b), 422.504(m), 423.503(b), and 422.505(n) to read as set out in the regulatory text.

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)

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 the aforementioned authorities, CMS promulgated regulations related to marketing and mandatory disclosures by MA organizations and Part D sponsors in 42 CFR part 422, subpart C (at § 422.111) and subpart V; as well as 42 CFR part 423, subpart C (at § 423.128) and subpart V. These regulations include the specific standards and prohibitions in the statute as well as standards and prohibitions promulgated under the statutory authority granted to the agency. Additionally, under 42 CFR 417.428, most marketing requirements in subpart V of part 422 apply to section 1876 cost plans. Because these proposals are applicable to MA organizations, Part D plan sponsors and cost plans, we collectively refer to these entities as ''plans.'' Finally, CMS has authority to adopt additional contract terms for cost plans (section 1876(i)(3)(D)), MA plans (section 1857(e)(1)), 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.

In the January 2021 final rule (86 FR 5864), we codified much of the communications and marketing guidance previously found in the Medicare Communications and Marketing Guidelines (MCMG). In this proposed rule, we propose to codify additional guidance 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 proposing 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 proposing 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. Currently, CMS guidance for additional ID card standards resides in the MCMG. We are proposing to codify existing guidance for ID card requirements under §§ 422.2267(e)(30) and 423.2267(e)(32). In addition, we will renumber the remaining required content beginning with the Federal Contracting statement, currently 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. The disclaimer provides important safeguards for Medicare beneficiaries enrolled in Part D plans that only provide access to preferred cost sharing through a limited number of pharmacies by alerting these beneficiaries that the preferred costs may not be available at the pharmacy they use, and by providing information to these beneficiaries about how to access the list of pharmacies offering prescription drugs at a preferred cost in the beneficiary's area. We therefore propose to codify the requirements for this disclaimer at § 423.2267(e)(40). We also note that, as required under § 422.500, MA plans that offer the Part D benefit must comply with Part 423 rules.

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. We propose to include these two requirements under §§ 422.2265(b)(13), 423.2265(b)(14), 422.2265(b)(14), and 423.2265(b)(15), respectively.

3. Multi-Language Insert

The multi-language insert (MLI) is a standardized document that informs the reader that interpreter services are available in Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese; the 15 most common non-English languages in the United States. Beginning in 2012, the Medicare Marketing Guidelines (MMG) required plans to include the MLI with the Summary of Benefits (SB), Annual Notice of Change (ANOC)/Evidence of Coverage (EOC), and the enrollment form (most recently in section 30.5.1 of the 2017 MMG, issued on June 10, 2016). The issuance of the MLI was independent of the translation requirements for 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, as currently required under §§ 422.2267(a)(2) and 423.2267(a)(2). However, the MLI guidance in the MMG did require plans to also include the required statement in any language that met the 5 percent threshold but was not already included on the MLI.

On May 18, 2016, the Office for Civil Rights (OCR) published a final rule (81 FR 31375) implementing section 1557 of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148). Section 1557 of the PPACA 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 final rule 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 the February 2020 proposed rule, CMS proposed an availability of non-English translations disclaimer. The disclaimer consists 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. 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 deferring to OCR's oversight and management of any requirements related to non-English disclaimers is in the best interest of the Medicare program.

It is important to note that none of the 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 requires 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=ACSST1Y2019.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 Complaint Tracking Module (CTM) cases related to ''language'' and found that several cases report beneficiary confusion stemming from not fully understanding materials based on a language barrier. In retrospect, we now believe that solely relying on the requirements delineated in OCR's 2020 rulemaking for covered entities to convey the availability of interpreter services is insufficient for the MA, cost plan, and Part D programs and is not in the best interest of Medicare beneficiaries who are evaluating whether to receive their Medicare benefits through these plans and who are enrolled in these plans. We believe it is counterproductive to have regulatory requirements for interpreter services without an accompanying requirement to inform beneficiaries that the service is available.

We are proposing to reinstitute a requirement to use the MLI under §§ 422.2267(e)(31) and 423.2267(e)(33). Similar to the previously required version, the MLI will 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 propose to require plans to 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. Finally, we propose to require the MLI to be included with all required materials listed in §§ 422.2267(e) and 423.2267(e). If OCR were in the future to finalize broader or more robust requirements associated with interpreter services than what CMS is proposing and plans adopted those broader or more robust OCR requirements, CMS will consider plans compliant with the MLI requirements we have proposed in this rule.

4. Third-Party Marketing Organizations

As most recently expressed in an October 8, 2021 HPMS memo, we have become increasingly concerned with the activities of third-party marketing organizations (TPMOs) and the impact of those activities on Medicare beneficiaries. We have seen a significant increase in third party marketing (for example, television ads, direct mailers) in the past few years. In addition, we have seen a significant increase in marketing related complaints from beneficiaries directly attributed to the activities of TPMOs. In fact, when comparing 2020 to the first eleven months of 2021, marketing based CTM complaints have more than doubled. We believe the increase in complaints is attributed to third-party advertising that misleads beneficiaries and results in them contacting third-parties to find out how they can get the advertised benefits. Based on the CTM data, CMS also has reviewed several sales and enrollment call recordings between TPMO staff and beneficiaries. Many of these calls demonstrate that beneficiaries are confused by these TPMOs, including confusion regarding who they are speaking to, what plans the TPMOs represent, and that the beneficiary may be unaware that they

are enrolling into a new plan during these phone conversations. CMS acknowledges that in some instances TPMOs can serve a role in helping beneficiaries find a plan that best meets their needs. However, CMS believes additional regulatory oversight is required to protect Medicare beneficiaries from bad actors 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 their behalf. Therefore, CMS believes additional regulatory oversight is required to protect Medicare beneficiaries from confusing and potentially misleading activities. CMS is proposing several updates to various sections of parts 422 and 423, subpart V.

We first propose 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 plan or plans to making an enrollment decision. In addition, the proposed definition includes 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 are customers of an MA or Part D plan or customers of an MA or Part D plan's FDRs. CMS is specifically seeking 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.

We next propose a required standardized disclaimer be used by TPMOs, in §§ 422.2267(e)(41) and 423.2267(e)(41), 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.'' MA organizations and Part D sponsors will need to ensure that any TPMO with which they do business, either directly or indirectly, utilizes this disclaimer were appropriate. MA organizations and Part D sponsor may 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. Statements from TPMOs such as ''we will help pick the best plan for you'' are misleading to beneficiaries as they generally mean the TPMO's help will be limited to the plans they offer. For those TPMOs who truly offer every option in a given service area, the disclaimer will not be required. We propose the disclaimer to be prominently displayed on the TPMO's website and marketing materials, including all print materials and television advertising that meet the definition of marketing. We also propose requiring 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, this disclaimer must be provided within the first minute of the call. We believe the disclaimer will help to reduce the type of beneficiary confusion CMS observed when we listened to TPMO-based sales calls.

Finally, we are proposing new TPMO oversight responsibilities in §§ 422.2274 and 423.2274, covering agent, broker, and other third-party requirements. The proposed requirements will fall under a newly created §§ 422.2274(g) and 423.2274(g), with the heading ''TPMO oversight,'' and will work in conjunction with the current FDR requirements, when applicable, in §§ 422.504(i) and 423.505(i). We propose that, as a part of their oversight responsibilities, plans that do business with a TPMO, either directly or indirectly through an FDR, are responsible for ensuring that the TPMO adheres to any requirements that apply to the plan. In doing so, we are making it clear that an MA or Part D plan cannot purchase the services of a TPMO, and thereby evade responsibilities for compliance. This proposal includes 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. We believe it is the responsibility of the MA organization or Part D sponsor to have knowledge of how and from where leads or enrollments are obtained. We believe this requirement is necessary to address the types of confusing and potentially misleading activities that, as previously discussed, CMS understands to have resulted in hundreds of Complaint Tracking Module complaints related to TPMOs identified by CMS from 2020 and 2021. In order to ensure beneficiaries are enrolled in the plan that best meets their needs, MA organizations and Part D sponsors must have knowledge and oversee all leads and enrollments. We also propose 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. We believe these proposed reporting requirements will ensure that plans are made aware of all activities associated with the chain of enrollment.

In addition, we are proposing beneficiary notifications associated with TPMO lead generating activities. In our experience, lead generating activities are typically conducted by a TPMO who uses advertisements containing information regarding MA or Part D plans or programs as a means of enticing beneficiaries to respond, for example by calling an ''800'' number seen on TV or in a direct mail piece. When a beneficiary responds, their information is collected and becomes a ''lead'' that can then be provided to a licensed agent or broker, typically based on renumeration, who can complete an enrollment. CMS has received a number of complaints from partners such as state regulators, State Health Insurance Assistance Programs (SHIPs), and Senior Medicare Patrol (SMP) who have expressed concerns that beneficiaries are being contacted directly by agents and brokers without having knowledge of how the agent had their contact information. We have also received a number of CTM cases where beneficiaries have expressed similar concerns. Based on our review of these cases, it seems clear that it is not a case of unsolicited telephonic contact, which is currently prohibited under §§ 422.2264(a)(2)(iv) and 423.2264(a)(2)(iv); rather it is a case of a beneficiary filling out a business reply card or responding to an advertisement that does not make it clear that doing so will result in being contacted by an agent or broker. We are proposing to require that plans ensure that TPMOs conducting lead generating activities must 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. We believe this requirement will 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, 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 proposed requirements, if implemented, would complement and strengthen existing requirements. For example, under §§ 422.2262(a)(1)(iii) and 423.2262(a)(1)(iii), plans must not engage in activities that could mislead or confuse Medicare beneficiaries. As previously discussed, we are concerned this requirement is not being met as it applies to certain TPMO activities performed on behalf of plans or in connection with marketing for plans. MA organizations and Part D sponsors are ultimately responsible for the marketing and enrollment activities done by them or on their behalf, ensuring that marketing is not misleading or confusing. The proposed disclaimers and notifications will ensure that beneficiaries are more informed. Moreover, the more robust reporting requirements and oversight proposed will create a better mechanism for plans to be made aware when beneficiary related issues to arise.

To reiterate and summarize, the proposed 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) and 423.2265(b)(14) 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. Proposed 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 incorporates by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Medicare Part D program. In the 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 each MA and 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 those 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 propose here 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. Proposal To 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.

In developing the MLR reporting format, CMS attempted to model it on the tools used to report commercial MLR data. This was in keeping with a 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. We also cited this policy when we amended our regulations to authorize the public release of the Part C and Part D MLR data that we collect for a contract year under §§ 422.2460 and 423.2460; we noted that the release of Medicare MLR data aligned with disclosures of MLR data that issuers of commercial health plans submit each year as required by section 2718 of the Public Health Service Act (81 FR 46162, 46405).

In the 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 56459), which appeared in the **Federal Register** on November 28, 2017 (hereinafter referred to as the November 2017 proposed rule), we proposed to modify the MLR reporting requirements by significantly reducing the amount of MLR data that MA organizations and Part D sponsors submit to CMS on an annual basis, starting with CY 2018. As part of an initiative to reduce the regulatory burden for MA organizations and Part D sponsors, we proposed to revise the MLR reporting requirements so that MA organizations and Part D sponsors would no longer be required to report the underlying data needed to calculate and verify the MLR and remittance amount, if any, for each contract; instead, they would only have to report each contact's MLR and the remittance amount, if any.

We received numerous comments on our proposed changes to the MLR reporting requirements in the November 2017 proposed rule, which we addressed 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), which appeared in the April 16, 2018 **Federal Register** (hereinafter referred to as the April 2018 final rule). Although MA organizations and Part D plan sponsors generally supported the proposed reduction in the amount of MLR data they would be required to submit on an annual basis, some commented that they did not expect their MLR reporting burden to be significantly reduced since they would still be required to collect and analyze the same information in order to calculate the MLR percentage and remittance amount. In response to comments that contended that we would be unable to conduct meaningful compliance oversight with the minimal amount of MLR data that we proposed to collect, we noted our continued 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) were calculated and reported accurately and sanctions under §§ 422.2410(c) and 423.2410(c) were appropriately applied. We expressed our belief that we could continue to effectively oversee MA organizations' and Part D sponsors' compliance by relying solely on audits (83 FR 16675) and finalized the proposed changes to the MLR reporting requirements at §§ 422.2460 and 423.2460. As a result, for CY 2018 and subsequent contract years, MA organizations and Part D sponsors are only required to report each contact's MLR and the remittance amount, if any.

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. For these reasons, which are discussed later in greater detail, we are proposing to reinstate the detailed MLR reporting requirements that were in effect for CYs 2014 through 2017. In addition, we are proposing to collect additional data on certain categories of expenditures, and to make conforming changes to our data collection tools.

One of the factors that has prompted us to reconsider our earlier decision to eliminate the detailed MLR reporting requirements is the increase both in the amount of remittances that MA organizations and Part D sponsors have reported owing, and in the number of contracts that failed to meet the MLR requirement, in the years since we changed the MLR reporting requirements. At the time we issued the November 2017 proposed rule to eliminate the detailed MLR reporting requirements, MA organizations and Part D sponsors had submitted MLR data only for CYs 2014 through 2015, when total annual remittances for all contracts averaged $29.6 million, and an average of 16 contracts failed to meet the minimum MLR requirement. Taking into account the preliminary CY 2016 MLR data that was available to CMS at the time we issued the April 2018 final rule, annual average remittances for CYs 2014 through 2016 totaled $91.8 million, and an annual average of 21 contracts failed to meet the MLR requirement. Thereafter, for CYs 2017 through 2019, the average amount of annual remittances more than doubled to $204.9 million, and the average number of contracts that failed to meet the MLR requirement nearly doubled to 40 contracts per year, even as the average number of contracts subject to the MLR requirement declined slightly.[132]

As MLR remittances have grown in scale and failure to meet the MLR requirement has become more common, the potential impact of errors that skew

[132] The average number of contracts subject to the MLR requirement was 608 per year for CYs 2014–2016 and 565 per year for CYs 2017–2019.

the MLR calculation also has grown beyond what our early experience administering the MLR requirements had led us to expect when we eliminated the detailed reporting requirement. This has become clear to us not only through observation and analysis of industry-wide changes in remittances, but also through anecdotal incidents. For example, in 2021, CMS was notified by an MA organization that it had discovered an error in one of its processes for determining the amount that it spent on prescription drugs, which caused the organization to miscalculate the MLR for 33 of its MLR submissions for CYs 2016 through 2018. For one contract, this resulted in the MA organization overstating its MLR for CY 2018 by 1.1 percent; when the error was corrected, it was determined that the contract—which the parent organization originally reported as having met the MLR requirement—had in fact failed to meet the MLR requirement, and as a result the organization was required to remit an additional $4 million to CMS for that contract alone.

Although it is possible that calculation errors such as in the above example only affect a handful of contracts, and therefore have limited impacts on the overall amount of remittances, we are mindful of how when CMS collected detailed MLR data pursuant to the reporting requirements that were in effect for CYs 2014 through 2017, we frequently detected potential errors or omissions in the reported data. When these issues 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, the MA organization or Part D sponsor often found it necessary to submit a corrected MLR Report that included changes to figures used to calculate the MLR.

In Table 2, information on the MLR submissions for CYs 2014 through CY 2017 (the contract years for which MA organizations and Part D plan sponsors reported detailed MLR data that CMS collected for CYs 2014 through 2017) is shown alongside information on the MLR submissions for CYs 2018 through 2019 (the contract years for which CMS collected minimal MLR data consistent with current §§ 422.2460 and 423.2460). Specifically, for each time period, the table shows the percentage of contracts that were flagged for potential errors during desk reviews and the percentage of contracts that submitted revisions to correct errors in the original MLR filing that had an impact on the MLR calculation. The percentage of contracts that submitted revised MLR data to correct errors in the original MLR calculation includes plan-initiated (that is, self-disclosed) resubmissions in addition to resubmissions resulting from desk reviews.

TABLE 2. COMPARISON OF PERCENTAGE OF CONTRACTS FLAGGED AND PERCENTAGE OF CONTRACTS THAT SUBMITTED CORRECTIONS THAT AFFECTED MLR CALCULATION UNDER FORMER AND CURRENT REPORTING REQUIREMENTS

	CYs 2014 to 2017 (former MLR reporting requirements)	**CYs 2018 to 2019** (current MLR reporting requirements)
% of contracts flagged during desk reviews	63% to 87%	1% to 2%
% of contracts that submitted corrections to errors that affected MLR calculation	18% to 37%	2% to 5%

As the table indicates, although we stopped collecting detailed MLR data for contract years after CY 2017, we have continued to perform desk reviews of the submitted data, although, due to the limited amount of information we receive, these are largely confined to confirming that, for contracts that reported failing to meet the 85 percent MLR requirement for a contract year and owing a remittance to CMS, the amount that the MA organization or Part D sponsor indicates it is required to remit is consistent with what we would expect based on the reported MLR and our records of the contract's revenues for the contract year. Given that we collect very little MLR data from MA organizations and Part D sponsors under current §§ 422.2460 and 423.2460, and the consequently limited nature of our current desk reviews, it is unsurprising that fewer contracts were flagged as potentially containing erroneous data for CYs 2018 and 2019 relative to CYs 2014 through 2017. We acknowledge that there may be valid explanations for the decline in the number of contracts that had to correct their MLR calculations, such as MA organizations and Part D sponsors gaining familiarity with the requirements for calculating their MLRs (although we would have expected any such decreases to be observed in the initial years of MLR reporting). However, we believe that the steep decline since CY 2017 in the number of contracts that revised and resubmitted their MLR data raises questions about whether errors or omissions affecting the calculation of the MLR that might have been flagged by CMS or discovered by MA organizations and Part D sponsors as a result of MLR desk reviews under the prior regulations are now simply going undetected. This, in turn, has led us to reconsider whether the savings we estimated would result from minimizing the MLR reporting requirements outweigh the potential cost of allowing errors that might have been discovered via desk reviews of the detailed MLR data to go undetected.

We believe the potential for costly errors in the MLR calculation should be a concern not only for the government, but also for MA organizations and Part D sponsors, for although it is possible that some may have overstated their MLRs and remitted lower amounts than were actually owed, it is also possible that others may have understated their MLRs and overpaid remittances. With respect to contract years for which MA organizations and Part D sponsors have reported the limited amount of MLR data they are required to submit under current §§ 422.2460 and 423.2460 (that is, CYs 2018 and 2019), we have been

made aware only of MLR calculation errors that resulted in the MA organization or Part D plan sponsor reporting that the MLR as originally reported for a contract was *higher* than the actual MLR, which in some cases led to CMS collecting remittance amounts that were *lower* than the amounts that were actually owed. However, with respect to contract years for which we collected detailed MLR data and conducted desk reviews (that is, CYs 2014 through 2017), MA organizations and Part D sponsors that were contacted about suspected errors in their MLR calculations would often, in the course of examining issues flagged by CMS, inform us that they had discovered that they had made other mistakes, which when corrected caused the MLR for the contract to increase.

CMS could invoke its audit authority under §§ 422.2480 and 423.2480 to require MA organizations and Part D sponsors to validate the data necessary to calculate MLRs, so that CMS is able to determine that that the MLRs and 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. As previously noted, CMS stated in the April 2018 final rule that we believed we could continue to effectively oversee MA organizations' and Part D sponsors' compliance by relying solely on audits (83 FR 16674). In response to comments that expressed concern that the audit burden would increase once we started relying on audits to monitor compliance, we stated that we did not expect that the changes to the MLR reporting requirements would cause MLR audits to be more burdensome than the MLR audits that were conducted in previous years. However, our response was based on an assessment that the burden associated with each individual audit would not increase, as we did not intend to change our MLR audit methodology. Upon further reflection, 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. Given the minimal data we currently receive from MA organizations and Part D sponsors, 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 would negate the savings that the April 2018 final rule estimated would result from the changes to the MLR reporting requirements.[133]

Furthermore, as we have continued to administer the MLR reporting requirements, we have come to recognize the limits and potential risks of an oversight approach that requires CMS to conduct time-consuming audits as the primary mechanism for identifying any errors that might impact the calculation of the MLR, and to appreciate the unique advantages of using desk reviews of detailed MLR data to identify outliers, anomalies, and omissions in the reported data that might indicate errors in the MLR calculation. An audit-only oversight approach is potentially problematic in the context of CMS' review of the MLR submissions that MA organizations and Part D sponsors are required to submit in advance of the general MLR filing deadline when one of their contracts fails to meet the minimum MLR requirement for two or more consecutive contract years. CMS requires that the MLR data for such contracts be reported early so that we have time to implement, prior to the open enrollment period, enrollment sanctions for any contract that fails to meet the MLR threshold for 3 or more consecutive years and contract termination for any contract that fails to meet the MLR threshold for 5 consecutive years. In the May 2013 Medicare MLR final rule (78 FR 31296), we explained that we were adopting this policy because, if we were to implement enrollment and termination sanctions after the start of the annual open enrollment period, this would create disruptions for beneficiaries who are newly enrolled in plans under a contract that is subject to enrollment sanctions, or all beneficiaries enrolled in plans under a contract that is subject to termination. We have typically required that these early MLR submissions be submitted to CMS in late July, a little more than 2 months before open enrollment begins.

Given the brief amount of time between when CMS receives these early MLR data submissions and the date when open enrollment begins, and the risk of disruption to beneficiaries if it is determined after open enrollment begins that a contract for which an early MLR submission was required failed to meet the MLR requirement for a third or fifth consecutive year, we believe it is particularly important that early MLR filers submit to CMS detailed MLR data, which can then be analyzed to quickly and independently identify potential errors in the MLR calculation. We believe this will reduce the likelihood that CMS will learn that a contract must be placed under the statutorily required sanctions at a time when enforcing those sanctions will force beneficiaries to enroll in another MA plan or in Medicare fee-for-service (FFS). Although that particular concern could perhaps be addressed by only requiring that early filers submit detailed MLR reports, that would not address the concerns raised in the preceding discussion about the potential cost to the government of uncollected remittances, or to MA organizations and Part D sponsors due to overpayment of remittances, when MLR calculation errors go undetected. The MLR data submitted for CYs 2014 through 2017 does not indicate that contracts that had to early report their MLR data made up a significant portion of the contracts that submitted MLR data that later had to be revised to correct errors that impacted the MLR calculation. We discuss the concerns about potential errors in early filers' MLR submissions to further illustrate the potential consequences of CMS not receiving detailed MLR data, which we did not fully appreciate when we adopted the current MLR reporting requirements. We clarify that we believe this concern makes it necessary that all MA organizations and Part D sponsors submit detailed MLR data that CMS can use to identify suspected errors that might affect the MLR calculation in a timely manner, and without having to rely on audits or self-disclosures.

In addition to the factors we have already discussed, we believe it is appropriate that we reevaluate our alignment with the commercial MLR rules. This is particularly true as it relates to the policy considerations that underlay our rulemaking to authorize the public release of the MLR data that MA organizations and Part D sponsors submit to us on an annual basis, as codified in our regulations at §§ 422.2490 and 423.2490. The analysis in the November 2017 proposed rule did not consider the benefits CMS associated with the release of Part C and Part D MLR data to the public, which we had enumerated the previous year in the proposed rule titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and

[133] 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).

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). 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 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'' (81 FR 80170), which appeared in the November 15, 2016 **Federal Register** (hereinafter referred to as 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. Given this background, in proposing to reinstate the detailed MLR reporting requirements, 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 in 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.

3. Proposed 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 proposed rule, we are proposing to reinstate the MLR reporting requirements that were in effect for CYs 2014 through 2017, with some modifications. Our proposed revisions to the regulation text would amend paragraph (a) of §§ 422.2460 and 423.2460 so that they are essentially as they were prior to the elimination of the detailed MLR reporting requirements as finalized in the April 2018 final rule. However, we propose to further amend § 422.2460(a) so that the regulation text explicitly provides that the MLR report submitted to CMS includes amounts paid for incurred claims for covered services (both Medicare benefits and supplemental benefits) and prescription drugs.

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 propose 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 propose 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.

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. In the years since CMS discontinued development of the MLR Reporting Tool, we have received multiple requests to continue updating and making this software publicly available so that it can be used as an aid for calculating MLRs in accordance with the current regulations and guidance. We agree that the use of CMS-developed MLR reporting software will help MA organizations and Part D sponsors to calculate their MLRs accurately. Although the MLR reporting software is unable to prevent all errors that might cause MLRs to be calculated incorrectly, particularly errors resulting from users entering erroneous data, we believe that MLR calculation errors are less likely to occur, and less likely to go unnoticed when they do occur, when MA organizations and Part D sponsors input the data elements for the MLR calculation into a standardized data collection tool that performs the mathematical operations to compute the MLR, including any applicable credibility adjustment, and contains built-in validation checks. In addition, we believe that we can further improve the usefulness of the software if MA organizations and Part D sponsors also submit to CMS the information entered into the MLR Reporting Tool and used to calculate the MLR for a contract. As part of our desk review process, we generate reports that identify specific issues flagged during desk reviews and whether any corrections to the reported data were necessary, which we can analyze to identify areas where we can improve the reporting guidance and validations in order to prevent errors in MLR submissions. As the agency responsible for developing the requirements for calculating and reporting MLR data, receiving and processing MLR data submissions, and

identifying compliance issues, we believe that CMS is uniquely positioned to use feedback generated through the submission and review of MLR data to learn about the various types of errors that may affect MA organizations' and Part D sponsors' MLR calculations, and to make changes both in our guidance and in the data collection tool itself that can prevent or steer MA organizations and Part D sponsors away from making certain errors that are known to have affected the MLR calculations of other MA organizations and Part D sponsors.

If our proposal to amend our regulations to require reporting of detailed MLR data is finalized, we intend to make three types of changes to the MLR Reporting Tool, which we list below:

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. These include changes in the treatment of fraud reduction expenses to remove the cap on these amounts. 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).

Second, we will separate out certain items that are currently consolidated into or otherwise accounted for in existing lines of the MLR Reporting Tool. Thus, we intend to 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, which will serve as a reminder to Part D sponsors that this amount needs to be subtracted from the numerator, and which we believe will provide more accountability in ensuring this amount has been accurately determined.

Third, we will separate out the current line 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 Parts 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. As noted previously, in the CY 2017 PFS proposed rule, we explained that we believed the public release of Part C and Part D MLR data would allow 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 (see 81 FR 46396 and 46397). To date, CMS has not separated out Medicare-covered and supplemental benefits into separate lines of the MLR Reporting Tool.

We intend 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 solicit 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).

Regarding 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), we intend to have MA organizations report these expenditures on multiple lines of the MLR Reporting Tool, which would 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 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 addition, we believe 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 are not proposing to require separate reporting of Part D supplemental benefit expenditures (that is, they will continue to be reported combined with other Part D expenditures).

In developing these additional supplemental benefit categories, we recognize that requiring MA organizations to separately report expenditures that they might not already be separately tracking, or that they are tracking using categories other than the ones listed in the MLR Reporting Tool, could create an additional burden. Accordingly, where different supplemental benefits are conventionally regarded as falling into the same category of benefit offering (for example, a comprehensive dental benefit might include both extractions and dental diagnostic services), although these can be treated as separate benefit offerings in the PBP, we grouped those benefits together under the same category (for example, ''Dental'').

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))

We believe that expenditures for dental, vision, and hearing should be separately reported because, in addition to being among the most widely-offered types of supplemental benefits, the amounts reported in the MLR Reporting Tool for each of those benefit types could be compared to the expenditures for each of those benefit types that are included in the base period experience section and the expected expenditures in the projected section of the Bid Pricing Tool (BPT). We believe reporting

expenditures related to the additional types and categories of supplemental benefits previously listed will increase accountability for the accuracy of the amounts used in the MLR calculation, and CMS will be able to analyze the reported data for indicators of potential inaccuracies, such as by flagging outliers for follow-up inquiries.

In compiling the previous list of supplemental benefit types and categories, we took 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, CY 2022), 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 proposes 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)). Based on our review of the percentage of plans offering each type of supplemental benefit, and the percentage that are offered under only one plan under a contract, we are not proposing to require separate reporting of expenditures for supplemental benefit types or categories offered by less than 10 percent of all MA plans in 2021. The exception is SSBCI that are not primarily health related, which we include 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 solicit 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 are interested in feedback that addresses 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 above benefit types or categories into larger categories.

As the preceding discussion suggests, 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 propose to collect, including the additional data we propose 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. 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). As previously noted, we propose to amend § 422.2490(b)(2) by adding new paragraph (b)(2)(ii), which would 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 would 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 would be reported in the Dental line in the MLR Reporting Tool, and that combined amount (assuming both plans had expenditures in the Dental category) would not be excluded from our public data release. 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 solicit 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 solicit 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.

4. Proposed 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 propose 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 propose to amend this paragraph to note that it is subject to an exception in new paragraph (e), which as proposed would 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) would 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.

We characterize this as a clarifying amendment, as 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 should be based on the contract year revenue figure available at the time of reporting, and should not be subject to change if the contract year

revenues increase or decrease through adjustments that take place in a future year. We note that the discussion of this policy appears in both the proposed and final rules under the heading ''Projection of Net Total Revenue'' (78 FR 12435; 78 FR 31292). The MLR final rule discusses how our policy not to reopen the MLR due to any payment reconciliation process is consistent with our view that the MLR should reflect how an MA organization or Part D plan sponsor decided to apportion the revenue it actually received for the contract year between patient care and quality improvement and other costs (78 FR 31293). The Medicare MLR final rule explains that we assume that MA organizations and Part D plan sponsors likely do not make their decisions about how to use the funds that are available to them based on an assumption that their revenue will be reduced or increased in a future year as a result of a future audit or reconciliation that changes the final Medicare payment amount. We believe that taking such future revenue adjustments into account would not be useful for assessing how a plan chose to allocate its available revenues.

In addition to our remarks in the 2013 Medicare MLR proposed and final rules, we believe it is clear based on other provisions in our MLR regulations that we have 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. For example, when MLR data submitted under § 422.2460 (for MA contracts) or § 423.2460 (for Part D contracts), calculations, or any other MLR submission required under our MLR regulations is found to be materially incorrect or fraudulent, under §§ 422.2480(d) and 423.2480(d), CMS is required to recoup the appropriate remittance amount. It would be unduly burdensome and time-consuming for both CMS and the relevant MA organization or Part D sponsor if, in lieu of requiring the MA organization or Part D sponsor to correct its MLR submission, CMS had to collect the MA organization's or Part D sponsor's relevant financial records, contracts, and other types of supporting documentation so the agency could calculate the correct MLR for a contract. That being the case, if CMS could not require the submission of corrected MLR data when deficiencies are found, whether by CMS or by the MA organization or Part D sponsor, CMS' ability to enforce the statutory MLR sanctions (codified in our regulations at §§ 422.2410(c) through (d) and 423.2410(c) through (d)) would be undermined. In addition, because our MLR data release regulations at §§ 422.2490 and 423.2490 provide that CMS releases to the public the data collected under §§ 422.2460 and 423.2460, if CMS could not require or allow resubmission of MLR data submitted under those regulations in order to correct errors in the original filing, it would be necessary for CMS to either release data that is known to contain errors, which could mislead beneficiaries who wish to use the MLR data to assess the relative value of Medicare health and drug plans, or to remove the erroneous data, which would create gaps in the dataset and limit the usefulness of MLR data as a resource for facilitating public evaluation of the MA and Part D programs (see 81 FR 46396 and 46397).

The proposed amendments to §§ 422.2460 and 423.2460 are consistent with 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). To date, CMS has accepted resubmission of MLR data submitted for a contract year without penalty up until the point when we collect remittances for contracts that have failed to meet the minimum MLR requirement for that contract year. CMS has typically collected remittances for a contract year through an adjustment to MA organizations' and Part D sponsors' monthly payments for July in the year that is 2 years after the contract year that is the subject of the MLR filing (for example, remittances based on CY 2015 MLR reporting were collected in July 2017). We have also required that MA organizations and Part D sponsors resubmit MLR data if it is determined that the original MLR submission contained errors that affected the calculation of the MLR or remittance amount after this date, although in such cases CMS reserves the right to issue sanctions as authorized by §§ 422.2480(d)(3) and 423.2480(d)(3). In deciding whether to issue sanctions, we will consider factors such as whether the error in the MLR filing was self-disclosed by the MA organization or Part D sponsor, whether the error appears to be the result of intentional misrepresentation, and whether any beneficiary harm (including disruptions to enrollment) occurred as a result of the error.

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 net 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 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 DIR [134] 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 under Part D plans by Part D sponsors), net of all pharmacy incentive payments, have grown faster than any other category of DIR [135] received by sponsors and 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 3, the growth in pharmacy price concessions from 2010 to 2020 has been a continuous upward trend with the exception of 2011.

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TABLE 3: 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.

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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.

While manufacturer rebates (a non-pharmacy price concession) account for the largest category of DIR, given the large growth in pharmacy price concessions that has resulted from the increased use of performance-based pharmacy payment arrangements, CMS is focusing on policy proposals in this section that would be applicable to pharmacy price concessions, and not non-pharmacy price concessions. Further, section 90006 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) prohibits the Secretary from implementing, administering, or enforcing the provisions of the final rule

[134] 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.*

[135] 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.

published by the Office of the Inspector General of the Department of Health and Human Services on November 30, 2020, and titled ''Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees'' (85 FR 76666) (hereinafter referred to as the rebate rule) prior to January 1, 2026. While CMS has independent statutory authority, pursuant to section 1860D–2(d)(1)(B) of the Act, to regulate the application of non-pharmacy price concessions to negotiated price, given the existing moratorium on implementation of the rebate rule and the differences between performance-based pharmacy payment arrangements and non-pharmacy price concessions, we are following an incremental approach and only proposing policies related to pharmacy price concessions at this time.

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.

Through comments received from the pharmacy industry in response to our Request for Information on pharmacy price concessions (included in the 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 (hereinafter referred to as the November 2017 proposed rule)), and our solicitation for comments on the potential policy approach for including pharmacy price concessions in the negotiated price discussed 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), and sponsor-reported DIR data, we further understand that the share of pharmacies' reimbursements that is contingent upon their performance under such arrangements has grown steadily each year. Further, sponsors and PBMs have been recouping increasing sums from network pharmacies after the point-of-sale (pharmacy price concessions) for ''poor performance,'' sums that are far greater than those paid to network pharmacies after the point-of-sale (pharmacy incentive payments) for ''high performance.'' 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 is proposing changes that would standardize how Part D sponsors apply pharmacy price concessions to negotiated prices at the point-of-sale.

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, and that establishing a minimum threshold for the price concessions to be applied at the point-of-sale would only serve to undercut these market forces. However, actual Part D program experience has not matched expectations in this regard. In recent years, less than 2 percent of plans have passed through any price concessions to beneficiaries at the point-of-sale. We now understand that sponsors may face market incentives to not 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 the November 2017 proposed rule, we published a ''Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale'' (82 FR 56419 through 56428). 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 timely 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 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 (85 FR 9002), 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 will be required to disclose their pharmacy performance measures to CMS.

After considering the comments received on the November 2018 proposed rule, and in light of more recent data indicating that pharmacy price concessions have continued to grow at a faster rate than any other category of DIR,[136] effective for contract year 2023, we propose 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 pharmacy price concessions. First, we propose to 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. 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 propose to define ''negotiated price'' as the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug, taking into account all pharmacy price concessions.

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–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.* As discussed later in this section of this proposed rule, pharmacy price concessions applied as DIR can lower plan premiums and increase plan revenues, 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 obscure the true costs of prescription drugs for consumers and the government.

[136] From 2018 to 2020, pharmacy price concessions increased by 50.4% while all other DIR increased by 23.5%.

a. Premiums and Plan Revenues

The main benefit to a Part D beneficiary of price concessions applied as DIR at the end of the coverage year (and not to the negotiated price at the point-of-sale) is a lower plan premium. A sponsor must factor into its plan bid an estimate of the expected DIR for the upcoming payment year. That is, in the bid the sponsor must lower its estimate of plan liability by a share of the projected DIR, which has the effect of reducing the price of coverage under the plan. Under the current Part D benefit design, applying price concessions after the point-of-sale as DIR reduces plan liability (and thus premiums) more than applying price concessions at the point-of-sale.

Therefore, to the extent that plan bids reflect accurate DIR estimates, the pharmacy and other price concessions that Part D sponsors and their PBMs negotiate, but do not include in the negotiated price at the point-of-sale, put downward pressure on plan premiums, as well as the government's subsidies of those premiums. The average Part D basic beneficiary premium grew at an average rate of only about 1 percent per year between 2010 and 2020 [137] and the average basic premium actually paid by beneficiaries has declined each year since 2017 as sponsors projected in their bids that DIR growth will outpace the growth in projected gross drug costs each year. The average Medicare direct subsidy paid by the government to cover a share of the cost of coverage under a Part D plan has also declined, by an average of 11.7 percent per year between 2010 and 2019, partly for the same reason.[138]

However, any DIR a sponsor receives that is above the projected amount factored into its plan bids increases revenues and contributes to plan profits, without necessarily being reflected in lower premiums. The risk-sharing construct established under the Part D statute at section 1860D–15(e) of the Act allows sponsors to retain as plan profit the majority of all plan revenues above the bid-projected amount. Given that plan bids, and, thus, plan revenues, are based on cost projections, the plan's actual experience may yield unexpected losses (when bid-based payments to plans—plan revenues—fall short of actual plan costs) or unexpected savings (when plan revenues exceed actual plan costs) for Part D sponsors. In order to limit Part D sponsors' exposure to unexpected drug expenses and the government's exposure to overpayments, Medicare shares risk with sponsors on the drug costs covered by their plan bids, using symmetrical risk corridors to cover or recoup a share of unexpected losses or savings.

Under the Part D risk corridors, if a plan's actual drug costs are within +/− 5 percent of the drug costs estimated in its bid, the plan assumes all of the losses or savings. If its costs are more than 5 percent above or below its bid, the government assumes a growing share of the losses or savings, and the plan assumes the remainder. Any unexpected losses or savings that a plan assumes affect its final profit margin. Thus, when a plan underestimates the amount of DIR that it will receive, any additional amount of DIR constitutes additional plan revenues. In the event that overall plan revenues exceed the amount projected in the plan sponsor's bid, the sponsor is permitted to retain most, if not all, of the excess amount, assuming that the sponsor has met the minimum MLR requirement. Our analysis of Part D plan payment and cost data indicates 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.

Due to the relative premium and other advantages that price concessions applied as DIR, including pharmacy price concessions, offer sponsors over lower point-of-sale prices, sponsors can have an incentive to opt for higher negotiated prices in exchange for higher DIR and, where price concessions are in the form of percentage-based fees, to prefer a higher net cost drug over a cheaper alternative. This may put upward pressure on Part D program costs and shift costs from the Part D sponsor to beneficiaries who utilize drugs in the form of higher cost-sharing and to the government through higher reinsurance and low-income cost-sharing subsidies.

b. Cost-Shifting

Beneficiary cost-sharing is generally calculated as a percentage of the negotiated price. When pharmacy price concessions and other price concessions are not reflected in the negotiated price at the point-of-sale (that is, are applied instead as DIR at the end of the coverage year), beneficiary cost-sharing increases, covering a larger share of the actual cost of a drug. Although this is especially true when a Part D drug is subject to coinsurance, it is also true when a drug is subject to a copayment because Part D rules require that the copayment amount be at least actuarially equivalent to the coinsurance required under the defined standard benefit design. For more than half of 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. For the millions of low-income beneficiaries whose out-of-pocket costs are subsidized by Medicare through the low-income cost-sharing subsidy, those higher costs are borne by the government. See the lowest possible reimbursement example later in this section of this proposed rule for an example of the effect the proposed change to the definition of negotiated price would have on the determination of beneficiary cost-sharing.

This potential for cost shifting to beneficiaries grows increasingly pronounced as pharmacy price concessions increase as a percentage of gross drug costs and continue to be applied outside of the negotiated price. Numerous research studies suggest that higher cost-sharing can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries and Medicare overall.[139] [140] [141] Moreover, higher cost sharing can negatively impact all beneficiaries, not just those who are low income. While most low-income beneficiaries are insulated from this cost-shifting due to statutorily limited copayments, low-income subsidy (LIS) Level 4 beneficiaries pay 15 percent coinsurance in the initial coverage limit, which in an environment where the negotiated price does not include all pharmacy price concessions could be cost-prohibitive for this population. Additionally, those beneficiaries who narrowly miss the LIS eligibility criteria are particularly vulnerable to such cost shifting. Given this, we believe it is

[137] By contrast, during this same period (2010–20), the average premium for a single individual in the commercial market grew by about 4 percent per year. *See* Kaiser Family Foundation 2020 Health Benefits Annual Survey, Page 40, *https://Files.kff.org/Attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf.*

[138] Plan Payment Data, 2010–19, available at *https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Plan-Payment-Data.html.*

[139] Michele Heisler et al., ''The Health Effects of Restricting Prescription Medication Use Because of Cost,'' *Med Care,* 2004 Jul;42(7):626–634, available at *https://www.ncbi.nlm.nih.gov/pubmed/15213486.*

[140] Peter Bach, ''Limits on Medicare's Ability to Control Rising Spending on Cancer Drugs,'' *New England Journal of Medicine* 2009, 360:626–633, available at *https://www.nejm.org/doi/full/10.1056/NEJMhpr0807774.*

[141] Sonya Blesser Streeter et al., ''Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions,'' *Journal of Oncology Practice 2011,* 7(3S):46s–51s, available at *http://ascopubs.org/doi/full/10.1200/jop.2011.000316.*

important to weigh the effects of current Part D policies, and the trade-offs between higher cost-sharing versus lower plan premiums, on beneficiaries' access to affordable prescription drugs.

Finally, beneficiaries progress through the four phases of the Part D benefit as their total gross drug costs and cost-sharing obligations increase. Because both of these values are calculated based on the negotiated prices reported at the point-of-sale, when pharmacy price concessions are not applied at the point-of-sale, the higher negotiated prices result in more rapid movement of Part D beneficiaries through the Part D benefit phases. This, in turn, shifts more of the total drug spend into the catastrophic phase, where Medicare liability is at 80 percent (paid as reinsurance) and plan liability is at 15 percent (which is much lower than the 75 percent plan liability for drugs in the initial phase and generic drugs in the coverage gap phase; plan liability with respect to ''applicable drugs'' in the coverage gap phase is 5 percent). With such cost-shifting to the government under current rules, Part D sponsors may have weak incentives, and, in some cases no incentive, to lower prices at the point-of-sale. See the Regulatory Impact Analysis in section V.D.8. of this proposed rule for a discussion of cost impacts to beneficiaries, the government, and plan sponsors of requiring all pharmacy price concessions to be included in the negotiated price at the point-of-sale.

c. Transparency and Competition

The significant growth in pharmacy price concessions in recent years and inconsistency in how pharmacy price concessions are treated by different Part D sponsors (that is, they are applied to the point-of-sale price to differing degrees or estimated and factored into plan bids with varying degrees of accuracy) has resulted in plans that are not consistent with each other with respect to the aggregate share of drug costs covered by the plan versus the beneficiary. Moreover, the disparate ways that Part D sponsors manage pharmacy price concessions reduces transparency of the point of sale cost to the beneficiary and can increase beneficiary confusion. For example, a beneficiary facing a choice between a plan offering a 10 percent coinsurance tier versus a plan offering $50 copay for a given drug, would have difficulty assessing the true cost at the point of sale and, as a result, may inadvertently select the more costlier option. This undermines beneficiaries' ability to make meaningful price comparisons and efficient choices when considering the combined cost sharing and premiums plans offer when choosing a plan. Second, if a sponsor's bid is based on an estimate of net plan liability that is lowered because the sponsor has been applying pharmacy price concessions as DIR at the end of the coverage year rather than using them to reduce the negotiated price at the point-of-sale, it follows that the sponsor may be able to submit a lower bid than a competitor that applies pharmacy price concessions at the point-of-sale. This lower bid results in a lower plan premium, which could allow the sponsor to capture additional market share. The competitive advantage accruing to one sponsor over another in this scenario stems only from a technical difference in how plan costs are reported to CMS. Therefore, the opportunity for differential treatment of pharmacy price concessions could result in bids that are not comparable and in premiums that are not valid indicators of relative plan efficiency.

3. Proposed Changes to the Definition of Negotiated Price (§ 423.100)

As previously discussed, Part D sponsors and PBMs have been recouping increasing sums from network pharmacies after the point-of-sale in the form of pharmacy price concessions. We addressed concerns about these pharmacy payment adjustments when we established the existing requirements for negotiated price reporting in the May 2014 final rule (79 FR 29844). In that rule, 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). However, when we formulated these requirements in 2014, the most recent year for which DIR data was available was 2012, and we did not anticipate the growth of performance-based pharmacy payment arrangements that we have observed in subsequent years.

We now understand that the reasonably determined exception we currently allow applies more broadly than we had initially envisioned because of the shift by Part D sponsors and their PBMs towards contingent pharmacy payment arrangements. As suggested by numerous stakeholders in response to the Request for Information in the November 2017 proposed rule (82 FR 56419 through 56428), nearly all performance-based pharmacy payment adjustments may be excluded from the negotiated price on the grounds that they cannot reasonably be determined at the point-of-sale. Specifically, several stakeholders have suggested to us that sponsors apply the reasonably determined exception to all performance-based pharmacy payment adjustments. These stakeholders assert that the amount of these adjustments, by definition, is contingent upon performance measured over a period of time that extends beyond the point-of-sale and, thus, cannot be known in full at the point-of-sale. Therefore, performance-based pharmacy payment adjustments cannot ''reasonably be determined'' at the point-of-sale as they cannot be known in full at the point-of-sale. These assertions are supported by the information plan sponsors report to CMS as part of the annual DIR reports. 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 the use of performance-contingent pharmacy payment arrangements by plan sponsors, 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 propose 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 propose 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.

Requiring that all pharmacy price concessions be included in the negotiated price, as proposed, will lead to more accurate comparability of drug prices, Part D bid pricing, and plan premiums. This increased level of accuracy should center the beneficiary by allowing them to better compare between plans' cost sharing and premiums, so that beneficiaries are able to identify the plan that best meets their individual needs. Moreover, when negotiated prices and plan premiums more accurately reflect relative plan efficiencies, there would not be unfair competitive advantages accruing to one sponsor over another based on a technical difference in how costs are reported. In short, because Part D is a market-based approach to delivering prescription drug benefits, and relies on healthy market competition, we believe the proposed changes to cost reporting could make the Part D market more competitive and efficient by allowing for a more consistent, accurate, ''apples to apples'' comparison of prices in the market.

a. All Pharmacy Price Concessions

In this proposed rule, we propose 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 regulatory change we propose to adopt changes the reporting requirements for Part D sponsors; it does not affect what sponsors may arrange in their contracts with network pharmacies regarding payment adjustments after the point-of-sale. We clarify this point because in comments on the solicitation in the November 2018 proposed rule (83 FR 62179) regarding a potential policy approach under which all pharmacy price concessions received by a plan sponsor for a covered Part D drug would be included in the negotiated price at the point-of-sale, some commenters posited that CMS requiring 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.'' We disagree. Mandating that all pharmacy price concessions be included in the negotiated price at the point-of-sale does not interfere with the negotiations between plan sponsors, their PBMs, and pharmacies. 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.

b. Lowest Possible Reimbursement

To effectively capture all pharmacy price concessions at the point-of-sale consistently across sponsors, we propose 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 section of this proposed 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. We believe, based on the overwhelming support received from commenters on the Request for Information in the November 2017 proposed rule and the potential change to the definition of negotiated price discussed in the November 2018

proposed rule, that this 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.

Regarding consistency in reporting, we believe that the proposed requirement 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 would, if implemented, provide a clearer reporting standard for Part D sponsors relative to the requirements in place today, which require Part D sponsors to assess which types of pharmacy payment adjustments fall under the reasonably determined exception. We expect this increased clarity would reduce sponsor burden in terms of the resources necessary to ensure compliance. Finally, we believe that requiring all pharmacy price concessions be included in the negotiated price at the point-of-sale would improve the quality of drug pricing information available across Part D plans and thus improve market competition and cost efficiency under Part D.

Requiring the negotiated price to reflect the lowest possible pharmacy reimbursement as proposed would move the negotiated price closer to the final reimbursement for most network pharmacies under current pharmacy payment arrangements, and thus closer to the actual cost of the drug for the Part D sponsor. We have learned from the DIR data reported to CMS and feedback from numerous stakeholders that pharmacies rarely receive an incentive payment above the original reimbursement rate for a covered claim. We gather that performance under most arrangements dictates only the magnitude of the amount by which the original reimbursement is reduced, and most pharmacies do not achieve performance scores high enough to qualify for a substantial, if any, reduction in penalties.

Finally, we propose 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 noted previously, we understand that such incentive payments are rare. Furthermore, even in those instances in which a pharmacy may qualify for such a payment, 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 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 emphasize 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 provide 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.

d. Additional Considerations

In order to implement the proposed change, we would leverage existing reporting mechanisms to confirm that sponsors are appropriately applying pharmacy price concessions at the point-of-sale. Specifically, 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 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. To implement the proposed change at the point-of-sale, Part D sponsors and their PBMs would load revised drug pricing tables that reflect the lowest possible reimbursement into their claims processing systems that interface with contracted pharmacies.

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 the Patient Protection and Affordable Care Act (PPACA), 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 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 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.

Although 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, we are not proposing to adopt such a mandate at this time. As demonstrated in the Regulatory Impact Analysis of this proposed rule (sections IV.D.8. and IV.E.2.), allowing plans flexibility with respect to the treatment of pharmacy price concessions for applicable drugs in the coverage gap will 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 CMS adopts the proposed approach, we will 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 solicit comment on whether there are other topics CMS will need to address in new guidance if we finalize the proposed approach. We also request 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 solicit 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.

4. Pharmacy Administrative Service Fees

As noted in the November 2018 proposed rule (83 FR 62179 and 62180), 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.

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 subregulatory guidance. Therefore, to avoid confusion among Part D sponsors and other stakeholders of the Part D program resulting from inconsistent terminology, we propose to add a regulatory definition for the term ''price concession'' at § 423.100 that is consistent with how that term is used in paragraphs (d)(1)(B) and (d)(2) of section 1860D–2 of the Act.

In considering how to define price concession, we believe it is important to define the term in a broadly applicable manner, while maintaining clarity. Accordingly, we propose to define price concession 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. 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.

We believe the proposed approach would be consistent with the statute, support consistent accounting by Part D sponsors of amounts that are price concessions, and ensure that certain forms of discounts are not inappropriately excluded from being considered price concessions. An alternative would be not to define ''price concession'' at all. However, this option would not support consistent accounting of amounts that are price concessions among Part D sponsors, which we believe is particularly important in light of the proposed change to the definition of negotiated price.

We note 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. Defining the term ''price concession'' as proposed 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.

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 hospitals 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 are seeking 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 seeks 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 remain mindful of the impact the MA program's policies have on the health care system as a whole, and strongly encourage MA organizations to continuously re-assess the need for flexibilities in their utilization management practices. We note 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 invite 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. The primary objective of this RFI is 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 is a general RFI related to prior authorizations on patient transfers during any PHE. While many commenters may choose to provide information in the context of the COVID–19 PHE, we welcome and encourage commenters to provide information in the context of any PHE.

Responses to this RFI may include, but are not limited to the following:

- The overall impact of both the relaxation and reinstatement of prior authorization requirements for patient transfer by MA organizations on the provision of appropriate patient care in hospital systems.
- The overall impact of both the relaxation and reinstatement of prior authorization requirements for patient transfer on MA organizations.
- Wait times for receiving a response from an MA organization about the authorization of a patient transfer.
- Information pertaining to industry guidelines that are used to inform prior authorization, including the extent to which such guidelines are evidence-based, the degree of transparency that exists for such guidelines, and the extent to which such guidelines are standardized.
- With respect to MA organizations, the denial rates and associated burden, including rates at which denials are upheld and overturned, for prior authorizations for patient transfer from hospitals to post-acute care facilities.
- Any consequences of delayed patient transfer from hospitals to post-acute care facilities.
- Recommendations for how CMS can accommodate hospital systems that face capacity issues through policy changes in the MA program.
- Examples of any contrast in a state's policies for payers (for example, Medicaid managed care) with respect to prior authorizations for patient transfer that do not pertain to MA organizations, and the effects of such policies on hospitals systems' ability to effectively manage resources.

We request that all respondents provide complete, clear, and concise comments that include, where practicable, data and specific examples.

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 our 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 through 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 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 organization's network, and are uploaded to the Health Plan Management System (HPMS) for an automated review. MA plans must have sufficient providers with 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 includes in its network telehealth providers for certain specialties. However, despite requiring a minimum number of behavioral health providers and encouraging use of telehealth providers, CMS understands that MA organizations may experience difficulties when building an adequate network of behavioral health providers.

In order to increase our understanding of issues related to access to behavioral health specialties for enrollees in MA plans, we are interested in comments from industry stakeholders related to the challenges MA organizations face when building an adequate network of behavioral health providers for MA plans. Therefore, we invite comment from interested stakeholders regarding these issues. Comments for this RFI can include, but are not limited to:

- 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 health plans, including wait times for appointments;
- The extent to which a behavioral health network affects a beneficiary's decision to enroll in an MA health plan;
- Challenges for behavioral health providers to establish contracts with MA health 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 health plans, including in rural areas that may have provider shortages;

- Suggestions from industry stakeholders on how to address issues with building adequate behavioral health networks within MA health plans.

C. Request for Comment on Data Notification Requirements for Coordination-Only D–SNPs (§ 422.107(d))

Section 50311(b) of the BBA of 2018 amended section 1859(f) of the Act by creating a new paragraph (8)(D)(i)(I) to require that the Secretary establish additional integration requirements for D–SNPs' contracts with State Medicaid agencies. In the April 2019 final rule, we implemented section 1859(f)(8)(D)(i)(I) of the Act by establishing at § 422.107(d) that any D–SNP that is not a FIDE SNP or HIDE SNP is subject to an additional contracting requirement effective January 1, 2021. Under this new requirement for the contract that is required between the D–SNP and the State Medicaid agency, 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 few months, all of which coincided with the COVID–19 public health emergency. Through this proposed rule we invite 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.

D. Collection of Information Requirements

This proposed rule contains several requests for information. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

We note that these RFIs are issued solely for information and planning purposes; they do not constitute a Request for Proposals (RFPs), applications, proposal abstracts, or quotations. These RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through these RFIs and will not accept unsolicited proposals. Respondents are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party's expense. We note that not responding to these RFIs does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential respondents to monitor these RFI announcements for additional information pertaining to these requests. In addition, we note that we will not respond to questions about the policy issues raised in these RFIs.

We will actively consider all input as we develop future plans and policies. We may or may not choose to contact individual respondents. Such communications would be for the sole purpose of clarifying statements in the respondents' written responses. Contractor support personnel may be used to review responses to these RFIs. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of these RFIs may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. These RFIs should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, we may publicly post the public comments received, or a summary of those public comments.

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 OMB's implementing regulations.

In order 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements.

A. Wage Data

To derive mean costs, we are using data from the most current U.S. Bureau of Labor Statistics' (BLS's) National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/current/oes_nat.htm*), which, at the time of drafting of this rule, provides May 2020 wages. In this regard, Table 4 presents BLS' 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 4—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	13–1198	40.53	40.53	81.06
Compliance Officers	13–1041	36.35	36.35	72.70
Computer and Information Systems Managers	11–3021	77.76	77.76	155.52

TABLE 4—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES—Continued

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Lawyer	23–1011	71.59	71.59	143.18
Software and Web Developers	15–1250	52.86	52.86	105.72

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.

B. Proposed Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within section II. of this proposed rule.

1. ICRs Regarding Enrollee Participation in Plan Governance (§ 422.107)

The proposed requirement and burden for D–SNPs to create one or more enrollee advisory committees will be submitted to OMB for review under control number 0938–TBD (CMS–10799). At this time, the control number has yet to be determined, but it will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request.

The proposed requirement and burden for D–SNPs to update audit protocols to require documentation of the enrollee advisory committees will be submitted to OMB for review under control number 0938–1395 (CMS–10717).

a. Creating One or More Enrollee Advisory Committees

At § 422.107(f), we propose 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 propose 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 proposed requirements. We believe that D–SNPs should work with enrollees and their representatives to establish the most effective and efficient process for enrollee engagement, and therefore, we chose not to propose the specific: (1) Frequency; (2) location; (3) format; (4) participant recruiting and training methods; (5) number of committees (for example, one committee at the State level to serve all of the MA organization's D–SNPs in that State or more than one committee); (6) utilization of existing committees which would meet the requirements of both §§ 438.110 and 422.107(f) (we expect this approach to be used by FIDE and HIDE SNPs); (7) use and adoption of telecommunications technology; and (8) other parameters. Instead, the only requirements proposed in this rule for an MA organization offering one or more D–SNPs in a State would be 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 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 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 proposed 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 requirement codified at § 438.110 for Medicaid managed care plans.

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 proposed enrollee advisory committee, detailed in the opening paragraph of this ICR, we expect the average time and annual cost for a MA organization to establish and hold an enrollee advisory committee meeting 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 requirement that the committee created by MMPs 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 proposed rule. We have used a 40-hour estimate and the services of a business compliance officer to assess burden with the understanding that a wide variety of approaches would probably be used.

Each MA organization offering one or more D–SNPs in a State would 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 this wide variability, we

solicit stakeholder comments on our assumptions and burden estimates.

For purposes of this proposed rule for establishing an enrollee advisory committee, we are estimating each MA organization would spend 40 hours at a cost of $3,242 (40 hr × $81.06/hr for a business operation specialist).

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. Of the 596 D–SNP PBPs for CY 2021, we estimate 478 do not have a corresponding Medicaid managed care plan that provides LTSS. Several of these 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 proposed requirement. Therefore, we estimate MA organizations operating D–SNPs will need to establish 260 new enrollee advisory committees.

Thus, the aggregate minimal annual burden for MA organizations operating D–SNPs to meet the proposed requirements of § 422.107(f) is 10,400 hours (260 new committees × 40 hr per committee) at a cost of $843,024 (10,400 hr × $81.06/hr). As stated above, the proposed requirement and burden will be submitted to OMB for review under control number 0938–TBD (CMS–10799).

b. Updates to Audit Protocols

As noted in section II.A.3. of this proposed rule, we anticipate updating the CMS SNP Care Coordination audit protocols [142] 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. Currently, control number 0938–1395 (CMS–10717) estimates the audit protocol and data request burden at 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). We believe MA organizations offering D–SNPs would retain a committee member list and meeting minutes as part of customary business practices; therefore, we do not believe reporting this documentation on the enrollee advisory committee would impact our currently approved 701 hr audit protocol estimate.

While we do not anticipate any changes to our active time estimates, if this proposal is finalized we would revise the SNP Care Coordination audit protocol prior to the effective date of the rule to provide stakeholders the ability to comment on the contents of the document. The CMS–10717 package would 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.

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

The following proposed HRA question changes will be submitted to OMB for review under control number 0938–TBD (CMS–10799). At this time, the control number has yet to be determined, but it will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request.

The proposed changes to our SNP audit protocols will be submitted to OMB for review under control number 0938–1395 (CMS–10717). Subject to renewal, the control number is currently set to expire on May 31, 2024. It was last approved on May 8, 2021, and remains active.

a. Added HRA Questions

As described in section II.A.4. of this proposed rule, we propose requiring that SNPs include specific questions on housing stability, food security, and access to transportation specified in sub-regulatory guidance as part of their HRAs. This proposal, if finalized, would result in SNPs having a more complete picture of the risk factors that may inhibit beneficiaries from accessing care and achieving optimal health outcomes and independence. We do not believe that collecting this information would 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 that many SNPs are already including questions related to housing stability, food security, and access to transportation in their HRA tools. Therefore, if this proposal is adopted, most SNPs would revise their HRA tools to use our standardized questions. 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. By standardizing HRA questions in our proposed rule, CMS would be able to collect those specific data elements; however, CMS will not be collecting data elements from the HRA as part of this collection of information.

We estimate a one-time burden (over the next three years) for the parent organizations offering SNPs to update their HRA tools in their care management systems and adopt our standardized questions on housing stability, food security, and access to transportation. It is possible that we would change the standardized questions in the future, thereby making the burden of our proposal more than a one-time burden. However, we have no plans at this point to change the standardized questions once we establish them. Therefore, we are unable to reliably estimate the additional burden in subsequent years.

We assume that each parent organization with one or more SNPs would update the care management system where an enrollee's HRA responses are recorded. We believe that it would take a software programmer 3 hours at $105.72/hr to update the care management system resulting in a cost of $317 (3hr × $105.72/hr) per parent organization. For CY 2021, there are 123 parent organizations with a SNP PBP. In aggregate, we estimate a one-time burden for updating the HRA tool of 369 hr (123 parent organizations × 3 hr) at a cost of $39,011 (369 hr × $105.72/hr). After the finalization and implementation of our proposed rule, we will reassess the impact of future updates to these HRA questions. As stated above, the proposed requirements and burden will be submitted to OMB for review under control number 0938–TBD (CMS–10799).

b. Updates to Audit Protocols

The proposed change to the HRA would also require an update to the CMS SNP Care Coordination audit protocols [143] that ensure the completed HRA includes the assessment of housing stability, food security, and access to transportation. Currently, audit protocol and data request burden are estimated at 701 hours per MA organization at an average hourly cost of $84.00/hr, totaling $58,884 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

[142] See *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.*

[143] See *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.*

we are adding a confirmation that the SNP's HRA includes the proposed changes as part of the SNP Care Coordination Audit protocols.

While we do not anticipate any changes to our active time estimates, if this proposal is finalized, we would revise the audit protocol documents prior to the effective date of the rule to provide stakeholders the ability to comment on the contents of the document. The CMS–10717 package would 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.

As stated in section II.A.4. of this proposed rule, CMS will consider collecting data from the SNPs on responses to the specified HRA questions. However, we are not proposing such requirements at this time. We welcome comment on our assumptions regarding the collection of information burden for this proposal.

3. ICRs Related to Refining Definitions for Fully Integrated and Highly Integrated D–SNPs (§ 422.2)

The following proposed changes will be submitted to OMB for review under control number 0938–TBD2 (CMS–10796). At this time, the control number has yet to be determined, but it will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request.

As described in section II.A.5. of this proposed rule, we propose 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 proposal for the FIDE SNP definition requires these plans to have exclusively aligned enrollment, cover Medicare cost-sharing, and cover the Medicaid benefits of home health, DME, and behavioral health through a capitated contract with the State Medicaid agency. We propose to 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 also propose to codify 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 proposed changes in the definition of FIDE SNP and HIDE SNP, a D–SNP may need to update its contract with the State Medicaid agency to come into compliance with the proposed changes at § 422.2. 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 proposed 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 proposed changes to these definitions at § 422.2 would impact our currently approved annual 30 hr contracting burden estimate for D–SNPs.

The proposed 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, if proposed changes to the FIDE and HIDE definitions are finalized, then we would update the content of the collection of information to reflect the changes to § 422.2. If this proposal is finalized, we would revise 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–TBD2 (CMS–10796). We believe including these forms in a separate OMB control number 0938–TBD2 (CMS–10796) exclusively for the D–SNP State Medicaid agency contracts is more operationally consistent with the collection of information required from MA organizations.

a. Service Area Overlap Between HIDE SNPs and Companion Medicaid Plans

Besides the updates to the documents currently under control number 0938–0935 (CMS–10237) described in this section, section II.A.5.f. of this proposed rule would require the service area of a FIDE SNP or HIDE SNP to overlap with companion Medicaid plans; therefore, the 20 HIDE SNPs that have service area gaps with their affiliated 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 20 impacted D–SNPs, or 7 D–SNPs, would choose to remain a HIDE SNP. The remaining 13 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.

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 20 D–SNPs impacted by the proposed the opportunity to expand the service area of the companion Medicaid plan in CY2025.

In section II.A.5.f. of this proposed rule, we discuss alternatives to the proposed changes to the FIDE SNP and HIDE SNP definitions regarding service area overlap with the companion Medicaid plan. For example, we are considering requiring a minimum level of service area overlap for the FIDE SNP or HIDE SNP and the companion Medicaid plans rather than full overlap. We request comment on how these alternatives may change the estimates for impacted D–SNPs if they were finalized.

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

As described in section II.A.6. of this proposed rule, we propose to add a 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. Proposed 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 the proposed requirements and associated burden follows:

a. State Medicaid Agency Contract Requirements

The following proposed changes will be submitted to OMB for review under control number 0938–TBD2 (CMS–10796). At this time, the control number has yet to be determined, but it will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request.

For States that opt to require the contract requirements at proposed § 422.107(e), States and plans would be required to modify the existing State Medicaid agency contract. These modifications would 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

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, half of which the States incur and half of which the Federal government incurs, associated with administering the Medicaid program. 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 would take a total of 24 hours at $143.18/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 proposed rule. This estimate includes the cost to negotiate with the D–SNPs on contract changes and engage with CMS to ensure contract changes meet the proposed requirements 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 after the effective date (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 the first 3 years. We further expect these 12 States to implement this one-time change during the first year it is effective.

Section 1903(a)(7) of the Act requires the Federal government to pay half the States' administrative costs. Therefore, for purposes of the COI we interpret that the states will incur costs for only 12 hours (0.5 × 24 hours); the other 12 hours of work are paid for by the Federal government and therefore we account for these other 12 hours in the RIA. This division of the 24 hours into two 12-hour parts is also consistent with COI requirements that aggregate amounts reflect hour and wage/hr burden. Thus, the cost to each State would be $1,718 per State (1 State × 12 hr × $143.18/hr). The aggregate burden to 12 States would be 144 hours (12 States × 12 hours/State) at an aggregate one-time cost of $20,618 (144 hr × $143.18/hr). 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 on States.

As mentioned previously, the other half of the burden will be presented in the RIA.

(2) MA Organization Burden

For the initial year, we expect each affected D–SNP would take 8 hours at $143.18/hr for a lawyer to update the contract with the State Medicaid agency to reflect the revised and new provisions proposed in this rule at § 422.107(e). Based on our assumptions of States likely to opt to require the proposed contract changes, we estimate between 40 to 80 MA organizations would be impacted in the first three years. Since we are uncertain of which extreme to use, we use the average, 60 MA organizations per year. We further expect the updates to be done in the first year these regulations are effective. In aggregate we estimate a one-time burden of 480 hours (60 MA organizations × 8 hr) at a cost of $68,726 (480 hr × $143.18/hr).

b. Limiting Certain Medicare Advantage Contracts to D–SNPs

The following proposed changes regarding additional Part C application respondents will be submitted to OMB for review under control number 0938–0935 (CMS–10237). Subject to renewal, the control number is currently set to expire on January 31, 2024. It was last approved on January 19, 2021 and remains active.

The following proposed changes regarding additional Part D application respondents will be submitted for OMB approval under control number 0938–0936 (CMS–10137). Subject to renewal, the control number is currently set to expire on July 31, 2024. It was last approved on July 27, 2021 and remains active.

We propose at § 422.107(e) to codify a pathway by which States would 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 would 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 would 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.

Our estimate is that 60 D–SNPs will be impacted by our proposed changes to § 422.107(e). Currently, 32 percent of D–SNPs are in D–SNP-only contracts; [144] 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 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 $72.70/hr for a compliance officer to review instructions and complete the proposal (including

[144] HPMS, Contract Management Reports 2020, SNP Type and Subtype Report, August 7, 2020.

submission) at a cost of $727 per contract (10 hr × $72.70/hr). Under this proposed rule, the currently approved burden for one-time Part C applications would increase by 410 hours (10 hr × 41 D–SNPs) and $29,807 (410 hr × $72.70/hr).

The burden 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 proposal (including submission) at a cost of $466 per contract (6.41 hr × $72.70/hr). The aggregate one-time burden for 41 D–SNPs to complete an initial Part D application for an MA–PD plan is 263 hours (6.41 hr × 41 affected D–SNPs) at a cost of $19,120 (263 hr × 72.70/hr).

We acknowledge 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 request comments on these impacts for a new contract under an already existing MA organization and if they should be included in our estimates.

c. Integrated Member Materials

As described in section II.A.6.b. of this proposed rule, to provide a more coordinated beneficiary experience, we propose at § 422.107(e) to codify 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. Proposed § 422.107(e)(1)(ii) 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 proposed § 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.a. of this preamble.

5. ICRs Related to Definition of Applicable Integrated Plan Subject to Unified Appeals and Grievances Procedures (§ 422.561)

The following proposed changes would be submitted to OMB for review under control number 0938–TBD2 (CMS–10796). At this time, the control number has yet to be determined, but it will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request. In § 422.561, we propose to expand 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 are also amenable to the unified grievance and appeals processes.

If finalized, additional D–SNPs would be implementing the unified grievance and appeals procedures under §§ 422.629 through 422.634. We anticipate that the D–SNPs impacted by this rule would be D–SNPs in California with exclusively aligned enrollment, including those plans receiving Cal MediConnect members at the end of the California capitated FAI demonstration.

Consistent with our currently approved burden estimates, we continue to 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 would take a business operation specialist 8 hours at $81.06/hr. In aggregate, we estimate a one-time burden of 104 hours (8 hr × 13 D–SNPs) at a cost of $8,430 (104 hr × $81.06/hr).

While new D–SNPs would use the CMS–10716 denial notice at 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's proposal. As indicated above, the rule's proposed changes will be submitted to OMB under control number 0938– TBD2 (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 would be a new requirement for the impacted D–SNPs, we note that the timeframe for sending 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.

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 proposed rule, we are proposing a revision to which costs accumulate toward the MOOP limit 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. CMS proposes 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, the MA plan must 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 proposal does not add additional requirements or burden.

This proposal would 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 believe there is additional material burden resulting to plans that would arise from the proposed changes. As such, non-PRA related burden can be found in section V.D.4 of this preamble.

7. ICRs Related to Network Adequacy (§ 422.116(a)(i)(ii) and (d)(7))

The following proposed changes, although carrying no burden, will be submitted to OMB for review under control number 0938–1346 (CMS–10636).

In this rule we propose to require compliance with CMS' network adequacy standards for initial and service area expansion (SAE) applicants as part of the MA application process. Therefore, our proposal would 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.

8. ICRs Related to the Disclaimer for Preferred Pharmacy (§ 423.2267(e)(40))

The following proposed 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 would be 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 would 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 would be codified in this proposed regulation. 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.

9. ICRs Related to Member Identification Cards (§§ 422.2267(e)(30) and 423.2267(e)(32))

The following proposed changes carry no burden. Although subject to PRA, Member Identification Cards are exempt 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 enrollees insurance. Based on the exemption we will not be submitting this to OMB for review.

This proposal 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 subregulatory 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 would 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 subregulatory guidance and therefore no further burden is imposed by codifying these standards in regulation.

10. ICRs Related to the Creation of a One-Page Multilanguage Insert (§§ 422.2267(e)(31) and 423.2267(e)(33))

The following proposed changes would be submitted to OMB for review under control number 0938–TBD2 (CMS–10802). At this time, the control number has yet to be determined, but it will be assigned by OMB upon their clearance of this proposed rule's collection of information request. OMB will set out an expiration date upon their approval of the final rule's collection of information request. This provision requires 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' 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 are proposing to require that MA plans and Part D plan sponsors provide the one-page document.

In estimating the burden of this one-page 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 a template that will be provided by CMS 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 those beneficiaries who request a paper copy, the proposed regulations require sending it 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 proposed 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.[145]

Of these 52 million beneficiaries we estimate that two fifths or 20,800,000 beneficiaries (52 million beneficiaries × 0.40) will request paper copies.

It follows that the aggregate cost of providing one extra sheet of paper is

[145] *https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldatamonthly/contract-summary-2021-09.*

$312,000 (20,800,000 enrollees × $0.015/sheet).

There is no labor cost. Had we assumed that each extra sheet will incur postage costs we would have to add about $43,333 (52 million enrollees × 2/5 requesting paper copies × 1/6 once per sheet × 1/16 ounces per pound × $0.20/pound). However, it is not clear the extent to which every sheet will bear a cost. We solicit 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.

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))

The following proposed disclaimer changes carry no burden submitted to OMB for review. Sections 422.2260, 422.2267(e)(41), 422.2274(g), 423.2260, 423.2267(e)(41), and 423.2275(g) would require MA organizations and Part D sponsors to insert CMS standard disclaimer on materials created by Third Party Marketing Organizations and would require MA organizations and Part D sponsor update training materials. The burden associated with this requirement would be the time and effort to copy the disclaimer on marketing materials 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 would be incurred by persons in the normal course of their activities and therefore considered to be usual and customary business practice.

The major cost associated with these requirements is the burden of updating policies and training. We note that many TPMOs such as field marketing organizations (FMOs), or other companies that a plan uses for marketing, lead generation, and enrollment functions already perform similar training in order to ensure compliance with their FDR requirements.

We estimate that it would take a business operation specialist 2 hours at $81.06/hr for a one-time update of procedures and training at a cost of $162 ($81.06/hr × 2 hr) per contract. In aggregate the one-time burden for 961 current contracts is 1,922 hours (2 hr × 961 contracts) at a cost of $155,797 (1,922 hr × $81.06/hr).

The major update is procedures and training. The burden of adding just one itm to the required disclosures is not being estimated since it is part of the normal varying disclosures done and as such is exempt from the PRA (5 CFR 1320.3(b)(2)).

12. ICRs Related to the Medicare MLR Reporting Requirements (§§ 422.2460 and 423.2460)

The proposed changes to the Medicare MLR Reporting Requirements will be submitted to OMB for review under control number 0938–1232 (CMS–10476).

In section II.G.2. of this proposed 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 proposed 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.

Our analysis of the estimated administrative burden related to the MLR reporting 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.

Another amount used in our calculations is the total number of hours spent on administrative work related to the Medicare MLR requirements that applied with respect to MLR reporting for contract years CY 2014 through CY 2017. In the information collection request that was previously approved by OMB under 0938–1232 (CMS–10476), CMS estimated that, on average, MA organizations and Part D sponsors would spend 47 hours per contract on administrative work related to Medicare MLR reporting, including: Collecting data, populating the MLR reporting forms, conducting internal review, submitting the reports to the Secretary, and conducting internal audits. This 47-hour figure was also used 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 16701), which appeared in the **Federal Register** on April 16, 2018 (hereinafter referred to as the April 2018 final rule), and revised the MLR reporting requirements that apply with respect to MLR reporting for CY 2018 and subsequent contract years, and it will be used in this proposed rule.

In calculating burden, we contrast the proposed requirements with those in the April 2018 final rule, which revised the MLR reporting requirements for all MA and Part D contracts, and the June 2020 final rule (84 FR 33796, 33850), which added a deductible-based adjustment to the MLR calculation for MA medical savings account (MSA) contracts. In reviewing the April 2018 final rule, we identified an overestimation in the calculations.

To explain the overestimation and to account for it in our burden calculation for this proposed rule, we present three tables: One table for the estimates of hourly burden per contract included in the April 2018 final rule, which established the current MLR reporting requirements (Table 5); a second table for our revised estimates of hourly burden in the April 2018 final rule (Table 6); and a third table for our estimates of the hourly burden of the proposed changes to the MLR reporting requirements. Having the calculated hourly burden per contract, we can then estimate dollar burden per contract and also aggregate hourly and dollar burden per contract.

We believe that presenting these 3 tables will aid the reader in navigating a set of calculations that are complicated by (1) the contrast between the burden estimate for the current MLR reporting requirements, as published in the April 2018 final rule, and our revised burden estimate for the current reporting requirements, which we provide here, and (2) the contrast between our revised burden estimate for the current reporting requirements and our burden estimate for the proposed reporting requirements. To provide further clarity, we number each row in the tables with a row ID so that appropriate narrative can be tied to overall calculation. For this reason, we initially focus on hourly burden. Once the hourly burden of this proposed rule is established, we calculate the per

contract and aggregate hourly and dollar burden.

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.

The calculations for hourly burden per contract that were included in the April 2018 final are summarized in Table 5.

TABLE 5: 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 5:

Row(1): The 47-hour figure, as explained in the opening paragraphs of this ICR, is CMS' estimate for the total amount of time MA organizations and Part D sponsors would spend per contract on administrative work related to 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 5.

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 2018 and 2020 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).

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 5), 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 CY (for CYs 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 estimate 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.

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 on administrative work under the MLR reporting requirements in effect for CYs 2014 through 2017 (Row (1) in Table 5). 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 5 and Row (7) in Table 6), with the remaining administrative tasks now estimated as taking the other 36.25 hours (47 hours − 10.75 hours). (Row (8) in Table 6). Table 6 presents a revision of Table 5 with the primary change being replacing 11.5 (Row (2) in Table 5) with 10.75 (row (7) in Table 6), with the other rows following by computation. Table 6 also differs from Table 5 is the addition of the per contract burden of calculation of the MSA deductible factor. This is explained in the narrative to Table 6.

TABLE 6: 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 now explain row (10), calculation of the deductible factor. In the June 2020 final rule, CMS estimated that it would take 5 minutes (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 6 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 (1/12 hour per contract × 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. This burden is eliminated under the current proposal because the software tool that will be used to report the detailed MLR data that CMS proposes will now calculate and apply the deductible factor, making it unnecessary for MA organizations to perform this calculation. The sole purpose of discussing this burden here is to illustrate the flow of logic in determining hourly burden as written in the previous rules.

This proposed rule introduces three items affecting per contract hourly burden. First, as noted in section II.G.3. of this proposed rule, if the proposed changes to the MLR reporting requirements are finalized, CMS expects 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 CY 2017. In making these updates, CMS would revise 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 would be eliminated.

Second, as discussed in section II.G.2. of this proposed rule, CMS proposes to reinstate the detailed MLR reporting requirements in effect for CYs 2014 through 2017.

Third, we propose to require that MA organizations provide more detailed information on the portion of the incurred claims component of the MLR numerator that represents expenditures for supplemental benefits. As discussed

in section II.G.3. of this proposed rule, to collect this information, we intend to add 18 additional fields to the MLR Report template in which MA organizations would enter their total expenditures for different types or categories of supplemental benefits. We also anticipate adding narrative fields in which users would 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 would 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, would increase the number of fields that would 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 administrative work 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.

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% × 33% + 11% × 5%). The computations are presented in Table 7. As previously indicated, 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.

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TABLE 7: 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 8: BURDEN (AGGREGATE and PER CONTRACT)

Row ID	Item	Burden	Notes
(15)	Total administrative burden (hr) per contract	47	(6)
(16)	Revised (2018 rule) burden (hr) per contract for then current form	10.75	(7)
(17)	Admin burden (hr) per contract for non-form items	36.25	(17)=(8) or (17)=(15)-(16)
(18)	Per contract burden for return to 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 hourly burden (hr) for return to form used for CYs 2014-2017 and removal of calculation of MSA deductible factor	47	(20)=(17)+(18)
(21)	Per contract burden (hr) for proposed form with new fields, this proposed rule	61.1	(21)=(20)+(14)*(20)
(22)	Current per contract burden (hr)	36.75055	(22) = (11)
(23)	Average increase (hours)/contract	24.34945	(23) = (21) - (22)
(24)	Wage/hr	$155.52	Wage Table
(25)	Per contract burden ($) for proposed form, this rule, with new fields	$3,787	(25)=(24)*(23)
(26)	Number of current contracts affected by MLR provisions	601	Estimate explained in opening paragraph of this ICR
(27)	Aggregate burden (hr), all contracts, with new fields, this rule	14,634	(27)=(26)*(23)
(28)	Aggregate burden ($), all contracts, with new fields, this rule	$2,275,880	(28)=(27)*(24)

Table 8 incorporates these three proposed 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 hourly burden per contract, and then calculates dollar burden per contract as well as aggregate burden (hourly and dollar) for all contracts. The rows of Table 8 are explained in the narrative following the table. The following presents explanations of the rows in Table 8.

- *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 proposed 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 proposal 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 CY 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 current proposal, 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 percent × 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 burden (hours) due to the proposed regulation of 24.34945 is obtained by subtracting from the total burden under the proposed regulation of 61.1 hours on Row (21) the current burden of 36.75055 hours on Row (22).
- *Row (24):* The $155.52/hr wage is obtained from the wage table.
- *Row (25):* The increased contract burden ($) $3,787 on Row (25) is obtained by multiplying the average increase in burden (hours) of 24.34945 on Row (23) by the wages per hour ($155.52) on Row (24).

- *Row (26):* The total number of contracts is presented in the opening paragraphs of this ICR.
- *Row (27)*: The aggregate increase in burden (hours) across all contracts of 14,634 is obtained by multiplying the 601 contracts (Row (26)) by the per contract increase in burden (hours) of 24.34945 on Row (23).
- *Row (28):* The aggregate increase in burden ($) across all contracts, $2,275,880, is obtained by multiplying the increase in burden (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 9 summarizes the relevant calculations in traditional COI format as one combined line item.

TABLE 9: 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	155.52	2,275,880

The average burden per contract as given on Row (25) of Table 8 is $3,787. 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 $4,032. 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 hours × 1.33 due to increased fields). Comparing the 62.67 total burden under the proposed MLR reporting requirement with the 36.75 hours under the current reporting requirements shows an increase in burden of 25.92 hours (62.67 − 36.75) at a cost of $4,031 (25.92 hours × $155.52/hr).

For Part D contracts, we estimate 12.6 additional hours of burden at an additional cost of $1,960. 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 hours + 47 hours × 5 percent). Thus, there is an additional hour burden of 12.6 hours (49.35 hours − 36.75 hours) at an additional cost of $1,960 (12.6 hours × $155.52/hr) per contract.

ICRs Related to Pharmacy Price Concessions in the Part D Negotiated Price (§ 423.100)

The proposed requirement and burden for Part D Sponsors to implement provisions related to pharmacy price concessions, discussed below, will be submitted to OMB for review under control number 0938–0982 (CMS–10174), as needed.

This provision would require that Part D sponsors apply all pharmacy price concessions to the point of sale price in all phases of the Part D benefit excluding for applicable drugs dispensed to applicable beneficiaries in the coverage gap. Under this proposal, beneficiaries would see lower prices at the pharmacy point-of-sale and on Plan Finder, beginning immediately in the year the policy would take effect, 2023. We anticipate that this proposed change would require Part D sponsors to make certain system changes related to the calculation of the amounts they report in one or two fields in the PDE data collection form. We anticipate that this would cause sponsors to incur one-time administrative costs.

To estimate the administrative costs associated with submission of PDE data, we consider the following factors: (1) The number of plan sponsors (or sponsors' intermediaries) submitting data; (2) the amount of data that must be submitted; and (3) the time required to complete the data processing and transmission transactions. This information is summarized in Table 10. Throughout the narrative, the row references refer to this Table.

Number of Part D Contracts (Respondents): The average number of Part D contracts per year (Row (B)) is 856 (based on 2019–2021 internal CMS data).

PDE Data Submission: 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 (D), 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 1,752,336.45 PDEs/contract (Row (D)) (1.5 billion divided by 856). A similar computation shows that the average number of PDEs per Part D enrollee is 30.5 (1.5 billion

PDE (Row (C)) divided by 49,229,626 enrollees (as of November 2021) (Row (A)).

Time Required to Process Data: The third factor that contributes to the burden estimate for submitting PDE data depends upon the time and effort necessary to complete data transaction activities. 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 $35.50/hr (for 2020) to process PDEs (Row E).

Using these numbers, we can compute individual contract and aggregate burden.

It would take 3.5 hours (Row G) on average for each respondent (contract) to process its 1,752,336.45 PDEs at a rate of 500,000 per hour (1,752,336.45 PDEs per contract (Row D) divided by 500,000/hr (Row (F)). The aggregate hours to process all 1.5 billion claims is therefore 2,996 hours (Row H) (3.5 hours/contract Row (G) × 856 contracts (Row (B)).

The average cost per contract (Row (I)) is $124.25 (3.5 hours (Row G) × $35.50/hr (Row E)). The aggregate one-time cost for all contracts is $106,358 (Row J), which can be obtained either by multiplying total hours (2,996 (Row (H)) by total contracts (856 (Row (B)) or by multiplying the cost per contract ($124.25 (Row I)) by the number of contracts (856 (Row B)).

TABLE 10: ESTIMATED ADMINISTRATIVE COSTS RELATED TO SUBMISSION OF PRESCRIPTION DRUG EVENT (PDE) DATA

Row ID	Item	Estimate	Source/Derivation	Description
A		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	1,752,336.45	(C) / (B)	Average PDEs per contract
E	Wage per hour (Non labor)	$35.50/hr	Drug industry's estimated cost/hr of electronic processing	Cost/hr of processing PDEs electronically
F		500,000	Drug industry's estimated average processing volume per hour	Number of Electronic PDEs processed per hour
G	Hours/respondent	3.5	(D) / (F)	Number of hours needed to process one contract's PDEs
H	Aggregate hours	2,996	(G) x (B)	Total hours to process all contracts
I	Cost per respondent	$124.25	(G) x (E)	Cost per contract to process PDEs
J	Total cost all contracts	106,358	Either (H) x (E) or (I) x (B)	Total cost for all contracts

C. Summary of Proposed Information Collection Requirements and Associated Burden Estimates

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TABLE 11. SUMMARY OF ANNUAL INFORMATIO COLLECTION REQUIREMENTS AND BURDEN

Regulation Section in Part 42 of the CFR	Item	OMB Control No. (CMS ID No.)	Respondent	Number of Respondents	Responses per Respondent	Total Responses	Time per Response (hours)	Total Time (hours)	Hourly Labor Cost of Reporting ($)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
422.107(f)	Solicit committee members	0938-INSERT (CMS-10799)	D SNPS	260	1	260	40	10,400	81.06	843,024	843,204
422.101	Update HRA System	0938-INSERT (CMS-10799)	SNP Parent Organizations	123	1	123	3	369	105.72	39,011	0
422.107(e)	Update Contracts with D-SNPs	0938-INSERT (CMS-10796)	State	12	1	12	12*	144	143.18	20,618*	0
422.107(e)	Update Contracts	0938-0935	D SNPS	60	1	60	8	480	143.18	68,726	0
422.107(e)(1)	Part C Contracts with only D SNPS	0938–0935	D SNPS	41	1	41	10	410	72.7	29,807	0
422.107(e)(1)	Part D Contracts with only D SNPS	0938–0936	D SNPS	41	1	41	6.41	263	72.7	19,120	0
422.561	Update Contracts	0938-INSERT (CMS-10796)	D SNPS	13	1	13	8	104	81.06	8,430	0
422.2267(e)(31) and 423.2267(e)(33))	1 pager multi-lanaguage insert	0938-INSERT	MA Plans and Part D Sponsors	961	21,644	20,800,000	0	0	0.015	312,000	312,000
422.2274(g) and 423.2274(g)	Update policies on 3rd party marketing	0938-INSERT	MA Plans	961	1	961	2	1,922	81.06	155,797	0
422.2460 and 423.2460	MLR	0938-1232	MA and Part D Contracts	601	1	601	24.34945	14,634	155.52	2,275,880	2,275,880
423.100	Part D Pharmacy Price Concessions	0938-0982	Part D Sponsors	856	1,752,336	1,500,000,000	3.5	2,996	35.5	106,358	106,358
	Totals			1,096		*Varies*	*Varies*	31,722	*Varies*	3,878,771	3,537,442

NOTES:

*For States, burdens, reflect 50 percent reduction to Federal Matching program (hours are halved)

**Includes MA only, MA PD, and PDP plans.

D. Submission of Comments

We have submitted a copy of this rule to OMB for its review of the rule's proposed information collection requirements and burden. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, please visit CMS's website at *https://www.cms.gov/Regulations andGuidance/Legislation/Paperwork ReductionActof1995/PRAListing.html,* or call the Reports Clearance Office at (410) 786–1326.

We invite public comments on the proposed information collection requirements and burden. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–4192–P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.

V. Regulatory Impact Statement

A. Statement of Need

This proposed rule would 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 proposed rule would also revise regulations related to MA and Part D plans, D–SNPs, other special needs plans, and cost contract plans. Additional proposed revisions would 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 proposals 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 proposals 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 proposed 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 proposed 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.

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 proposing 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 proposing 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 are proposing to 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). To implement the proposed change at the point-of-sale, Part D sponsors and their PBMs would load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems that interface with contracted pharmacies. This proposed provision would reduce out-of-pocket prescription drug costs, improve price transparency and market competition under the Part D program.

We have proposed to clarify 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 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). 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. While the total annualized costs for this rule are about $3.5 million a year, as indicated in Table 20, the net transfers

from the Trust Fund to enrollees and manufacturers exceed $100 million annually. 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 2021, that threshold is approximately $158 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 proposed 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 proposed rule was reviewed by OMB.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this proposed 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 proposed 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 proposed rule. For each person that reviews this proposed rule, the estimated cost is therefore $900 (8 hours × $114.24). Therefore, we estimate that the maximum total cost of reviewing this entire proposed rule is $2.7 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 proposed 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 proposed rule may have a significant economic impact on a substantial number of small entities, then the proposed 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.[146] 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 11) in section IV.C. of this proposed rule, as well as Table 20 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 $3.5 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 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 proposed 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).

[146] 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%2019%2C%202019.pdf.*

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) 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 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 proposed 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 paying the plan either—(1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from 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 proposed 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 proposed 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 package. 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 these 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 (AIP) definition at § 422.561. At § 422.561, we propose 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. 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. While we are not imposing new Medicaid requirements, the proposed AIP 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 proposed rule on Medicaid managed care plans is the one-time requirement to update their grievance and appeals procedures, which as estimated in Table 11, is a one-time cost of $8,430. Consequently, the Secretary has determined that this proposed rule will not have a significant impact on Medicaid managed care plans.

Therefore, the Secretary has certified that this proposed 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 proposed rule.

3. Rural Hospitals

Section 1102(b) of the Social Security 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 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 proposed 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 proposed rule, at § 422.107(f), we propose 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 propose 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 proposal intends to ensure enrollees are engaged in defining, designing, participating in, and assessing their care systems. Section IV.B.1. presents the collection of information burden for this provision.

To support D–SNPs in establishing enrollee advisory committees that meet the objective of this proposed 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.[147] 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.

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 proposed rule. In this section, we describe the impacts of our proposed 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 proposed 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 proposed 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.[148] 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

Under the proposal to require exclusively aligned enrollment for FIDE SNPs described in section II.A.5.a. of this proposed rule, we note 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 proposed requirement. Therefore, we do not believe the proposal will result in a significant reduction of Medicare payments from FIDE SNPs losing the frailty adjustment.

b. Capitation for Medicare Cost-Sharing for FIDE SNPs

We do not anticipate any cost transfers from the State to FIDE SNPs resulting from the proposals 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. Currently, all 69 FIDE SNPs include coverage of Medicare cost-sharing in their capitated contracts with the State Medicaid agency.[149] As noted in section II.A.5.b. of this proposed 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 under the definition proposed at § 422.2. 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 revenue, as none of the impacted D–SNPs receive the frailty adjustment.

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

As described in section II.A.6. of this proposed rule, we propose a 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. This proposal 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. Proposed paragraph (e)(1) 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.

[147] Resources for Integrated Care and Community Catalyst, ''Member Engagement in Plan Governance Webinar Series'', 2019. Retrieved from: *https://www.resourcesforintegratedcare.com/concepts/member_engagement.*

[148] See the locality pay tables for 2021 at *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2021/general-schedule/.*

[149] CMS Special Needs Plan Comprehensive Report, January 2021. Retrieved from: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data#:~:text=Special%20Needs%20Plan%20%28SNP%29%20Data%20%20%20,%20%202021-03%20%206%20more%20rows%20.*

a. State Medicaid Agency Contract Requirements

Section IV.B.4. of this proposed 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 proposed rule and consult with CMS to ensure contract changes meet the proposed 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 proposed § 422.107(e) would need to determine readiness and make changes to State policy. The State's time and cost for adopting this proposed rule would depend on the State's current level of integration. For example, 11 States currently have a policy for 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 proposed 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 request comment on what State resources are needed to use the pathway for requiring or achieving higher integration and collaboration with CMS as described in proposed § 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

We propose at § 422.107(e) to codify 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 proposed 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.

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 proposed rule, to provide a more coordinated beneficiary experience, we propose at § 422.107(e) to codify 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. Proposed § 422.107(e)(1) establishes factual circumstances that would commit CMS to certain actions under paragraphs (e)(2) and (3).

In section IV.B.4.c. of this proposed rule, we note that we do not intend through this proposal 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 as proposed 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. Our proposal, if finalized, would simply assure interested States that, under the conditions of proposed paragraph (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. Further, States already 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. Therefore, we do not estimate any additional burden for States or plans to implement integrated member materials as proposed 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 beneficiary materials. 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 proposed § 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 proposal on integrating member materials is $118,500.

d. Joint State/CMS Oversight

In section II.A.6.c. of this proposed rule, we discuss our proposals at § 422.107(e)(3) to better coordinate State and CMS monitoring and oversight of D–SNPs that operate under the conditions described at proposed 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 proposed § 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 propose 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 proposal would 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 would 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.

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

As described in section II.A.12. of this proposed rule, CMS proposes a revision to which costs are tracked and accumulate toward the MOOP limit for dually eligible enrollees in MA plans under § 422.101 for MA regional plans and § 422.100(f)(4) and (5) for all other MA plans. Our proposal would 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 proposal 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. However, in the short term, as we note above, MA organizations may prefer to reduce their profit margins, rather than substantially raise their bids and thereby reduce the rebate dollars available for supplemental benefits.

Specifically, CMS proposes 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 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 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, 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 would 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 would 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 proposed 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. As a result, the proposal 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 proposal would 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 proposal 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 proposal, we started with CY2022 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 proposal 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 12.

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 proposed policy 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 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 proposed changes would 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 proposal 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 proposal 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 12.

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 12. The total Federal costs of the proposal, net of Federal Medicaid savings and the Part B premium offset are shown in column 7 of Table 12.

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.

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TABLE 12: 10-YEAR AGGREGATE PROJECTED COSTS (MILLIONS $) FROM PROPOSED 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.

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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.

5. Special Requirements During a Disaster or Emergency (§ 422.100(m))

We are not scoring the proposed 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 proposed revisions clarify our current policy. More detailed arguments for not scoring are presented below after a discussion of the proposal.

Our proposed 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 inquiries. 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 disruption of access proposal has an impact because it is already complied with.

We also proposed 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 plans have experience with disasters or other changes in cost that arise annually. The nature of the business cycle shows that plans may experience losses due to 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 propose to 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.

- 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. Proposed Revisions to the Medical Loss Ratio Reporting Requirements (§§ 422.2460 and 423.2460)

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, would impose additional costs on the Federal Government.

The paperwork burden associated with these provisions, $2.3 million, is estimated in section IV.B.12. of this proposed rule, and is 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).

If our proposal to reinstate and add to the detailed MLR reporting requirements is finalized, we will 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. In the Regulatory Impact Analysis for the April 2018 final rule in which we 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. This has not been the case, as 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.

We anticipate that, if the proposed detailed MLR reporting requirements are finalized and CMS resumes 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 is 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 is proposing to require MA organizations and Part D sponsors to submit to us on an annual basis, starting with CY 2023.

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. 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 proposed 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 the table below. These 4 years represent the time period when detailed MLR data was submitted to CMS and subjected to desk reviews.

TABLE 13: 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	-----	-----

[1]The 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 proposed 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 proposed regulations, 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 14 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 14: 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

8. Pharmacy Price Concessions in the Part D Negotiated Price (42 CFR 423.100)

As discussed in section II.H.3. of this proposed rule, at § 423.100, we propose 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. As part of this proposal, we first propose to 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. Then, we propose a definition of ''negotiated price'' 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. The proposed requirement to apply pharmacy price concessions to the negotiated price at the point-of-sale would apply in all phases of the Part D benefit except with respect to applicable drugs dispensed to applicable beneficiaries in the coverage gap.

Plan sponsors may attempt to mitigate the effects from this change by modifying their benefits, such as making more frequent use of copay structures rather than coinsurance. There are limits to how much this can change, however, given that they must maintain actuarial equivalence to the defined standard design, where lower prices would result in lower cost sharing.

The proposal would have several impacts on prescription drug costs for government, beneficiaries, Part D sponsors, and manufacturers. Tables 15 and 16 summarize these impacts, which are discussed in more detail in the narrative that follows. We note that this proposal would also have one-time administrative costs for Part D sponsors. This cost is discussed in the Collection of Information section of this proposed rule.

a. Impact on Prescription Drug Costs for Government, Beneficiaries, Part D Sponsors, and Manufacturers

Table 16 summarizes 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 except for applicable drugs in the coverage gap. We estimate a modest potential indirect effect on pharmacy payment as a result of pharmacies' independent business decisions. Specifically, our 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 0.1–0.2 percent of Part D gross drug cost. We solicit comment on the potential indirect impact estimates of the pharmacy price concessions provision included in this rule. Table 16 reflects 10-year row sums of Table 15. For example, the second row of Table 15 lists a $33.1 billion savings to beneficiaries. The row header references row (I) of Table 15. The sum of the numbers in row (I) of Table K4 is $33.1 (1.7+1.9 . . . +5.7 = 33.1). Throughout this narrative, quantitative aspects of the discussion may be found in the corresponding labeled rows of Table 16.

Under this proposal, 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 (2023). (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 proposed change to the definition of negotiated price—if pharmacy price concessions are required to be passed through to beneficiaries at the point of sale as proposed, 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 for the average beneficiary would be large enough to lower their overall out-of-pocket costs. 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.

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 impacts assume that the proposed definition of ''negotiated price'' would apply for all Part D drugs in all phases of the Part D benefit, except for applicable drugs in the coverage gap. While this exclusion would increase the complexity of the point-of-sale transaction, pharmacies and PBMs have experience with similar elements of the program today, such as accounting for the coverage gap discount program. Given the significance of these amounts to overall premiums and their competitive position, we expect that pharmacy price concessions after the point of sale will remain in place during the coverage gap. The alternative section demonstrates how requiring the price concessions in the coverage gap could lead to larger premium increases, which would not be desirable for plan sponsors.

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TABLE 15*: IMPACT (BILLIONS) OF CONCESSIONS EXCLUDES APPLICATION TO APPLICABLE DRUGS IN THE COVERAGE GAP

Label	Item/Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
(A)	Gross Drug 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 16.

TABLE 16*: 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 15 and 16 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.

E. Alternative 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. Proposed 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. Proposed Alternatives Related to Pharmacy Price Concessions in the Part D Negotiated Price (§ 423.100)

As discussed in section II.H.3. of this proposed rule, we propose 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 proposed 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 except with respect to applicable drugs in the coverage gap. In this alternative analysis, we consider the added impact of requiring application of pharmacy price concessions to the negotiated price of applicable drugs in the coverage gap also.

Table 17 shows the increased savings to enrollees. Ten-year total savings to enrollees increase 37 percent from $21.3 billion as indicated in Table 16 to $29.1 billion. As explained in the previous narratives, the total savings to enrollees accounts for both cost-sharing savings and expected premium increases.

TABLE 17. TOTAL IMPACTS TO ENROLLEES FOR 2023 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 (in billions)	$0.0	-$1.6	-$1.7	-$1.8	-$2.2	-$2.5	-$2.9	-$3.3	-$3.8	-$4.3	-$4.9	**-$29.1**	**-$21.3**
Cost-Sharing	$0.0	-$2.4	-$2.6	-$2.8	-$3.3	-$3.8	-$4.4	-$5.1	-$5.8	-$6.6	-$7.5	**-$44.3**	**-$33.1**
Premium	$0.0	$0.8	$0.9	$1.0	$1.1	$1.3	$1.5	$1.8	$2.0	$2.3	$2.6	**$15.2**	**$11.8**

*Negative numbers indicate savings; positive numbers indicate costs. Numbers are in billions of $

Table 18 shows increased savings to pharmaceutical manufacturers if pharmacy price concessions are applied to applicable drugs in the coverage gap. As can be seen, savings to manufacturers increase by 23 percent since as presented in Table 16, the savings are $14.6 billion without application in the coverage gap while with application to applicable drugs in the coverage gap the savings are $17.9 billion.

TABLE 18: TOTAL IMPACTS TO MANUFACTURERS FOR 2023 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 (in billions)	$0.0	-$1.1	-$1.3	-$1.4	-$1.5	-$1.7	-$1.8	-$2.0	-$2.2	-$2.4	-$2.6	-$17.9	-$14.6

*Negative numbers indicate savings; positive numbers indicate costs. Numbers are in billions of dollars ($).

Table 19 shows the impact to the Government. The Federal expenditures increase 27 percent, from the $40.0 billion presented in Table 16 without application in the coverage gap, to $50.7 billion if the pharmacy price concessions are applied to the point-of-sale price of applicable drugs in the coverage gap. As explained in the narrative of section IV.D.8. of this proposed 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 $50.7 billion is a transfer. More specifically, the identical Rx that was formerly paid for by enrollees is now being paid for by the Government.

TABLE 19: TOTAL IMPACTS TO GOVERNMENT FOR 2023 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 (in billions)	$0.0	$2.9	$3.3	$3.5	$4.0	$4.5	$5.1	$5.8	$6.4	$7.2	$8.0	$50.7	$40.00
Direct Payments	$0.0	$6.1	$6.7	$7.2	$8.1	$8.9	$9.9	$10.9	$12.0	$13.2	$14.5	$97.6	$76.70
Reinsurance	$0.0	-$1.7	-$1.9	-$2.1	-$2.1	-$2.1	-$2.0	-$2.0	-$1.9	-$1.8	-$1.7	-$19.3	-$15.80
LI Cost-Sharing	$0.0	-$1.7	-$1.8	-$1.9	-$2.3	-$2.7	-$3.2	-$3.7	-$4.3	-$4.9	-$5.6	-$32.2	-$24.40
LI Premium	$0.0	$0.3	$0.3	$0.3	$0.4	$0.4	$0.5	$0.5	$0.6	$0.7	$0.7	$4.6	$3.50

*Negative numbers indicate savings; positive numbers indicate costs. Numbers are in billions of dollars ($).

F. Accounting Statement and Table

In accordance with OMB Circular A–4, Table 20 depicts an accounting statement summarizing the assessment of the benefits, costs, and transfers associated with this regulatory action.

TABLE 20: ACCOUNTING STATEMENT (MILLIONS OF DOLLARS)

Category	Estimate at 7% (In 2022 Dollars)	Estimate at 3% (In 2022 Dollars)	Years Covered	Affected Stakeholders
Net Annualized Monetized Cost	3.5	3.5	CYs 2023-2032	MA organizations, Part D sponsors, and contractors for the Federal Government
Net transfers from the Medicare Trust Fund	(3790.0)	(3930.1)	CYs 2023-2032	The transfers in this row combine: (i) transfers arising from the pharmacy price concessions provision from the Medicare Trust Fund to plan enrollees and pharmaceutical manufacturers; and (ii) transfers arising from the MOOP provision from the Medicare Trust Fund to States and providers of duals.
Transfers to the United States Treasury	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 20 is based on the summary of costs presented in Tables 21 and 22. Tables 21 and 22 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 5 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 21 and 22). The MLR provision is a savings to the Treasury (the corresponding loss in equal amount to the plans is not shown in the Tables 21 and 22). 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 21 and 22 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 20 reflects annualized transfers to the Treasury and annualized transfers from the Trust Fund for the MOOP and pharmacy price concessions provision but these annualized amounts do not reflect the savings to enrollees and manufacturers. Thus, complete detailed amounts on all provisions may be found in Tables 21 and 22.

TABLE 21: SUMMARY TABLE OF COSTS and TRANSFERS BY PROVISION AND YEAR (MILLIONS OF DOLLARS)

	2023 Cost	2023 Transfers	2024 Cost	2024 Transfers	2025 Cost	2025 Transfers	2026 Cost	2026 Transfers	2027 Cost	2027 Transfers
Total Costs	2.4		2.5		4.8		3.6		3.6	
Total transfers to the United States Treasury		20.3		21.5		22.9		24.4		25.9
Total Transfers from the Medicare Trust Fund		(2,340.0)		(2,543.7)		(2,747.9)		(3,152.3)		(3,656.9)
MOOP		(40.0)		(43.7)		(47.9)		(52.3)		(56.9)
Enrollee Advisory Committee					0.9		0.9		0.9	-
HRA			0.0							
HIDE, FIDE Definition					0.0					
D-SNP contracts					1.0					
Past Performance					0.0					
Unified Appeals/Grievances	0.0									
Third Party Marketing					0.2					
Marketing Multi-lanaguage insert					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 cost to TF		(2,300.00)		(2,500.00)		(2,700.00)		(3,100.00)		(3,600.00)
Rx Savings Enrollees		1,100.0		1,200.0		1,300.0		1,500.0		1,800.0
Rx Savings Manufacturers		900.0		1,000.0		1,100.0		1,200.0		1,400.0

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 reflect savings, and negative numbers reflect costs.

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TABLE 22: SUMMARY TABLE OF COSTS AND TRANSFERS BY PROVISION AND YEAR (MILLIONS OF DOLLARS)

	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	3.6		3.6		3.6		3.6		3.6		32.1
Total transfers to the United States Treasury		27.5		29.1		30.4		32.6		34.0	268.6
Total Transfers from the Medicare Trust Fund		(4,063.6)		(4,569.1)		(5,174.7)		(5,780.5)		(6,386.0)	(40,414.8)
MOOP		(63.6)		(69.1)		(74.7)		(80.5)		(86.0)	(614.8)
Enrollee Advisory Committee	0.9		0.9		0.9		0.9		0.9		6.9
HRA											0.0
HIDE, FIDE Definition											
D-SNP contracts											1.0
Past Performance											
Unified Appeals/Grievances											-
Third Party Marketing											0.2
Marketing Multi-lanaguage insert	0.3		0.3		0.3		0.3		0.3		2.1
MLR Paperwork	2.3		2.3		2.3		2.3		2.3		20.5
MLR Treasury		27.5		29.1		30.4		32.6		34.0	268.6
MLR Contractor	0.2		0.2		0.2		0.2		0.2		1.6
Rx cost to TF		(4,000.00)		(4,500.00)		(5,100.00)		(5,700.00)		(6,300.00)	(40,000.00)
Rx Savings Enrollees		2,100.00		2,500.00		2,800.00		3,200.00		3,600.00	21,300.00
Rx Savings Manufacturers		1,500.00		1,600.00		1,800.00		1,900.00		2,100.00	14,600.00

F. Conclusion

The previous analysis, together with the preceding preamble, provides an RIA. This rule at an annual cost of $ 3.5 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 $3.8 to $3.9 billion annually. We estimate that this rule generates $2.4 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 proposed rule was reviewed by the Office of Management and Budget.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 14, 2021.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, 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 Centers for Medicare & Medicaid Services proposes to 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, 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.

(v) For plan year 2025 and subsequent years, durable medical equipment as defined in § 440.70(b)(3);

(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. Adding paragraphs (f)(4)(i) and (ii) and (f)(5)(iii);
■ b. Revising paragraphs (m)(1) introductory text, (m)(2) introductory text, (m)(3) and (4), and (m)(5)(i); and
■ c. Adding paragraph (m)(6).

The additions and revisions read as follows:

§ 422.100 General requirements.

* * * * *

(f) * * *

(4) * * *

(i) *Tracking of deductible and catastrophic limits and notification.* MA plans are required to track the maximum out-of-pocket limit described in paragraph (f)(4) of this section based on accrued out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members and health care providers when the limit has been reached.

(ii) [Reserved]

(5) * * *

(iii) MA plans are required to track the maximum out-of-pocket limit described in paragraph (f)(5) of this section based on accrued out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members and health care providers when the limit has been reached.

* * * * *

(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 one of the conditions described 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 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 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 the word ''incurred'' and adding in its place the word ''accrued''.

■ 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 standardized questions specified by CMS in subregulatory guidance as follows:

(A) One or more questions on housing stability.

(B) One or more questions on food security.

(C) One or more questions on 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 MA requirements consistent with § 422.2267(e) and §§ 423.2267(e) and 438.10(h) 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. At the beginning of the applicable contract year, this credit no longer applies and if the application is approved, the MA organization must be in full compliance with this section.

* * * * *

■ 7. Section 422.166 is amended by adding paragraph (i)(12) to read as follows:

§ 422.166 Calculation of Star Ratings.

* * * * *

(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.

* * * * *

■ 8. 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 2.5 or less on CMS Star Ratings, as identified in § 422.166.

(E) Met or exceeded 13 points for compliance actions.

(*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.

* * * * *

■ 9. 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.

* * * * *

■ 10. 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 non-compliance.* A notice of non-compliance 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 non-compliance 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 non-compliance 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.

* * * * *

■ 11. 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), 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.

* * * * *

■ 12. 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, home health services as defined in § 440.70 of this chapter, durable medical equipment as defined in § 440.70(d)(3) of this chapter, or nursing facility services are covered for the enrollees.

* * * * *

■ 13. 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.

■ 14. 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.

* * * * *

■ 15. 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, that 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—

* * * * *

■ 16. 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.

* * * * *

■ 17. 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 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 § 422.504(i), but may also be entities that are not FDRs but provide services to customers including an MA plan or an MA plan's FDR.

■ 18. 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.

* * * * *

■ 19. 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 calendars days from receipt of CMS confirmation of enrollment or by last day of month prior to 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; and

(vi) Is excluded from the translation requirement under paragraph (a)(2) 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, 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.

■ 20. 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 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.

■ 21. 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.

■ 22. 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

■ 23. 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.

■ 24. Section 423.100 is amended by removing the definition of ''Negotiated prices'' and adding in alphabetical order definitions for ''Negotiated price'' and ''Price concession'' 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.

* * * * *

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.

* * * * *

■ 25. 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 2.5 or less on CMS Star Ratings, as identified in § 423.186.

(E) Met or exceeded 13 points for compliance actions.

(*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.

* * * * *

■ 26. 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 non-compliance.* A notice of non-compliance 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 non-compliance 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 non-compliance 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.

* * * * *

■ 27. 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 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 § 422.504(i) of this chapter, but may also be entities that are not FDRs but provide services to customers including an Part D sponsor or an Part D sponsor's FDR.

■ 28. 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.

* * * * *

■ 29. 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 last day of month prior to 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; and

(vi) Is excluded from the translation requirement under paragraph (a)(2) 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.

■ 30. 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 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.

■ 31. 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, 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: January 4, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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