CY23 MAPD Final Rule Summary

PROVISIONS OF THE FINAL RULE (CMS-4192)

A. Improving Experiences For Dually Eligible Individuals (p. 40)

3. Enrollee Participation in Plan Governance (p. 40)

c. Proposal for D-SNP Enrollee Advisory Committee

CMS finalized its proposal without change to require MAOs sponsoring D-SNPs to have one or more state specific enrollee advisory committees which could be combined with required Medicaid MLTSS committees. CMS declined to add more prescriptive requirements at this time but provided additional detail through its responses to comments, including the following:

- CMS declined to require multiple committees but noted that states could require additional committees based on specific populations or PBPs and that nothing in the proposed requirement would preclude the use of subcommittees with respect to unique D-SNP subpopulations. While committees are not required at the PBP level, MAOs with multiple D-SNPs could choose to have multiple committees that best represent their service areas and eligibility populations,
- CMS will provide technical assistance including through the ICRC and by sharing promising practices in the future.
- CMS reiterated its intent noted in the proposed rule to update the CMS audit protocols for D-SNPs to request documentation of enrollee advisory committee meetings but will not require advisory committee documents to be shared publicly due to market sensitivities.
- CMS may consider more prescriptive requirements, as needed, based on implementation experience.
- CMS noted that facilitation could be delegated, but the D-SNP remains responsible for compliance.
- CMS also clarified that enrollee participation in an advisory committee is neither a marketing activity nor a personal enrollee health-related activity that would fall under § 422.134, so the authorities and limits that are specific to those activities under MA regulations would not apply. However, MA organizations are prohibited from providing cash, gifts, prizes, or other monetary rebates as an inducement for enrollment or otherwise by sections 1851 and 1854 of the Act. D-SNPs should ensure that any incentives be structured to avoid an inadvertent impact on enrollee eligibility for public benefits. In addition, the provision of stipends, transportation reimbursement, or anything else of value implicates the Anti-Kickback Statute so D-SNPs must ensure that the provision of reimbursement to these members complies

with the AKS and other applicable law. CMS will provide future technical assistance to D-SNPs on this issue to help avoid unintended consequences related to plan compliance or enrollee eligibility for public programs.

- Advisory committees are not required for I-SNPs or C-SNPs but are also encouraged.

4. Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessments (§ 422.101) (p.66)

CMS is finalizing language at § 422.101(f)(1)(i) **that requires SNPs to include one or more questions on housing stability, food security, and access to transportation from a list of screening instruments specified by CMS** (forthcoming in sub-regulatory guidance) **as part of their initial and annual health risk assessments** (HRAs) **beginning in contract year 2024.**

The sub-regulatory guidance will include the option to use State-required Medicaid screening instruments that include questions on these domains.

Special notes on comments - CMS Language:

CBOs or other sub-contractors for HRA completion: "SNPs can choose to utilize community-based organizations or other entities as subcontractors to conduct HRAs or portions of an HRA, and we have seen successful examples of this both with SNPs and MMPs. SNPs and MMPs are responsible for ensuring that their subcontractors meet all CMS care coordination requirements." (p. 91)

***Medicaid HRA* –** "As described in Medicare Part C Plan Technical Specifications for D-SNPs, CMS will accept a Medicaid HRA that is performed within 90 days before or after the effective date of Medicare enrollment as meeting the Part C obligation to perform an HRA, provided that the requirements in § 422.101(f)(1)(i) are met." (p. 91)

State requirements will be considered - "We will consider State requirements in establishing the list of screening tools in sub-regulatory guidance. As a result, the sub-regulatory guidance will include the option to use any State-required Medicaid screening instruments that include questions on these domains." (p.91)

Use of other sources on enrollee social risk factors - "We clarify that the new requirement at § 422.101(f)(1)(i) does not say that SNPs are to use the HRA as the only source of information on enrollee social risk factors. In addition to HRAs, we encourage SNPs to use sources of information outside of the HRA process in order to ensure that SNPs have a complete picture of an enrollee's physical, psychosocial, functional, and social needs and their personal goals. This can include, but is not limited to, interactions between enrollees and providers, care coordinators, other members of the integrated care team, or community-based organizations. This information can assist with the development of and any updates to an enrollee's individualized care plan. Though SNPs may use a variety of sources of information to better understand their enrollees' needs, we are finalizing a requirement for SNP HRAs to include questions from a list of CMS-specified screening tools about housing stability, food security, and access to transportation because all SNPs are required at § 422.101(f)(1)(i) to conduct a comprehensive HRA. Making this requirement part of the HRA ensures all SNPs are universally collecting this information, at minimum, in their assessments, regardless of any other sources of information on enrollee social risk factors they may use." (pp. 94-95)

Validated screening instruments - "In developing this sub-regulatory guidance, we will consider the extensive work that health plans, the Federal Government, tool developers, and other stakeholders have

already done to research and validate screening instruments. We clarify that we did not propose to create new measures, nor did we intend to require that SNPs adopt new assessment tools wholesale. Rather, we proposed to require SNPs to incorporate CMS-specified standardized questions about housing stability, food security, and access to transportation into their HRAs; we had intended that existing standardized questions, from existing validated assessment tools. would be specified by CMS for use by SNPs.

Although we are not finalizing a requirement for SNPs to use CMS-specified standardized questions, we are finalizing a requirement that SNPs use questions from a list of screening instruments specified by CMS in sub-regulatory guidance. We anticipate this list will include validated, widely used assessment tools that include questions on housing stability, food security, and access to transportation." (p. 96)

I-SNPs are not excluded - "We disagree that assessing nursing facility residents for social risk factors in HRAs provides no apparent benefit. An enrollee residing in a nursing facility or other congregate housing setting can have concerns about the stability of their living situation. And, as we noted in the proposed rule preamble at 87 FR 1860, people may move between settings, including from an institutional placement to the community. In addition, I-SNPs may enroll individuals living in the community who require an institutional level of care, for whom housing stability could be of particular concern. I-SNPs, like other SNPs, are required at § 422.101(f)(1)(i) to conduct an initial as well as annual comprehensive HRA. We believe that the benefit of better understanding enrollee needs outweighs any potential burden of adding a few questions to the required assessment. However, we recognize that the types of questions that may be relevant for community-dwelling SNP enrollees may be less relevant for I-SNP enrollees who reside in a nursing facility. Therefore, we are allowing some flexibility for SNPs by finalizing regulatory language at § 422.101(f)(1)(i) which requires SNPs to include questions from a list of CMS- specified screening instruments on these three topics in the initial and annual HRA." (p. 98)

Timeframe & enforcement - "We appreciate the commenters' input on the implementation timeline for our proposal. We are finalizing a requirement at § 422.101(f)(1)(i) that SNPs must include questions from a list of screening instruments specified by CMS in sub-regulatory guidance on housing stability, food insecurity, and access to transportation beginning contract year 2024. We will ensure compliance with the Paperwork Reduction Act as we strive to post the sub-regulatory guidance by the end of 2022. This would leave more than a year from publication of this final rule for SNPs to come into compliance. (p 99)

Using the SDOH information/health plan follow-up – "We agree that it is important for SNPs to not only assess their enrollees for social risk factors, but also connect them to needed services based on enrollee goals and preferences, whether such services are plancovered benefits or referrals to community resources. We clarify that the SDOH data collected as part of an HRA would be used to inform a SNP enrollee's individualized care plan based on the enrollee's goals. The language we are finalizing at § 422.101(f)(1)(i) does not require SNPs to submit HRA data to CMS. However, as we outlined in the proposed rule at 87 FR 1859, we continue to consider whether, how, and when we could have SNPs report this data to CMS under other regulations. If SNPs do submit this data to CMS in the future, we believe having such information could help us better understand the prevalence and trends in certain social risk factors across SNPs and consider ways to support SNPs in improving enrollee outcomes." (pp. 101-102)

Relation to Individualized Care Plan and Model of Care - "The information gathered in the HRAs must be used to inform the development of the individualized care plan per § 422.101(f)(1)(i) and (ii). Section 422.101(f)(1)(i) requires the SNP to ensure that the results from the initial and annual HRAs are addressed in the individualized care plan. Section 422.101(f)(1)(ii) also provides that the individualized care plan must be developed and implemented in consultation with the beneficiary. The SNP must take

steps to provide the services or connect the enrollee with appropriate services in order to accomplish the goals identified in the individualized care plan. The SNP can take these social risk factors into account in the development and implementation of the individualized care plan, even if the SNP is not accountable for resolving all social risk factors."

"As per § 422.101(f)(1), the enrollee's providers should be included as part of the interdisciplinary care team (ICT) and the information from HRAs should be shared with the ICT as described in the SNP's MOC." (p. 109)

"§ 422.101(f)(1)(i) does not stipulate that specific plan personnel must conduct the HRA. CMS does not require physicians to oversee providers or other staff when conducting an HRA and allows SNPs flexibility to determine the level of clinical expertise needed to conduct the HRA. CMS does not preclude the use of telehealth to conduct HRAs. SNPs must conduct their HRA in a manner that is consistent with the plan's approved MOC; approval of the MOC is required by § 422.101(f)(3)." (p. 109)

CMS Audits – "We remind the commenter who expressed concerns about how SNP auditors may interpret this proposed requirement that CMS welcomes stakeholder feedback on the audit protocols when the collection becomes available for public comment under the Paperwork Reduction Act of 1995. We also remind commenters of the requirement at § 422.503(b)(4)(vi) for MA organizations to adopt and implement an effective compliance program to prevent, detect, and correct non-compliance with CMS's program requirements, including the requirement at § 422.101(f)(1)(ii) that SNPs must develop and implement an individualized care plan." (p. 104)

HIPAA & Privacy Protections – "At a minimum, all MA plans, including the SNPs that are subject to this new requirement, must ensure the confidentiality of enrollee records under § 422.118 and the Health Insurance Portability and Accountability Act (HIPAA) Security and Privacy Rules at 45 CFR part 164. Enrollee records that must be protected under § 422.118 include the information collected as part of health risk assessments, and we believe that information gathered through SNP HRAs is protected health information (as defined in 45 CFR 160.103) subject to protection under HIPAA rules. We agree that information related to social risk factors is particularly sensitive and should be handled accordingly. We do not intend to specify how SNPs store this information." (p. 106)

Syncing with NCQA. Gravity Project, MIPS, NQF – "A few commenters noted the Social Need Screening and Intervention quality measure under development from NCQA. Several others noted the work of the Gravity Project, supported by the Office of the National Coordinator for Health Information Technology, including the USCDI v2. A commenter strongly encouraged alignment with USCDI v2. A few commenters supported leveraging and aligning with the work of the Gravity Project, as well as ensuring alignment with other programs. A commenter noted CMS's proposal is consistent with the February 1, 2022 National Quality Forum Measure Applications Partnership recommendations to CMS for screening for social drivers of health and public data on those screening positive for social drivers of health. Another commenter cited a proposal for a similar quality measure for use in the Merit-Based Incentive Payment System for physicians and Inpatient Quality Reporting program for hospitals. . . The proposed NCQA measure does not require use of a specific tool or questions, but would allow use of questions from a list of selected validated assessment instruments, similar to the new requirement finalized here at § 422.101(f)(1)(i). We anticipate our list of screening instruments in subregulatory guidance will overlap with the list of screening instruments NCQA includes in the specifications for its proposed measure, which will provide the opportunity for SNPs to align their compliance with the new requirement at § 422.101(f)(1)(i) with data to be used for the proposed NCQA measure. We believe the result will still be an increased ability for interoperable data exchange among SNPs." (p. 107)

Initial, & Reassessment, HRAs –" We clarify that the questions should be included in all HRAs used by SNPs." (p. 108)

5. Refining Definitions for Fully Integrated and Highly Integrated D-SNPs (§§ 422.2 and 422.107. (p. 112)

CMS finalized its proposed revisions of definitions for FIDE and HIDE SNPs with some clarifications. CMS acknowledges commentors suggestions that States need support to take actions that make HIDE SNP or FIDE SNP designation attainable for D-SNPs and that they should work with Congress on requirements and strategies to integrate care and increase State funding. While it is outside the scope of this rulemaking CMS says it will consider whether there are additional opportunities to address this in the future. CMS clarifies this proposal does not impact the ability for HIDE SNPs and coordination-only D-SNPs to operate alongside FIDE SNPs. CMS also said it will consider comments requesting changes in the definition of FIDE SNPs to reflect that integration can also be achieved where plans operate within the same parent company. CMS also clarifies that the phrase "capitated contract with the State Medicaid agency" may be a Medicaid managed care contract for coverage of Medicaid benefits by a Medicaid MCO, or, for a HIDE SNP, a prepaid inpatient health plan (PIHP) or prepaid ambulatory health plan (PAHP), depending on the scope of coverage of Medicaid services but that all of these contracts are subject to the Medicaid actuarial soundness requirements of 42 CFR 438.4.

a. Exclusively Aligned Enrollment for FIDE SNPs (**§ 422.2) (p. 118)**

Currently, FIDE SNPs are not required to have exclusively aligned enrollment, therefore some FIDE SNPs may be serving members from a separate company's Medicaid managed care plan, or from Medicaid Fee for Service (FFS). CMS finalized its proposal (without change) to require that all FIDE SNPs must have exclusively aligned enrollment. The proposal also allows a cross walk and a separate PBP in order to maintain enrollment and access to frailty adjustments for portions of the aligned enrollment meeting FIDE requirements. The proposal prohibits FIDE SNPs from enrolling partial duals effective 2025 but CMS will allow a separate PBP to retain enrollment for partial duals. CMS made a number of clarifications in its responses to comments including the following.

- Partial duals could also continue to enroll in HIDE or coordination only D-SNPs.
- CMS also clarifies that the crosswalk exception being redesignated in the final rule to§ 422.530(c)(4)(i) is available under current law.
- CMS notes some commenters were opposed to this proposal, fearing CMS would limit integrated plan options in some states. However CMS notes that States may also choose to require – through their State Medicaid agency contracts under § 422.107 – that MA organizations create separate plan benefit packages, with one for exclusively aligned enrollment and the other for unaligned enrollment, so these plans could continue to serve enrollees as HIDE SNPs or coordination only D-SNPs.
- CMS also clarifies they did not propose regulations requiring that the State limit enrollment in the capitated Medicaid MCO to only those enrollees in the FIDE SNP for Medicare, it only limits the FIDE SNP designation to D-SNPs with State contracts requiring exclusively aligned enrollment.
- To maximize flexibility for States that newly implement exclusively aligned enrollment, CMS declined to codify in regulation the requirement that enrollment effective dates for exclusively aligned enrollment must be matching. CMS will monitor where there are misaligned effective dates upon implementation of this rule and will strive to provide technical assistance and share promising practices.

- In response to commenters suggestion that states be allowed shared savings to incent exclusively aligned enrollment, CMS notes their limitations to change MA payment parameters outside of the context of a demonstration or test of a payment model under section 1115A of the Act.

b. Capitation for Medicare Cost-Sharing for FIDE SNPs and Solicitation of Comments for Applying to Other D-SNPs (p.132)

CMS proposed that FIDE SNPs be required to capitate Medicaid payments for cost sharing including for QMB and non-QMB FBDEs. (All FIDEs except for those in TN now are capitated for cost sharing.) CMS finalized this provision as proposed but changed the effective date to 2025 to accommodate TN.

- The FIDE SNP capitated contract with the State must include State payment of Medicare cost-sharing for full-benefit QMB dually eligible beneficiaries. States may elect to extend coverage of Medicare cost-sharing, including coinsurance, for Medicare beneficiaries eligible for full Medicaid benefits who are not QMBs, (such as SLMB+ beneficiaries), as specified in the Medicaid State plan. The requirements around non-QMBs and covered services are complex. The SNP Alliance recommends reading CMS comments on page 136 of the final rule (PDF) for additional detail.
- CMS clarifies that the requirement for FIDE SNPs to cover the Medicaid payment of Medicare cost-sharing does not dictate the particular payment amounts for covered services. Nor does this final policy address all operational details for identifying Medicare cost-sharing obligations for specific services in the context of specific provider payment arrangements. CMS pointed out again that FIDE SNPs also have Medicaid MCO contracts that are subject to CMS review for actuarial soundness.
- CMS also points out that States can require use of particular payment methodologies for certain providers through contracts with D-SNPs to ensure sufficient access and quality of care meets the needs of D-SNP members and can direct Medicaid managed care plans to use certain payment arrangements in connection with Medicaid coverage provided certain requirements are met at § 438.6(c).

CMS requested feedback on applying this provision to all D-SNPs and 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 including impact on States, Medicaid managed care plans, D-SNPs, providers, and beneficiaries but CMS did not adopt any proposals related to this information request.

c. Scope of Services Covered by FIDE SNPs (p. 140)

(1) Need for Clarification of Medicaid Services Covered by FIDE SNPs (p. 140)

In its proposal CMS cited a need for clarification of this section because they have not operationalized contract reviews to reach full integration and that the FIDE SNP designation should represent the highest levels of integration. CMS adopts revisions as proposed to paragraph (2) of the definition of a FIDE SNP at § 422.2 except for a delay until 2025 for inclusion of Parts A and B Medicare cost-sharing and a technical change in home health references to align with current definitions as noted in item (4) below.

- For contract year 2023 and 2024, the required Medicaid covered services are all primary and acute care benefits and long-term services and supports, including coverage of nursing facility services for a period of at least 180 days during the coverage year, consistent with the current regulation and practice.

- Beginning with contract year 2025, the required Medicaid-covered benefits are all primary and acute care benefits (including Medicare cost-sharing for Medicare Part A and Part B benefits), long-term services and supports, including coverage of nursing facility services for a period of at least 180 days during the coverage year, Medicaid home health (as defined in § 440.70), medical supplies, equipment, and appliances (as described in § 440.70(b)(3)), and Medicaid behavioral health services. CMS indicates that States that wish to have FIDE SNPs operate in their State will need to review and, as necessary, update their MCO Medicaid managed care contracts to include this full scope.

- Also these updates would mean that all Medicaid benefits in these categories would be covered by the MCO that is affiliated with the FIDE SNP, to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in the FIDE SNP without any exceptions. Because the same legal entity must have the MA contract with CMS for the D-SNP and the Medicaid MCO contract with the State, and the enrollment in the FIDE SNP must be limited to dually eligible individuals who are also enrolled in the MCO, this entity is functionally all the FIDE SNP.

CMS stated that some while commenters were concerned about loss of FIDE SNP status, relatively few FIDE SNPs would not meet this requirement and those that did not could still remain as HIDE SNPs or coordination only D-SNPs and that the benefits of this approach outweigh the alternatives, while striking a balance retaining flexibility for states.

(2) Requiring FIDE SNPs to Cover All Medicaid Primary and Acute Care Benefits (p. 146)

CMS also adopted its proposed revisions to the FIDE SNP definition in paragraph (2)(i) of § 422.2 to limit the FIDE SNP designation to D-SNPs that cover primary care and acute care services and Medicare cost-sharing – to the extent such benefits are covered for dually eligible individuals in the State Medicaid program – through their capitated contracts with State Medicaid agencies**.** CMS stated that NEMT services are not considered primary or acute care and that they did not get any other suggestions for additional carve outs in this category.

(3) Requiring FIDE SNPs to Cover Medicaid Behavioral Health Services (p.148)

CMS adopts its proposal (without modification) that FIDE SNPs cover behavioral health 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 benefits to the extent Medicaid coverage is available to individuals eligible to enroll in a FIDE except as approved by CMS. CMS declined to provide additional time for phasing in this change.

In addition, CMS adopted as proposed an amendment to § 422.107 to add a new paragraph (h) to adopt a standard for limited exclusions from the scope of Medicaid benefits coverage by FIDE SNPs and HIDE SNPs of certain behavioral health services. This proposal requires 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.

CMS states that behavioral health is essential to providing high-quality, effective care for dually eligible individuals and that FIDE SNPs should provide the broadest level of integration. CMS also points out that since most FIDE SNP contracts include behavioral health benefits, relatively few (24) FIDE SNPs will be impacted, indicating the market has already moved in this direction.

Where state carve outs preclude inclusion, D-SNPs may still meet HIDE SNP or coordination only requirements and/or be redesignated as HIDE SNPs with enrollees remaining in the same plan, thereby avoiding disruptions in care though some would lose the frailty adjuster. CMS clarifies that it did not propose to establish requirements related to approving a State's decision to include certain services in their Medicaid programs. States also have the ability to establish linkages between behavioral health providers and D-SNPs to facilitate coordination of care if the State believes that is preferable to including such behavioral health services in the Medicaid MCO contract held by the FIDE SNP.

(4) Requiring FIDE SNPs to Cover Medicaid Home Health and Durable Medical Equipment (p.156)

CMS finalized its proposals with one technical modification, to add new paragraphs (2)(iv) and 2(v) to the FIDE SNP definition at § 422.2 to require that the capitated contract between the State Medicaid agency and the legal entity that offers the FIDE SNP must include Medicaid home health services as defined at §440.70 and Medicaid DME as defined at § 440.70(b)(3). In the final rule, CMS made a technical correction to paragraph (2)(v) to use the phrase "medical equipment, supplies, and appliances" to better track the regulation text at § 440.70(b)(3).

CMS points out that this provision would be governed under state Medicaid contract requirements. Under current regulation at § 422.107(c)(1), the State Medicaid agency contract must document the D-SNP's responsibility to coordinate the delivery of Medicaid benefits for its enrollees. Therefore States and D-SNPs should already be communicating related to these Medicaid benefits.

d. Clarification of Coverage of Certain Medicaid Services by HIDE SNPs (422.2) (p.160)

Consistent with the changes for FIDE SNPs, CMS adopts its proposal (without modification) to update the HIDE SNP definition by requiring at minimum that the HIDE SNP provide MLTSS or behavioral health services. CMS further clarifies that LTSS services include "community based LTSS and some days of nursing facility coverage services during the plan year" or "behavioral health to the extent Medicaid coverage of such services is available to individuals eligible to enroll in a HIDE SNP in the state". However, CMS also clarifies that HIDE SNP plans are not required to have exclusively aligned enrollment.

CMS clarifies that if the MA organization offering a D-SNP – or the MA organization's parent organization, or another entity that is owned and controlled by its parent organization – has a Medicaid managed care contract with the State that includes coverage of Medicaid behavioral health benefits but excludes coverage of Medicaid LTSS, the MA organization may qualify as a HIDE SNP provided other applicable requirements (such as a compliant Medicaid State agency contract, as required by § 422.107 and, beginning January 1, 2025, minimum service area requirements are met. CMS further clarifies that the HIDE SNP definition, either currently or as amended in this final rule, does not require the affiliated Medicaid plan to be an MCO contract, it could be a PAHP or PIHP; Medicaid managed care regulations in 42 CFR part 438 establish the requirements for a "capitated managed care contract".

This provision also replaces the current use of "coverage, consistent with State policy" language by more clearly articulating the minimum scope of Medicaid services that must be covered by a HIDE SNP, using the phrase "to the extent Medicaid coverage of such benefits is available to individuals eligible to enroll in a highly integrated dual eligible special needs plan (HIDE SNP) in the State."

e. Medicaid Carve-outs and FIDE SNP and HIDE SNP Status p.(164)

CMS adopted as proposed, requirements for 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 of the rule. They also finalized their proposal 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) by codifying 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. Exceptions do not apply to primary and acute care or Medicaid covered cost sharing.

D-SNPs 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 (behavioral health) or constitutes a small part of the total scope of Medicaid LTSS (or behavioral health) provided to the majority of beneficiaries eligible to enroll in the D-SNP.

CMS again clarifies that these proposals would not require that States carve in benefits if they prefer not to do so because MA program regulations permit a D-SNP to be offered without the MA organization (or its parent organization or an entity also owned by its parent organization) having a capitated contract for coverage of Medicaid behavioral health or LTSS benefits.

CMS will continue to review SMACs and Medicaid contracts to assess the scope of existing or future carve outs and to assess whether these specific carve-outs meet criteria in light of the specific facts in a given situation. In addition, they may consider future rulemaking to revise the standard in § 422.107(g) and (h) if necessary.

f. Service Area Overlap between FIDE SNPs and HIDE SNPs and Companion Medicaid Plans (p. 175)

CMS finalized its proposed amendment to the FIDE SNP definition at § 422.2 by adding new paragraph (6) and the HIDE SNP definition at § 422.2 by adding new paragraph (3) to require that the capitated contracts with the State Medicaid agency cover the entire service area for the D-SNP for plan year 2025 and subsequent years. This will facilitate all FIDE SNP and HIDE SNP enrollees having access to both Medicare and Medicaid benefits from a single parent organization. CMS did not propose to limit the service area of the companion Medicaid plan to that of the D-SNP service area. Therefore, the companion Medicaid plan may have a larger service area than the D-SNP.

Currently, under what CMS refers to as an unintended loop-hole in § 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.

CMS indicates that all FIDE SNPs already meet these criteria, and only 15 of the 219 HIDE SNPs have unaligned service areas and all operate in states allowing non-HIDE SNPs. CMS also confirmed that the service area requirement finalized applies to FIDE SNPs and HIDE SNPs at the PBP level and that states are provided flexibility for coordination-only D-SNPs to which this policy does not apply. CMS will reach out to States impacted by this change to provide technical assistance in advance of the contract year 2025 MA bidding cycle.

An MA organization impacted by this proposal would have several pathways to comply with the change to the definition of HIDE SNP at § 422.2. The options include using the crosswalk exception at § 422.530(c)(4)(i) in section II.A.6.a. of this final rule in conjunction with dividing an existing FIDE or HIDE SNP into two (or more) separate D-SNPs, with the service area of the FIDE or HIDE SNP being within the service area of the affiliated Medicaid managed care plan.

CMS acknowledges the difficulties between timelines for state procurements and CMS timelines but suggests that HIDE SNPs that are not able to align their MA service area with the affiliated Medicaid plan's service area for contract year 2025, may be able to continue operating as a non-HIDE D-SNP and regain HIDE status once the service areas align.

CMS also points out that there is no need for a D-SNP to terminate and disrupt current enrollee coverage because an impacted MA organization can keep operating in the existing service area for both the D-SNP and Medicaid plan, however beginning with plan year 2025, the D-SNP would not qualify for FIDE SNP or HIDE SNP designation. An affected plan not changing its service area would be required to update the contract with the State Medicaid agency required by § 422.107 to include the notification requirement specified at § 422.107(d).

CMS also clarifies that actual enrollment in the HIDE SNP and the affiliated Medicaid managed care plan is not required to be aligned. Some States directly contract with D-SNPs under a single contract that meets both the managed care contract requirements under 42 CFR part 438 and the D-SNP contract requirements under § 422.107, but this is not required, and a State may use a Medicaid managed care contract under Part 438 and a separate contract for § 422.107 purposes.

CMS did not adopt other mechanisms considered, such as specifying an overlapping percent of enrollment or service area. They acknowledged the difficulty for health plans to meet both Medicare and Medicaid network adequacy standards in rural areas. Regarding network requirements to align the D-SNP's and companion Medicaid plan's provider networks, they will consider issuing future guidance and rulemaking.

6. Additional Opportunities for Integration through State Medicaid Agency Contracts (§422.107)(e) (p. 186)

a. Limiting Certain MA Contracts to D-SNPs (p.18)

CMS adopted its proposals (without significant modification) to codify a pathway where if a State requires an MA organization to establish a MA contract that only includes one or more D-SNPs with exclusively aligned enrollment within a State and for that D-SNP to then utilize integrated materials, the MA organization may apply for such a contract using the existing MA application process. The language at § 422.107(e)(1)(i) gives States the flexibility to require an MA organization to apply and seek CMS approval for one or more D-SNP-only contracts, which

would provide more transparency in D-SNP performance with consumers and states, facilitating D-SNP specific measurement, models of care and networks that further insight into plan performance.

CMS adopts administrative steps described at § 422.107(e)(2) to permit a new D-SNP-only contract that 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. CMS would provide States with additional information on timelines and procedures in sub-regulatory guidance and would follow the steps consistent with existing timeframes and procedures for the submission of applications, bids, and other required materials to CMS without exceptions for implementation in a future contract year, the earliest of which would be 2024.

CMS recommends that states consult with CMS, MA organizations, and other stakeholders on whether and how to pursue this step toward integration but notes significant state control over whether and which MAOs can offer D-SNPs in their states. CMS indicates that MA organizations with existing contracts that are required by the State to separate out the D-SNP with exclusively aligned enrollment would not be required to create a new legal entity and would be permitted the additional MA contract. CMS also indicates they will consider future rulemaking on whether to expand the ability for States to request to CMS separate D-SNP contracts for D-SNPs that do not have exclusively aligned enrollment.

As part of this proposal CMS finalized its proposal for a new crosswalk exception (to be codified at § 422.503(c)(4)(ii)) to allow MA organizations to seamlessly move existing D-SNP enrollees into a D-SNP-only contract created under this proposal.

While there is much discussion in this FR in response to commenters concerns about how this change impacts appropriate measurement for duals, current CAI and Star ratings, and related bonus payments including flaws in current measurement methodologies specific to duals, CMS dismissed most concerns noting that few plans will be affected and that current time frames allow for addressing some of the issues raised. CMS notes its transparency goals can only be accomplished through separate Star Ratings specific to the performance of D-SNPs within a State. Although States may separately collect quality data for D-SNP enrollees, those data would not feed into Star Ratings. States also would not be able to collect CAHPS or HOS data specific to a D-SNP PBP, because the surveys are administered at the contract level.

CMS notes that in the CY 2023 Advance Notice and CY 2023 Rate Announcement, they discuss confidential stratified reporting of certain quality measures by dual eligible status, and developing a health equity index, both of which may help support efforts to address disparities in care and advance health equity and will aid MA organizations in focusing quality improvement on dually eligible enrollees. However they acknowledge such reporting would not feed into Star Ratings at this time. Substantive changes to the Star Ratings and the addition of a health equity index would need to be proposed through rulemaking.

b. Integrated Member Materials (p.205)

CMS adopts its proposal to allow D-SNPs with exclusively aligned enrollment to use integrated member materials with a slight modification. Under the pathway adopted in § 422.107(e)(1)(i), CMS will coordinate with a State that chooses to require, through its State Medicaid agency contract, that a D-SNP with exclusively aligned enrollment use an integrated SB, Formulary, and

combined Provider and Pharmacy Directory (at minimum.) Applicable Medicaid managed care and MA requirements and standards would continue to apply to the integrated materials.

CMS anticipates that there would be operational and administrative steps at the CMS and State level that would be necessary before a D-SNP could implement use of integrated communications materials, such as collaboration and coordination by CMS and the State on potential template materials, identification of potential conflicts between regulatory requirements at 42 CFR parts 422 and 423 for D-SNPs generally and 42 CFR part 438 and State law for the D-SNP's affiliated Medicaid MCO, and setting up a process for joint or coordinated review and oversight of the integrated materials

CMS also states they did not intend through this rule to significantly change timelines for plans to prepare materials nor did they intend to require any State to mandate that D-SNPs use integrated materials. In order to make it clear that current processes remain, CMS finalized a modification to the regulation text at § 422.107(e)(1)(ii) to require that the integrated model materials meet Medicare and Medicaid managed care requirements consistent with applicable regulations in parts 422, 423, and 423 of the chapter.

Because of insufficient review time under current deadlines and processes (which do not change under this new provision), CMS intends to work in good faith with states and intends that such efforts include the work to develop model integrated materials before the State Medicaid agency contract submissions are due for the contract year for which the D-SNP would use the integrated materials, and before D-SNP-only contracts are finalized. CMS will work with states to ensure that integrated models are provided to D-SNPs in a timely manner and intends to set clear timelines for review with the States. Specifically, CMS indicates they aim to work with States to issue to the affected D-SNPs the required materials and instructions annually by the end of May for the following plan year.

CMS notes problems with differences in enrollment dates for Medicare and Medicaid . When these occur, CMS and the State will jointly decide on a strategy to implement integrated materials while minimizing beneficiary confusion. CMS also acknowledges the importance of model materials and will be creating models based on experience in the FAI and a related demonstration in Minnesota and will also collaborate with States to ensure that they appropriately integrate Medicare and Medicaid information for beneficiaries. CMS also indicates as experience is gained, they may consider future rulemaking to establish integrated disclosure and communication materials where the applicable statutory authority permits sufficient flexibility.

CMS also considered including the EOC and the ANOC in the scope of this process and clarifies that this rule would not preclude CMS and States from collaborating on other integrated materials through the same process. CMS says they intend to develop an integrated Member Handbook (also known as the EOC) and ANOC for contract year 2024 through the PRA process, which will include making the documents available to the public for review and comment during the publication of 60- and 30-day **Federal Register** notices. These models will be based on models created for the FAI and the demonstration in Minnesota.

c. Joint State/CMS Oversight (§ 422.107)(e) (p. 222)

(1) State Access to the Health Plan Management System (p.222)

CMS finalized without modification its proposal allowing 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). (These are the MA organizations offering D-SNPs with exclusively aligned enrollment that maintain one or more contracts that only include one or more D-SNPs with a service area limited to that state.)

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 those MA contract(s). However, this proposal would not limit CMS's discretion to make HPMS accessible in other circumstances not described in the proposal.

CMS will consider other options for permitting expanded HPMS access for State Medicaid officials over time, but in the regulation adopted here access to States is tied to the D-SNP-only contracts for D-SNPs with exclusively aligned enrollment that are required to use specified integrated enrollee materials.

(2) State-CMS Coordination on Program Audits (p. 226)

CMS finalized without modification its proposal to 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 § 422.107(e)(1). (These are the exclusively aligned D-SNPs under a contract number limited to certain D-SNPs in that state.) CMS would also offer to work with States to attempt to avoid scheduling simultaneous State and Federal audits. CMS clarifies it did not intend to limit discretion to coordinate with States in the audit process outside of the parameters in proposed § 422.107(e)(3)(ii); CMs 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 (p. 228)

CMS indicates it will proceed to use existing authority and flexibility for the review of medical provider networks network exceptions and to solicit and receive input from State Medicaid agencies as described in the proposed rule. CMS intends to reach out to States when a MA organization with a D-SNP contract described in § 422.107(e)(1) (exclusively aligned enrollment) 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.

When an MA plan fails to meet the specific network adequacy standards in § 422.116(b) through (e), currently the MA plan may request an exception to these network adequacy criteria. 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 according to the rule 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. CMS notes that states may have useful information and insight to factors relevant to such standards.

CMS did not propose to adopt specific regulation text in § 422.107(e)(3) regarding potential collaboration with State Medicaid agencies in connection with adjudicating requests for an exception to network adequacy requirements for D-SNPs that operate under the conditions described at proposed paragraph (e)(1) because a regulatory amendment is not necessary to support this process; however, the proposed rule outlined how it expects this type of engagement between CMS and States to work.

CMS also adopted its proposal to amend network requirements § 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 the Final Rule.).

d. Comment Solicitation on Financing Issues (p. 231)

Based on FAI experience, CMS sought feedback on assessing whether there are ways to take two elements of MMP financial methodology and apply them 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. CMS did not propose new Medicare or Medicaid policies in this discussion but requested public comments on possible future initiatives.

While CMS does not believe they have the statutory authority to include Medicaid experience as part of the Medicare MLR requirement and is not proposing to require an integrated MLR for integrated products, they pointed out that 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. CMS received a wide array of comments on this topic which it will consider for future guidance on this topic, however CMS reiterates that it is not a current proposal.

MA supplemental benefits and State-specific D-SNP requirements may impact Medicaid-related costs and utilization, and actuarial soundness standards in 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. CMS received a wide array of suggestions on this topic, including advice about how to improve consistency in data and processes used in actuarial soundness. CMS indicated they will take relevant input into account as it considers updates to CMS's Medicaid Managed Care Rate Development Guide, as well as other avenues to provide guidance and technical assistance on this topic.

7. Definition of Applicable Integrated Plan Subject to Unified Appeals and Grievances Procedures (§ 422.561) (p. 239)

CMS adopts its proposal to expand the universe of D-SNPs that are required to have unified grievance and appeals processes by reorganizing the definition of applicable integrated plan in § 422.561 through addition of new subsections to show separate definitions before and after January 1, 2023 to indicate three conditions additional plans to be included would meet. CMS makes a slight modification for clarity where there are references to other paragraphs within the definition and to clarify paragraph (2)(ii)(C) in the third condition as indicated in the third bullet below.

After January 1, 2023 the definition of applicable integrated plans would include certain combinations of Medicaid managed care plans and D-SNPs that are not FIDE SNPs or HIDE SNPs but meet three other conditions where 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.

- 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.
- 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 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.
- 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 categories of Medicaid benefits: home health services as defined in § 440.70 of the chapter, medical supplies, equipment, and appliances as described in §440.70(b)(3) of the chapter, or nursing facility services as defined in § 440.155 of the chapter. (Adopted as modified for clarity.)

CMS indicates that 95 applicable integrated plans in eleven states are currently operating with very few questions or concerns. Because the landscape of integrated plans has evolved in the past several years, CMS believes there are integrated D-SNPs other than FIDE SNPs and HIDE SNPs for which a unified grievance and appeals process is feasible. Expanding the process to these plans would simplify the grievance and appeals steps for beneficiaries enrolled in those plans. While plans newly covered by the definition of applicable integrated plan will have less than a year to ensure that they have appropriate processes in place, most of the plans anticipated to be covered by the revised definition in 2023 currently operate as MMPs in California, and thus have several years' experience operating very similar unified appeals and grievance processes so CMS declines to extend the timeline for implementation.

CMS clarifies that this rule includes in the definition of applicable integrated plans, a subset of D-SNPs that are not HIDE SNPs or FIDE SNPs but still share membership with the Medicaid MCO. Plans covered under the existing definition of applicable integrated plans at § 422.561, meaning FIDE and HIDE SNPs that have exclusively aligned enrollment, will continue to be applicable integrated plans.

CMS also clarifies that the Medicaid benefits covered by the applicable integrated plan will be delineated as covered benefits in the Medicaid managed care contract that the D-SNP has with the State Medicaid agency or other Medicaid MCO and will be the only Medicaid benefits subject to the unified appeals and grievance process. Grievance and appeals policies for non-capitated benefits remain unchanged. To the extent Medicaid and D-SNP plans are under different legal entities, the two entities must communicate and coordinate under current requirements at §§ 422.629 through 422.634.

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)) (p. 245)

CMS adopted its proposal without modification 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.

This change allows an exception to the prohibition at § 422.503(b)(5) on an entity accepting new enrollees in a cost contract plan while offering an MA plan in the same service area applicable to: (1) a parent organization owning a controlling interest in a separate legal entity accepting new enrollees under a cost contract plan, and (2) another separate legal entity owned by the same parent organization as the legal entity accepting new enrollees under a cost contract plan.

A waiver of § 422.503(b)(5) in Minnesota's administrative alignment demonstration in order to allow long standing FIDE SNPs whose parent companies had cost contracts to participate, provided an opportunity to test whether creating an exception for D-SNPs would result in substantial shifts of D-SNP enrollees to cost contract plans offered under the same parent organization. Data collected under the demonstration indicated that it did not result in a substantial number of enrollees moving from the D-SNP to the cost contract plan.

Creating this exception to § 422.503(b)(5) for D-SNPs allows 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, as well as making it available more broadly to other plans.

CMS will monitor patterns of dually eligible enrollment and disenrollment in applicable cost contract plans and D-SNPs. To the extent there is any pattern that suggests that plan sponsors are persuading D-SNP enrollees to move into cost contract plans, CMS would investigate and pursue corrective actions or additional rulemaking, potentially removing or restricting the exemption finalized in this rule.

9. Requirements to Unify Appeals and Grievances for Applicable Integrated Plans (§§ 422.629, 422.631, 422.633, and 422.634) (p.250)

Based on initial implementation experience and feedback from stakeholders, CMS adopted as proposed several adjustments, clarifications, and corrections to the regulations governing unified appeal and grievance procedures at §§ 422.629 through 422.634.

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

CMS adopted as proposed its revisions to § 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 and to reorganize § 422.629(d) to improve the readability of the provision.

b. Technical Correction (§ 422.629(k)

CMS adopted as proposed a technical correction to replace the word "organization" with "reconsideration" and remove the word "decision" from the end of the sentence in § 422.629(k)(4)(ii) for clarity and consistency in the text.

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

CMS adopted as proposed its addition of language to clarify that an enrollee's representative includes any person authorized under State law to accommodate State Medicaid

program appointments including the reorganization of paragraph (l)(1). Specifically, CMS revised 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. CMS also moved the content of current paragraph (l)(1)(ii) that deals with rights of assignees to a new § 422.629(l)(4) as discussed in section II.A.9.d. of this final rule.

d. Clarifying the Role of Assignees and Other Parties (§ 422.629(l))

CMS adopted as proposed a number of proposed changes including:

- Moving the content of § 422.629(l)(1)(ii) to new paragraph (l)(4).
- Adding new language at § 422.629(l)(1)(ii) in its place addressing who can be an enrollee's representative.
- Adding a new paragraph (l)(4) to clarify which individuals or entities can request an integrated reconsideration and are considered parties to the case but who do not have the right to request an integrated grievance or integrated organization determination.
    - In paragraph (l)(4)(i), permitting an assignee of the enrollee (that is, a physician or other provider who has furnished or intends to furnish a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service) to request an integrated reconsideration.
    - In paragraph (l)(4)(ii) permitting 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 order to specify how the MA "prompt payment" rules at § 422.520 governing payment of claims apply to applicable integrated plans, CMS adopted its proposed to add a new paragraph (d)(3) to require applicable integrated plans to process payment requests according to the prompt payment provisions set forth in § 422.520, which would mirror the current provision at § 422.568(c).

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

CMS adopted as proposed, changes to § 422.633(e)(1), to clarify who may file a request for an expedited post-service integrated reconsideration (that is, one that is related to payment). This change 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. CMS proposed to specify in §422.633(e)(1)(i) that expedited post service integrated reconsideration requests are limited to those requested by an enrollee, and in § 422.633(e)(1)(ii) that providers acting on behalf of an enrollee may only request pre-service expedited integrated reconsiderations.

CMS adopted as proposed adding language at § 422.633(f)(3 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. CMS excludes integrated reconsiderations about Part B drugs from the authority for extensions in order to be consistent with current § 422.633(f), which provides that integrated reconsidered determinations regarding Part B drugs must comply with the timelines governing Part B drugs established in §§ 422.584(d)(1) and 422.590(c) and (e)(2).

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

CMS adopted as proposed a number of changes in § 422.634(d) and provides a list of the timeframes for effectuation after the amendments made by this final rule. CMS changes adopted are listed below.

- Clarifications of descriptions of timeframes for authorizing services in all situations where an applicable integrated plan's decision is reversed.
- Reorganization of § 422.634(d) to more explicitly address each scenario that an applicable integrated plan would face when effectuating a reversal.
- In proposed paragraph (d)(1), 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.
- To require 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.
- Timeframes for applicable integrated plans to effectuate all decisions are covered in § 422.634; this includes effectuation after reversal by the applicable integrated plan, the IRE, a State fair hearing, or at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council.

10. Technical Update to State Medicaid Agency Contract Requirements (§ 422.107) (p. 263)

CMS adopted its proposal to strike the reference to Medicare in section § 422.107(c)(6) that lists minimum requirements for State Medicaid agency contracts. Paragraph (c)(6) required that the contract document the verification of an enrollee's eligibility for "both Medicare and Medicaid." However CMS indicates 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 because all MA plans, including D-SNPs, already verify Medicare eligibility as part of accepting beneficiary coverage elections under § 422.60.

CMS notes that it did not propose a change to the contract requirement that the D-SNP validate the enrollee's Medicaid eligibility. CMS also noted that this did not affect the requirement that the state contract must document the categories and criteria for eligibility for dually eligible individuals to be enrolled under the SNP, including as described in sections 1902(a), 1902(f), 1902(p), and 1905 of the Act. Therefore, the D-SNP contracts with States should describe how States provide D-SNPs with information needed to enroll dually eligible individuals including how to determine the status for each dual eligibility categories to be included.

11. Compliance with Notification Requirements for D-SNPs that Exclusively Serve Partial Benefit Dually Eligible Beneficiaries (§ 422.107(d)) (p.265)

CMS finalized its proposed amendments to § 422.107(d) to provide that partial-benefit-only D-SNPs are not required to meet the notification requirement in new § 422.107(d)(1) when the MA organization also offers a D-SNP with enrollment limited to full-benefit dually eligible individuals that meets the integration criteria at § 422.2 and is in the same State and service area and under the same parent organization. However, CMS confirmed that States remain able to use their contracts with D-SNPs to require MA organizations to notify the State Medicaid agency of admissions for partial-benefit dually eligible enrollees. CMS is still gathering information on the initial implementation of the data notification requirement at § 422.107(d) and will use feedback from this rule and its work with plans and states to update guidance and regulation if needed.

CMS also confirmed that a D-SNP that serves partial-benefit dually eligible individuals without a corresponding full-benefit-only D-SNP in the same service area would be able to continue operating as long as the contract with the State Medicaid agency includes the notification requirement at § 422.107(d)(1).

In response to comments, CMS emphasized that States must implement the notification requirement at § 422.107(d) in a way that complies with all applicable State and Federal laws and acknowledges there are limitations to D-SNPs' ability to notify States of certain inpatient admissions for high-risk enrollees with substance use disorder, as well as to their ability to coordinate these individuals' care, absent enrollee consent for the disclosure of such information. CMS encourages D-SNPs to collaborate with their States to identify and address concerns regarding compliance with other statutes and regulations, including the Health Insurance Portability and Accountability Act HIPAA of 1996 and 42 CFR part 2.

CMS also indicated it would consider an analysis on the relevance of supplemental benefits to partial-dually eligible individuals enrolled in D-SNPs to determine if establishing minimum criteria through rulemaking is warranted.

12. Attainment of the Maximum Out-of-Pocket (MOOP) Limit (§§ 422.100 and 422.101) (p.269)

CMS adopted its proposed change (with a small technical modification) to 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. CMS declined to change the effective date of CY 2023.

CMS amended §422.100(f)(4) and (5) and §422.101(d)(4) to provide that MA organizations are responsible for tracking out-of-pocket spending accrued by enrollees and must alert both the enrollee and the contracted provider(s) if an enrollee has reached the MOOP limit. In addition for consistency with the April 2022 Final rule changes in MOOP, CMS makes a technical change at §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.

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.

CMS received broad support from beneficiary advocates and providers, MedPAC and MACPAC for this proposal as well as opposition from plans. CMS acknowledged that this change "will raise MA bids for basic benefits, especially for D-SNPs and other MA plans with a high percentage of dually eligible enrollees, and thereby potentially reduce rebates available for a range of supplemental benefits to the extent MA organizations are unable or unwilling to reduce profit margins or other costs to account for the added MA plan costs for services provided after an enrollee meets the MOOP limit."

CMS cited its belief that for most MA organizations, most (if not all) of the added costs for implementation of the MOOP proposal could be absorbed by reductions in plan profit margins and still allow MA organizations to achieve D-SNP profit margins that are comparable to the overall MA profit margins. CMS also said they recognize that MA organizations with smaller D-SNP margins, including

some regional and nonprofit organizations, may have more difficulty absorbing the full costs of the proposal by reducing margins but that the advantages of this proposal outweigh the disadvantages. CMS cited MedPAC data that nonprofit D-SNPs had lower average 2019 gain/loss (profit) margins of 2.5 percent which are still higher than the overall nonprofit MA margin of .09 percent. CMS also was not convinced that the added bid costs attributable to the proposal would necessarily translate into reductions in valuable supplemental benefits for dually eligible enrollees or to jeopardize the ability to pay down Part D premiums and offer zero-premium plans. CMS noted a 2022 regulatory change which will raise the in-network mandatory MOOP limit to $8,300 starting in 2023, reducing the costs of this proposal to D-SNPs and other MA plans that adopt the mandatory MOOP limit.

CMS also refutes data indicating that D-SNP enrollees already have higher access to primary care providers and cites certain Stars measures to substantiates concerns that access to and availability of healthcare for dually eligible individuals in D-SNPs is less than that for MA enrollees who are not dually eligible.

CMS also rejected commenter concerns that this proposal could impact value-based payments to providers, saying this policy would in no way restrict the ability of MA organizations to negotiate payment rates with their providers, including the ability to negotiate capitated or semi-capitated payment arrangements and that where full cost sharing is included in a negotiated single fee schedule there should be no increase in the bids unless the state reduces its Medicaid payments. CMS also rebuffs arguments they are superseding State authority to establish the methods a State requires D-SNPs that operate in the State to employ in determining administration of Medicaid's responsibility for cost sharing, because Medicare is primary to Medicaid and the policy necessarily impacts Medicaid as a secondary payer.

CMS indicates that some MA organizations have established D-SNPs with a lower, voluntary MOOP and subsequently raised cost-sharing for other Part A and B services above levels that are actuarially equivalent to the Original Medicare benefit for those services . CMS believes this practice to be manipulative of the benefit review process with the potential to violate the requirement at §422.254(b)(4) that MA plans provide a benefit that is at least actuarially equivalent to Original Medicare. Implementation of the MOOP proposal would provide that the flexibility allowed to raise service-specific cost-sharing to encourage use of the lower, voluntary MOOP, would ensure that use of the MOOP limit actually limited cost-sharing under the plan benefit.

13. Comment Solicitation on Coordination of Medicaid and MA Supplemental Benefits (p.292)

In the proposed rule, CMS described a number of ways that State Medicaid agencies can use their D-SNP contracts under § 422.107 to coordinate D-SNP supplemental benefits with Medicaid benefits and sought comment on how CMS considers a FIDE SNP's supplemental benefits as meeting the uniformity requirements in cases where some dually eligible individuals receive the benefit under the FIDE SNP's Medicaid managed care contract while other enrollees receive the benefit as an MA supplemental benefit because they are not eligible for Medicaid benefits under State Medicaid eligibility criteria. CMS noted that it was considering whether an amendment to § 422.100(d)(2) would be appropriate regarding this approach to uniformity for supplemental benefits when a FIDE SNP arranges supplemental benefits this way and sought comments on that issue as well as other ways D-SNPs and States can work together to coordinate Medicare and Medicaid benefits in order to improve D-SNP enrollee experiences and outcomes. CMS will use comments received to inform their collaboration with states and D-SNPs.

(a) Using the D-SNP MOC to Coordinate Medicaid Services (p.294)

CMS sought comments on CMS guidance or regulations that may warrant clarification, and whether using D-SNP MOC to coordinate Medicaid services create any unintended obstacles to

accessing services among dually eligible beneficiaries. The D-SNP MOC, required by § 422.101(f), also provides a vehicle for State Medicaid agencies to work with D-SNPs to meet State goals to improve quality of care and address social determinants of health. State Medicaid agencies may work with D-SNPs with service areas in the State to include (and, through the State Medicaid agency contract at § 422.107, require inclusion of) specific elements in the MOC and how the D-SNP delivers covered items and services consistent with the MOC.

Some commenters expressed concern with the State's ability to leverage the MOC with Medicaid requirements and the possible addition of any State requirements that may be duplicative or in conflict with the MOC-specific requirements. A few commenters suggested potential ways to improve coordination such as training for States on Federal requirements, a national State specific requirements repository, and better alignment of MOC reviews. CMS appreciated suggestions for improving coordination and indicated they will consider these comments in future rule making and guidance.

(b) Coordinating Coverage of Medicare Cost-Sharing (p.295)

CMS solicited comments on State and MA organization experiences and challenges in coordinating benefits, CMS guidance or regulations that may warrant clarification, and whether current policies create any unintended obstacles to accessing services among dually eligible beneficiaries. In particular CMS sought comments around the 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, which works differently depending 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. Commenters noted the need for accuracy and actuarial soundness for such rate setting. CMS indicated it will consider opportunities for future Medicaid rate-setting guidance on the issue.

14. Converting MMPs to Integrated D-SNPs (p.296)

CMS is proceeding with its intentions to work with the States participating in the capitated financial alignment model during CY 2022 to develop a plan for converting MMPs to integrated D-SNPs. CMS made one modification in the timeline to extend the FAI demonstration through 2025 for states that submit a transition plan to CMS as described below. In implementing this new direction, CMS cited numerous factors that have changed the integration landscape since the creation of the FAI demonstration including as the growth of D-SNPs and enrollment, experience gained through the FAI, integrated Grievance and Appeals processes and new benefit flexibilities addressing SDOH needs. The CMS process is based on experience with earlier transitions as well as those currently happening in CA, for working with states and plans to make these changes including additional proposed rule provisions and sought comment on its approach.

While CMS received comments supporting this approach, numerous commenters were opposed to this change and instead asked to continue the FAI, expressing concern that certain aspects of integrated coverage in the MMPs may be hard to replicate or are otherwise not currently available in integrated D-SNPs, including integrated enrollment processing in which enrollment and disenrollment functions are conducted through states, passive enrollment, shared state savings, and funding for ombudsman programs. In response, CMS indicated that although outside the scope of this rule, it will consider whether there are additional opportunities to further integrate enrollment and/or financing in the future

and will continue to think through its ability to use waiver authority under section 1115A of the Act as part of any MMP transition.

After receiving numerous comments on the need for more time to implement this approach, CMS is making an adjustment to its original timeline in order to facilitate smooth transitions and will offer States the opportunity to continue demonstrations (temporarily) under the FAI, under "conditions described in this section and where authorized by section 1115A of the Act." However, States interested in this opportunity will still need to convert all MMPs to integrated D-SNPs as early as possible, but no later than December 31, 2025.

"States pursuing converting their MMPs into integrated D-SNPs should submit a transition plan to CMS by October 1, 2022. This transition plan should reflect each State's individual circumstances and outline, for example, the State's commitment to (a) maximize integration attained through the capitated financial alignment demo and a seamless transition to integrated D-SNPs, (b) sustain dedicated ombudsman support without Federal grant funding, and (c) a stakeholder engagement process to promote collaborative discussion on the planning and implementation of the transition to integrated D-SNPs. The transition plan should also identify specific policy and/or operational steps that need to occur to fulfill the commitments. These could include, but are not limited to, executing Medicaid procurement executing Medicaid procurement and/or D-SNP contracting processes; obtaining necessary State legislative or additional Medicaid authorities, if applicable; and/or identifying and executing system changes and processes to implement exclusively aligned enrollment."

If a State chooses not to convert MMPs to integrated D-SNPs, CMS will work with the State on an "appropriate MMP conclusion" by December 31, 2023. (Subsequent Q&A with MMCO indicates that for those states, this means the FAI would end by this date.)

B. Special Requirements during a Disaster or Emergency (§ 422.100(m)) (p. 303)

Refer to p. 303 of the final rule for discussion and comments by CMS.

C. Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application (§ 422.116) (p. 327)

CMS adopts its proposal to revise § 422.116(a)(1)(ii) to provide that beginning for contract year 2024, an applicant for a new or expanding service area must demonstrate compliance with this section (network adequacy rules) as part of its application for a new or expanding service area and that CMS may deny an application on the basis of an evaluation of the applicant's network for the new or expanding service area.

CMS also adopts its proposal that such plans receive a 10 percent 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.

However, CMS makes a **significant change** in response to many concerns submitted about the timing issues with this proposal. CMS also adopts the provision that in addition, applicants may use an LOI, signed by both the MA organization and the provider or facility with which the MA organization has started or intends to negotiate, in lieu of a signed contract at the time of application and for the duration of the application review, to meet network standards. As part of the network adequacy review process, applicants must notify CMS of their use of LOIs to meet network standards, in lieu of a signed contract and submit copies upon request and in the form and manner directed by CMS. At the beginning of the applicable contract year, the credit and the use of the LOIs no longer apply, and if the application is

approved, the MA organization must be in full compliance with this section, including having signed contracts with the provider or facility.

D. Part C and Part D Quality Rating System (p.338)

Summary of this section: This final rule **finalizes a technical change** at § 422.166(i)(12) proposed in the January 2022 proposed rule to enable CMS to calculate 2023 Star Ratings for **three Healthcare Effectiveness Data and Information Set (HEDIS) measures** that are based on the Health Outcomes Survey (HOS). It also **finalizes provisions adopted in the March 31st COVID-19 IFC and the September 2nd COVID-19 IFC to enable CMS to calculate the 2021 and 2022 Star Ratings** due to the COVID-19 pandemic.

- ***Provision Related to the HEDIS Measures Calculated from the HOS from the January 2022 Proposed Rule*** (pp. 343 - 345) - CMS is finalizing, without modification, the provision at § 422.166(i)(12) to codify special rules for the calculation of the 2023 Star Ratings for the three HEDIS measures that are collected through the HOS (Bladder Control, Physical Activity, and Reducing Falls Risk).

CMS Language: "As described in the April 2019 final rule (CMS-4185-F) (84 FR 15772 through 15773), for measures derived from the HOS, the disaster policy adjustment is for 3 years after the extreme and uncontrollable circumstance.

Based on the comments received and the timing of the HOS administration, we proposed to amend § 422.166(i) to specifically address the 2023 Star Ratings, for measures derived from the 2021 HOS only, by adding § 422.166(i)(12) to remove the 60 percent rule for affected contracts. By removing the 60 percent rule, all affected contracts (that is, contracts affected by the 2020 COVID-19 pandemic) with at least 25 percent of their enrollees in FEMA designated Individual Assistance areas at the time of the disaster will receive the higher of the 2022 or 2023 Star Rating (and corresponding measure score) for each of the HEDIS measures collected through the HOS as described at § 422.166(i)(3)(iv) for the 2023 Star Ratings.

. . These three areas – bladder control, physical activity, and reducing falls risk – are important for beneficiaries' health and well-being, even during a PHE. It is CMS's view that including these measures in Star Ratings will provide valuable information for people with Medicare on important areas of focus for avoiding serious health problems.

As a reminder, as required at § 422.504(o), MA organizations must develop, maintain, and implement business continuity plans, including policies and procedures for disaster or emergency situations. Therefore, we do not believe it is appropriate to eliminate use of these measures entirely in the Star Ratings."

- ***Provisions in the March 31st COVID-19 IFC*** - This final rule also responds to comments on and finalizes a series of changes to the 2021 and 2022 Star Ratings to accommodate the disruption to data collection posed by the COVID-19 pandemic (FR 85 19271-19275) that were established in the March 31st COVID-19 IFC.

    - *HEDIS, CAHPS, and HOS Data Collection and Submission for 2021 Star Ratings and 2022 Star Rating* - CMS is finalizing without modification the provisions eliminating for 2020 the requirement to submit HEDIS and CAHPS data for MA contracts at §

422.152(b)(6) and for cost plans at § 417.472(i) and (j), and to submit CAHPS data for Part D contracts at §§ 423.156 and 423.182(c)(3).

Additional note by CMS: "Although the HOS data collection was completed as scheduled in fall 2020, CMS agrees that the COVID-19 PHE significantly impacted the validity of the two HOS outcome measures. CMS issued the HPMS memorandum "Medicare Health Outcomes Survey (HOS) Outcome Measures Moved to Display for 2022 and 2023 Star Ratings," on August 5, 2021 announcing that the Improving or Maintaining Physical Health and Improving or Maintaining Mental Health measures would be moved to the display page on CMS.gov with a note that the comparisons were pre- and post-pandemic and that the measures would not be included in the 2022 and 2023 Star Ratings because of validity concerns related to the COVID19 PHE. These two measures were therefore not included in the 2022 Star Ratings, and they will not be included in the 2023 Star Ratings."

- *Adjustments to the 2021 Star Ratings Methodology Due to Lack of HEDIS and CAHPS Data* - CMS finalizes without modification the provisions, as codified at §§ 422.166(j)(1) and 423.186(j)(1), to use the 2020 Star Ratings HEDIS and CAHPS data for the 2021 Star Ratings.

- *Use of 2020 Star Ratings to Substitute for 2021 Star Ratings in the Event of Extraordinarily Compromised CMS Capabilities or Systemic Data Issues* – CMS did not have to substitute for 2021 Star Ratings, so the interim rule was not finalized.

- *Guardrails* - CMS finalized without modification the provisions at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to delay the use of guardrails until the 2023 Star Ratings.

CMS Language (page 586) "§ 422.166 Calculation of Star Ratings. (a) * * * (2) * * * (i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and Part D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program."

(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. * * * *

- *Improvement Measures* - CMS finalized without modification the provisions at §§ 422.166(g)(3), 423.186(g)(3), 422.166(f)(1)(i), and 423.186(f)(1)(i), to apply the higher

ratings after calculating the overall and summary ratings with and without the Part C and/or D improvement measures for all contracts only for the 2022 Star Ratings.

- *QBP Calculations for New Contracts* - CMS finalized the definition at § 422.252 without modification, such that for only the 2022 QBP ratings that are based on 2021 Star Ratings, a new MA plan is defined as one that is offered by a parent organization that has not had another MA contract for the previous 4 years.

- *Provisions in the September 2nd COVID-19 IFC* - CMS finalized without modification the provisions at §§ 422.166(i)(11) and 423.186(i)(9) to codify special rules for the calculation of the 2022 Star Ratings. All Part C and Part D contracts that were operational during 2020 qualified for the relevant disaster adjustments for the 2022 Star Ratings.

E. Past Performance (§§ 422.502, 422.504, 423.503, and 423.505) (p. 359)

CMS is codifying the new bases for application denial based on past contract performance as paragraphs (b)(1)(i)(C) - **Bankruptcy filing or under bankruptcy proceedings, (b)(1)(i)(D) - low Star Ratings, and (b)(1)(i)(E) - Compliance Actions.**

They are also codifying CMS' compliance actions which are NONCs, WLs, and CAPs in §§ 422.504(m) and 423.505(n). They note that the basis for application denial based on past contract performance is not applicable for MA organizations establishing new D-SNP-only contracts under § 422.107(e) as described in section II.A.6.a.

CMS Language: "As for using the overall Star Rating instead of the Part C or Part D Summary rating, CMS notes that existing termination authority at §§ 422.504(a)(17) and 423.505(b)(26) is based on low ratings for either the Part C or Part D summary rating. Using the overall Star Rating for past performance would be inconsistent with the application of Star Ratings for termination. To ensure clarity, CMS has modified the regulatory text to clarify that CMS will use the Part C or Part D summary Star rating for past performance purposes."

CMS is finalizing their proposal with a modification to require that a contract have two consecutive years of Part C Summary, Part D Summary, or a combination of Part C and Part D Summary ratings of 2.5 or below to receive a denial of new applications or service area expansions. CMS will use the two most recent Star Ratings period – that is, those that fall in the 12-month lookback period as specified in 42 CFR 422.502(b)(1) and 423.503(b)(1).

CMS' contract and past performance methodology is calculated at the legal entity level. CMS contracts with a legal entity that covers one or more contracts. If any one of the contracts under the legal entity meets any one of the reasons for denial, **all new applications and service area expansions under that legal entity will be denied.**

CMS Language: "We do not feel a formal appeals process is necessary for compliance actions. CMS notes that a formal appeal process is available for applicants whose application has been denied for past performance reasons specified in this rule. . . . We are finalizing as proposed with a few modifications.

The first modification is to use 2 years of Star Ratings for Part C Summary, Part D Summary, or a combination of Part C and Part D Summary ratings.

The second modification is to clarify that CMS is using the Part C Summary and Part D Summary Star ratings. The final modification is to clarify that the 13 compliance action points are allotted on a per contract basis."

<u>CMS Language:</u> (P. 587) § 422.502 "Evaluation and determination procedures. * * * * * (b) * * * (1) Except as provided in paragraphs (b)(2) through (4) of this section, if an MA organization fails during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part C program under any current or prior contract with CMS under title XVIII of the Act, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part. (i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant does any of the following:

(A) Was subject to the imposition of an intermediate sanction under subpart O of this part or a determination by CMS to prohibit the enrollment of new enrollees in accordance with § 422.2410(c), with the exception of a sanction imposed under § 422.752(d).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(b)(14).

(C) Filed for or is currently in State bankruptcy proceedings.

(D) Received any combination of Part C or D summary ratings of 2.5 or less in both of the two most recent Star Rating periods, as identified in § 422.166.

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

(1) CMS determines the number of points each MA organization accumulated during the performance period for compliance actions based on the following point values: (i) Each corrective action plan issued during the performance period under § 422.504(m) counts for 6 points. (ii) Each warning letter issued during the performance period under § 422.504(m) counts for 3 points. (iii) Each notice of noncompliance issued during the performance period under § 422.504(m) counts for 1 point.

(2) CMS adds all the point values for each MA organization to determine if any organization meets CMS' identified threshold *****"

<u>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) (p. 372)</u>

CMS codifies additional guidance and standards from the MCMG that were 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, CMS codifies 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, CMS codifies requirements to address concerns associated with third-party marketing activities.

After a complex history of changing policy around such notices, CMS is adopting as proposed its revised requirements for notification for beneficiaries with limited English proficiency that translator services are available in order to provides a clear path for this portion of the population to properly understand and access their benefits. CMS is requiring a multi-language insert (MLI) to be a separate full-page document that is included or provided with all required documents.

CMS also proposed to change the definition of Third-party Marketing Organization (TPMO) and finalized the definition of TPMO at §§ 422.2260 and 423.2260 with an update to clarify that the definition includes individual agents and brokers as well as organizations.

Finalized changes to the marketing requirements are as follows:

- Sections 422.2260 and 423.2260 are revised to add a definition for Third-Party Marketing Organization (TPMO).
- Sections 422.2265(b)(13), 423.2265(b)(14), 422.2265(b)(14), and 423.2265(b)(15) are revised to add instructions on how to appoint a representative and to add enrollment instructions and forms.
- Sections 422.2267(e)(30) and 423.2267(e)(32) are revised to add the Member ID card and requirements for the card as a model document.
- Sections 422.2267(e)(31) and 423.2267(e)(33) are revised to add the Multi-Language Insert.
- Sections 422.2267(e)(41) and 423.2267(e)(41) are revised to add the Third-Party Marketing disclaimer.
- Section 423.2267(e)(40) is revised to add the Limited Access to Preferred Cost-Sharing disclaimer.
- Sections 422.2274 and 423.2274 are revised to apply MA and Part D oversight to TPMOs.

G. 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) (p.389)

CMS finalized its proposal to reinstate the detailed MLR reporting requirements that were in effect for CYs 2014 through 2017 and to include a number of modifications and updates to those previous reporting requirements including expanding requirements to include expenditures for supplemental benefits. CMS outlines criteria for inclusion of supplemental benefit costs and lists a number of supplemental benefit categories as examples of those that they would include in this reporting requirement. Modifications to the MLR data requirements for supplemental benefits expenditures will be set forth in a revision to the MLR Paperwork Reduction Act package (CMS-10476, OMB 0938-1232) and made available to the public for review and comment under the standard PRA process. In addition, CMS finalized as proposed additional requirements to collect additional data on certain categories of expenditures, and to make conforming changes to data collection tools as well as certain reporting and resubmission requirements.

H. Pharmacy Price Concessions in the Negotiated Price (§ 423.100) (p.418)

Currently a Part D sponsor or its pharmacy benefit manager (PBM) may receive compensation after the point of sale that serves to lower the final amount paid by the sponsor to the pharmacy for the drug. This post-point-of-sale compensation is called Direct and Indirect Remuneration (DIR). DIR is factored into CMS's calculation of final Medicare payments to Part D plans and includes rebates from manufacturers, administrative fees above fair market value, price concessions for administrative services, legal settlements affecting Part D drug costs, pharmacy price concessions, drug costs related to risk-sharing settlements, or other price concessions or similar benefits offered to some or all purchasers from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred under the Part D plan (see § 423.308).

CMS states concerns that 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. When concessions are not applied at the point of sale it 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. Thus, more vulnerable and sick beneficiaries who utilize drugs end up paying a larger share of the actual cost of a drug.

CMS notes that total DIR reported by Part D sponsors has been growing significantly in recent years. Citing recent data indicating that pharmacy price concessions have continued to grow at a faster rate than any other category of DIR, CMS has finalized its proposed policy to amend § 423.100 to define the term "negotiated price" to ensure that the prices available to Part D enrollees at the point of sale are inclusive of all possible pharmacy price concessions for each drug. This will reduce cost sharing for beneficiaries with the most serious health conditions though it may also result in premium increases for some others. The policy does not change how much LIS-eligible beneficiaries pay in cost-sharing or premiums, and therefore the low-income subsidy will continue to protect the most vulnerable populations.

The new definition of negotiated price at § 423.100 will be effective January 1, 2024 (a one-year delay from the original proposed date of 2023.). Under this definition, the negotiated price must be the lowest possible reimbursement a network entity will receive, in total, for a particular covered Part D drug, including all price concessions and any dispensing fees, but excluding additional contingent amounts that increase prices. It will clarify 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 and will enhance transparency at point of sale. Data collected will reflect a price paid to a pharmacy for a covered Part D drug net of all possible downward adjustments and thus PDE data will be populated and reported for the price of the drug on which beneficiary cost-sharing is determined. CMS will use existing reporting mechanisms to confirm that sponsors are appropriately applying pharmacy price concessions to the negotiated price.

CMS finalizes its proposal without modification to define "price concession" to include any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor at § 423.100. CMS confirms that under the definition of negotiated price adopted in this final rule, the negotiated price must include pharmacy price concessions, and does not require inclusion of non-pharmacy price concessions, such as manufacturer rebates.

CMS also finalizes its proposal with modification to use the negotiated price determined using the lowest possible reimbursement to the pharmacy across all phases of the Part D benefit, including for applicable drugs in the coverage gap phase. Accordingly, CMS revises the definition of negotiated price at §423.2305 to clarify that the negotiated price must be inclusive of all pharmacy price concessions in the coverage gap phase of the Part D benefit but that sponsors continue to have the flexibility to elect which non-pharmacy price concessions are to be passed through at the point of sale.