On April 29, 2022, the Centers for Medicare and Medicaid Services (“CMS”), issued the final rule on Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (the “Final Rule”). CMS promotes the Final Rule as advancing “CMS’ strategic vision of expanding access to affordable health care and improving health equity in Medicare Advantage (MA) and Part D through lower out-of-pocket prescription drug costs and improved consumer protections.” With a few exceptions, the Final Rule is a wholesale codification of the proposed rule. Except as noted below, the requirements of the Final Rule are effective January 1, 2024.
1. **Enrollee Participation in Dual Eligible Special Needs Plan ("D-SNP") Governance (§ 422.107)**

CMS proposed extending enrollee advisory committee requirements to D-SNPs. CMS finalized this proposal, requiring all D-SNPs to establish and maintain one or more enrollee advisory committees for each state in which the D-SNP is offered, including a reasonably representative sample of individuals enrolled in the D-SNP or other individuals representing those enrollees. The Final Rule also requires D-SNPs to consult with their enrollee advisory committees on various issues, including ways to improve access to covered services, coordination of services, and health equity for underserved populations. CMS reasons “the health system is stronger when we listen to the people we serve,” and noted that public comments, which strongly supported these changes, “reinforced [their] belief that the establishment and maintenance of an enrollee advisory committee is a valuable beneficiary protection to ensure that enrollee feedback is heard by managed care plans and to help identify and address barriers to high-quality, coordinated care for dually eligible individuals.”

Under the Final Rule, an organization that operates a D-SNP that is affiliated with a Medicaid managed care plan (i.e., under the same parent organization) is allowed to use one enrollee advisory committee to satisfy both CMS and State Medicaid enrollee advisory committee requirements.

CMS did not agree with commenters who asked for more detailed requirements on the operation of the enrollee advisory committees. Instead, CMS chose to give D-SNPs more flexibility in structuring the enrollee advisory committees so as to “permit D-SNPs—and the enrollees participating on the advisory committees—to tailor these committees based on the local needs of enrollees.”

2. **Standardized Housing, Food Insecurity, and Transportation Questions on Health Risk Assessments ("HRAs") (§ 422.101)**

CMS proposed to require all SNPs (D-SNPs, chronic condition SNPs and institutional SNPs) to include one or more standardized questions on the following three domains (i) housing stability; (ii) food security; and (iii) access to transportation as part of their HRAs. Under the Final Rule, beginning in 2024, SNP HRAs must include at least one question on each of the three domains from a list of screening instruments to be specified by CMS in subregulatory guidance. CMS noted these changes were broadly supported by public commenters. Considering the impact social risk factors and unmet social needs can have on health, CMS asserts these changes will help better identify the risk factors that may inhibit enrollees from accessing care and achieving optimal health outcomes, enabling MA SNPs to take these risk factors into account in enrollee care plans. CMS also advises the Final Rule will equip MAOs with the “person-level information” that will help them better connect people to covered services, social service organizations, and public programs that can help resolve housing instability, food insecurity, or transportation challenges.

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

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CMS finalized its proposal to require, for 2025 and subsequent years, that all fully integrated dual eligible special needs plan (“FIDE SNPs”) must have exclusively aligned enrollment, i.e., their enrollment is limited to individuals who are enrolled in the affiliated Medicaid managed care plan (“MCO”), and cover Medicare cost-sharing and the following three categories of Medicaid benefits: home health, durable medical equipment, and behavioral health services through a capitated contract with the State Medicaid agency. CMS made clear, in proposing that all FIDE SNPs have exclusively aligned enrollment, CMS is requiring that all FIDE SNPs will be limited to full benefit dually eligible individuals beginning in 2025.

CMS also finalized its proposal to require, for plan year 2025 and subsequent years, that each highly integrated dual eligible special needs plan’s (“HIDE SNP”) have a service area that completely overlaps the service area of the affiliated MCO with the capitated contract with the State.

The Final Rule make clear that a plan will meet the definition of a FIDE SNP or HIDE SNP even if the State Medicaid contract has CMS-approved carve outs for long-term services and supports or behavioral health services that (i) apply primarily to a minority of the beneficiaries eligible to enroll in the D-SNP who use such services, or (ii) constitute a small part of the total scope of such services provided to the majority of beneficiaries eligible to enroll in the D-SNP.

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

CMS finalized its proposal to codify new pathways through which States can use State Medicaid Agency contracts or “SMACs” with D-SNPs to require that D-SNPs with exclusively aligned enrollment (a) establish contracts that only include one or more D-SNPs within a State, and (b) integrate materials and notices for enrollees. CMS believes this will help individuals better understand their coverage. Further, because Star Ratings are assigned at the contract level, CMS hopes this will lead to greater transparency on the quality ratings for D-SNPs, allowing CMS and States to better identify disparities between dually eligible beneficiaries and other beneficiaries and target interventions accordingly.

CMS also finalized its proposal to codify mechanisms to better coordinate State and CMS monitoring and oversight of D-SNPs when a State has elected to require these additional levels of integration, including granting State access to CMS’s Health Plan Management System (“HPMS”). CMS believes its proposals would improve Federal and State oversight of D-SNPs (and their affiliated MCOs) through greater information-sharing among government regulators.

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

CMS finalized its proposal to require that the MOOP limit in an MA plan (after which the plan pays 100 percent of MA costs for Part A and Part B services) be calculated based on the accrual of all cost-sharing in the plan benefit, regardless of whether that cost-sharing is paid by the beneficiary, Medicaid, other secondary insurance, or remains unpaid (including cost-sharing that remains unpaid because of State limits
on the amounts paid for Medicare cost-sharing and dually eligible individuals’ exemption from Medicare cost-sharing). According to CMS, the change will result in more equitable payment for MA providers serving dually eligible beneficiaries.

CMS acknowledged that the new rule would raise MA bids for basic benefits, especially for D-SNPs and other MA plans with a high percentage of dual eligible enrollees, and thereby potentially reduce rebates available for supplemental benefits to the extent MAOs 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. However, CMS believes that most (if not all) of the added costs for implementation of the new MOOP requirement could be absorbed by reductions in plan profit margins and still allow MAOs to achieve D-SNP profit margins that are comparable to overall MA profit margins.

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

Consistent with the proposed rule, CMS finalized the requirement that MAOs must comply with the special requirements at § 422.100(m) to ensure access for enrollees to covered services throughout a disaster or emergency period as long as there is a disruption of access to healthcare services in the service area, including when the end date is unclear and the declaration has been renewed several times. CMS clarified that a disruption of access occurs when the interruption or interference to accessing healthcare services occurs in the service area under § 422.112(a), including interruptions limited to a specific area such as a county. So long as impacted enrollees are unable to access contracted providers or contracted providers cannot provide needed services, MAOs must comply with the special requirements. MAOs have the initial responsibility to assess whether there is a disruption in access based on the information available regarding access to healthcare services in each service area where a disaster or emergency declaration has been made. CMS also may direct MAOs to comply with the special requirements if it determines enrollees have access problems. The obligation to comply with the special requirements would end 30 days after the latest of the last disaster/emergency declaration is ended (whether state of federal) or there is no longer a disruption to access of health care. CMS notes, however, that MAOs are free to continue the special requirements for a longer period of time if they so choose; the 30-day transition is the minimum requirement.

CMS will issue subregulatory guidance explaining how § 422.100(m) works via both HPMS and the CMS Current Emergencies website as appropriate.

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

To the disappointment of MAOs, CMS finalized its proposal to require MAOs to demonstrate network adequacy as a condition of CMS approval of their initial and service area expansion applications. CMS will reinstitute network adequacy reviews as part of the application process commencing with the CY2024 application cycle. Applicants will receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the
contracted network in the pending service area. The credit will apply at the time of application and for the duration of the application review.

In a change to the proposed rule and contrary to CMS current policy, the Final Rule allows applicants to use a Letter of Intent (“LOI”), signed by both the MAO and the provider or facility with which the MAO has started or intends to negotiate, in lieu of a signed contract at the time of application and for the duration of the application review, to meet network standards. Applicants will be required to notify CMS of their use of LOIs to meet network standards.

At the beginning of the applicable contract year, the credit and the use of LOIs will no longer apply and, if the application is approved, the MAO must be in full compliance with network adequacy, including having signed provider and facility contracts.

Any MAO organization that utilizes LOIs for the application of a new or expanding service area will be required to participate in a triennial network adequacy review by CMS to evaluate compliance with network adequacy standards. The triennial review would occur during the first year the plan is operational in its new service area.


Due to the scope and duration of the COVID–19 public health emergency, CMS adopted a technical change to the 2022 Star Ratings methodology for extreme and uncontrollable circumstances to make it possible for CMS to calculate 2022 Star Ratings for MA contracts. The Final Rule adopts without modification a technical change at § 422.166(i)(12) to enable CMS to calculate 2023 Star Ratings for three Healthcare Effectiveness Data and Information Set measures that are based on the Health Outcomes Survey: Monitoring Physical Activity, Reducing the Risk of Falling, and Improving Bladder Control.


CMS finalized its proposal to include an organization’s record of Star Ratings, bankruptcy issues, and compliance actions in its past performance methodology, which is used to determining whether an organization will be prohibited from expanding or entering into a new contract with CMS. Under the Final Rule, an initial or service area expansion application will denied if, during the 12 months preceding the application deadline, the applicant: (i) failed to maintain a fiscally sound operation in accordance with CMS requirements; (ii) filed for or is currently in State bankruptcy proceedings; (iii) 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; or (iv) met or exceeded 13 points for compliance actions for any one contract.
Points for compliance actions will be assessed as follows:

- A corrective action plan = 6 points
- A warning letter = 3 points
- A notice of noncompliance = 1 point

10. Increasing Plan Oversight of Third-Party Marketing Organizations ("TPMO") and Addressing Other Marketing and Communications Requirements (§§ 422.2260 and 423.2260, 422.2267 and 423.2267, 422.2274 and 423.2274)

CMS finalized its proposed requirements that are intended to increase plan oversight of and accountability for the actions of TPMOs and their subcontractors. The finalized definition of TPMOs is:

[O]rganizations and individuals, including independent agents and brokers, who are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment (the steps taken by a beneficiary from becoming aware of an MA plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § 422.2, but may also be entities that are not FDRs but provide services to an MA plan or an MA plan’s FDR.

The only changes made to the final definition were to include "individuals" as potential TPMOs, and to clarify that agents and brokers are TPMOs.

Under the Final Rule, MAOs and Part D sponsors must require their TPMOs to use a standardized disclaimer on their website and marketing materials, including all print materials and television advertising that meet the definition of marketing.[1] The disclaimer must be provided verbally, electronically, or in writing, depending on how the TPMO is interacting with the beneficiary. Where the TPMO is providing information through telephonic means, the TPMO would be required to provide the disclaimer within the first minute of the call. The disclaimer would not be required if the TPMO offered all plans available in a given service area.

Finally, the Final Rule requires MAOs and Part D sponsors when doing business with a TPMO, either directly or indirectly through a downstream entity, to implement the following as a part of their oversight of TPMOs:

- When a TPMO is not otherwise an FDR,[2] ensure that the TPMO adheres to any requirements that apply to the MA or Part D plan.
- Contracts, written arrangements, and agreements between the TPMO and the MA or Part D plan, or between the TPMO and the plans’ FDR, must ensure the TPMO: (i) discloses to the MAO or Part D sponsor any subcontracted relationships used for marketing, lead generation, and enrollment; (ii) records all calls with beneficiaries in their entirety, including the enrollment process; (iii) reports to plans monthly any staff disciplinary actions or violations of any
requirements that apply to the MA or Part D plan associated with beneficiary interaction to the plan; and (iv) uses the TPMO disclaimer discussed above.

- Ensure that the TPMO, when conducting lead generating activities, either directly or indirectly for the MAO or Part D sponsor, when applicable: (i) disclose to the beneficiary that his or her information will be provided to a licensed agent for future contact. This disclosure must be provided verbally when communicating with a beneficiary through telephone, in writing when communicating with a beneficiary through mail or other paper, and electronically when communicating with a beneficiary through email, online chat, or other electronic messaging platform. (ii) disclose to the beneficiary that he or she is being transferred to a licensed agent who can enroll him or her into a new plan.

11. Greater Transparency in Medical Loss Ratio (“MLR”) Reporting (§§ 422.2460 and 423.2460, 422.2490 and 423.2490)

CMS has reinstated the more detailed MLR reporting requirements that had been in effect for contract years 2014 to 2017, which required reporting of the underlying data used to calculate and verify the MLR and any remittance amount, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, and regulatory fees. The detailed reporting requires MAOs to submit narratives explaining their reported quality improvement activity methodologies—including a line item specifically dedicated to fraud reduction. CMS also updated the MLR Reporting Tool to include separate line items for certain supplemental benefits categories, noting its flexibility to expand or contract the data fields is important to “allow CMS to collect data that is sufficiently detailed to enable us to understand benefit expenditures, verify and increase accountability for the accuracy of MLR calculation and accommodate evolving policy and program needs.”

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

Part D sponsors are required to provide beneficiaries with access to “negotiated prices” for covered Part D drugs. This point-of-sale price is used to calculate beneficiary cost-sharing as well as other program purposes including to determine plan, manufacturer (in the coverage gap), and CMS liability during the course of the payment year, subject to final reconciliation following the end of the coverage year. Consistent with the proposed rule, the Final Rule eliminates the exception for contingent pharmacy price concessions from the definition of “negotiated prices” at 42 C.F.R. § 423.100[3].

Beginning January 1, 2024, the negotiated price is defined as the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor’s intermediary (that is, the amount the pharmacy will receive net of the maximum negative adjustment that could result from any contingent pharmacy payment arrangement and before any
additional contingent payment amounts, such as incentive fees). The new definition of “negotiated price” will apply to all phases of the Part D benefit, including the coverage gap phase. Under the proposed rule, Part D sponsors were given the flexibility whether to apply the new definition to applicable drugs during the coverage gap.

The new definition includes the following:

Negotiated price means prices for covered Part D drugs that meet all of the following: (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug; (i) Includes all price concessions (as defined in § 423.100) from network pharmacies or other network providers; and (ii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices; (2) Is reduced by those discounts, direct or indirect subsidies, rebates, non-pharmacy price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale.

CMS also finalized the definition of the previously undefined term “price concession”, which is used in the definition of negotiated price:

Price concession means any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Examples of price concessions include but are not limited to: Discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.

ENDNOTES

[1] “We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area. Please contact Medicare.gov or 1-800-MEDICARE to get information on all of your options.”

[2] CMS did not clarify in the Final Rule when a TPMO would not be an FDR.

[3] “Negotiated prices” excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale.

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