

# Issue Brief

FEDERAL ISSUE BRIEF • January 7, 2022

## CMS Issues Proposed Notice of Medicare Advantage and Part D Benefit Parameters for 2023

The Centers for Medicare and Medicaid Services (CMS) have issued a proposed rule that would revise the Medicare Advantage (MA) (Part C) program and Medicare Prescription Drug Benefit (Part D) program regulations to implement changes related to marketing and communications, past performance, Star Ratings, network adequacy, medical loss ratio (MLR) reporting, special requirements during disasters or public emergencies, and pharmacy price concessions.

The proposal would also revise regulations related to dual eligible special needs plans (D-SNPs), other special needs plans, and cost contract plans.

CMS says that “an increasing number of Medicare beneficiaries receive services through MA and Part D. Over 27 million beneficiaries are enrolled in MA plans (including plans that offer Part D prescription drug coverage), and approximately 24 million beneficiaries are enrolled in standalone Part D plans.

Additionally, some MA enrollees are concurrently enrolled in Medicaid, with an increasing number of these dually eligible beneficiaries enrolled in Medicare managed care, Medicaid managed care, or both. About 3.7 million dually eligible beneficiaries currently receive their

Medicare services through dual eligible special needs plans (D-SNPs).

Publication is scheduled for January 12. A display copy is at: <https://public-inspection.federalregister.gov/2022-00117.pdf>.

A 60-day comment period ending March 7 is provided.

### COMMENT

There is no table of contents in this proposal. CMS needs to look at the promulgation of its own regs. A table of contents is an absolute requirement to assist the reader. It's time to stop repeating ancient history, and telling us they appreciate comments that agree with the agency's positions.

CMS provides the following table of the proposal's major sections. The material is quoted, except we have added full names to the acronyms. (Page 15)

Once again, we are inserting page numbers to help readers locate more information on pertinent sections.

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Summary of Major Provisions of Rule	Description	Impact
1. Enrollee Participation in Plan Governance (§ 422.107)	We propose to require that any MA organization offering a dual eligible special needs plan (D-SNP) must establish one or more enrollee advisory committees in each State to solicit direct input on enrollee experiences.	There is on average an annual impact of \$0.9 million for establishing and maintaining these advisory committees with however a wide range of variability.
2. Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessments (§ 422.101)	Building on CMS's experience with other programs and model tests, we propose to require that all SNPs include standardized questions on housing stability, food security, and access to transportation as part of their health risk assessments.	For the initial year of implementation, there is an impact on Medicare Advantage special needs plans to update systems. We are unable to reliably estimate the additional burden in subsequent years.
3. Refining Definitions for Fully Integrated and Highly Integrated D- SNPs (§§ 422.2 and 422.107)	We propose to require, for 2025 and subsequent years, that all Fully Integrated Dual Eligible Special Needs Plans (FIDE SNPs) have exclusively aligned enrollment, as defined in § 422.2, and cover Medicaid home health, durable medical equipment, and behavioral health services through a capitated contract with the State Medicaid agency. We propose to require that each (Highly Integrated Dual Eligible (HIDE) SNP's capitated contract with the State apply to the entire service area for the D-SNP for plan year 2025 and subsequent years. Consistent with existing policy outlined in sub-regulatory guidance, we also propose to codify specific limited benefit carve-outs for FIDE SNPs and HIDE SNPs.	There is a one-time impact to update contracts.
4. Additional Opportunities for Integration through State Medicaid Agency Contracts (§ 422.107)	We propose to codify new pathways through which States can use the State Medicaid agency contracts to require that certain D-SNPs with exclusively aligned enrollment (a) apply and request to establish contracts that only include one or more D-SNP within a State, and (b) integrate materials and notices for enrollees. We also propose mechanisms to better coordinate State and CMS monitoring and oversight of certain D- SNPs when a State has elected to require these additional levels of integration, including granting State access to certain CMS information systems.	There is a one-time \$1.1 million impact shared among the Federal Government, State governments, and MA organizations to create new contracts and to update systems to review the new materials.
5. Attainment of the Maximum Out-of- Pocket Limit (MOOP) (§§ 422.100 and 422.101)	We propose to specify that the maximum out-of-pocket limit in an MA plan (after which the plan pays 100 percent of MA costs) is calculated based on the accrual of all cost-sharing in the plan benefit, whether that cost sharing is paid by the beneficiary, Medicaid, other secondary insurance, or remains unpaid because of State limits on the amounts paid for Medicare cost-sharing and dually eligible individuals' exemption from Medicare cost-sharing.	The proposal would increase Medicare spending by \$3.9 billion over 10 years. That cost is partially offset by lower Federal Medicaid spending of \$2.7 billion and the portion of Medicare spending paid by beneficiary Part B premiums, which totals \$600 million over 10 years. The net 10-year cost estimate for the proposal is \$614.8 million.
6. Special Requirements during a Disaster or Emergency (§ 422.100(m))	This proposal would clarify the period of time during which MA organizations must comply with the special requirements to ensure access for enrollees to covered services throughout a disaster or emergency (including Public Health Emergency (PHEs)) periods, especially when the end date is unclear and the period renews several times. We also propose an additional condition, that there is a disruption in access to health care for enrollees, for triggering the special requirements imposed by § 422.100(m)(1).	None anticipated.
7. Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application (§ 422.116)	We are proposing to amend § 422.116 to require an applicant to demonstrate compliance with network adequacy standards as part of the MA application process for new and expanding service areas and to adopt a time-limited 10 percentage point credit toward meeting the applicable network adequacy standards for the application evaluation.	None anticipated.
8. Allow CMS to Calculate Star Ratings for Certain Measures for 2023 Given Impacts of the COVID-19 Public Health Emergency (§ 422.166)	We propose making a technical change at § 422.166(i)(12) to enable CMS to calculate 2023 Star Ratings for three Healthcare Effectiveness Data and Information Set measures that are based on the Health Outcomes Survey.	None anticipated.

Summary of Major Provisions of Rule	Description	Impact
9. Past Performance Methodology to Better Hold Plans Accountable for Violating CMS Rules (§§ 422.502 and 422.503)	We are proposing to include Star Ratings, bankruptcy issues, and compliance actions in our methodology going forward.	None anticipated.
10. Marketing and Communications Requirements on MA and Part D Plans to Assist Their Enrollees (§§ 422.2260 and 423.2260, 422.2267 and 423.2267, 422.2274 and 423.2274)	<p>Through rulemaking, we will address the concerns with Third-Party Marketing Organizations (TPMOs) by means of proposed updates to the communications and marketing requirements under 42 CFR parts 422 and 423, subpart V.</p> <p>We propose to require MA and Part D plans to create a multi-language insert that would inform the reader, in the top fifteen languages used in the U.S., that interpreter services are available for free. We propose to require the inclusion of the multilanguage insert whenever a Medicare beneficiary is provided a CMS required material as defined under §§ 422.2267(e) and 423.2267(e).</p> <p>Lastly, we propose codifying a number of current sub-regulatory communications and marketing requirements.</p>	There is an annual impact of \$0.3 million to print the multi-language insert.
11. Greater Transparency in Medical Loss Ratio Reporting (§§ 422.2460, 422.2490, and 423.2460)	To improve transparency and oversight concerning the use of Trust Fund dollars, we are proposing to reinstate the detailed MLR reporting requirements that were in effect for contract years 2014–2017, which required reporting of the underlying data used to calculate and verify the MLR and any remittance amount. In addition, we are proposing the collection of additional details regarding plan expenditures so we can better assess the accuracy of MLR submissions, the value of services being provided to enrollees, and the impacts of recent rule changes.	Medicare Advantage organizations and Part D sponsors are expected to pay an additional \$268.6 million in remittances to the Treasury over a 10-year period. There is an annual additional \$2.3 million administrative cost to MA organizations and Part D sponsors for complying with these provisions, as well as a \$0.2 million cost to the government for Federal contractors.
12. Pharmacy Price Concessions to Drug Prices at the Point of Sale (§ 423.100)	We are proposing to eliminate the exception for pharmacy price concessions that cannot reasonably be determined at the point of sale. We are also proposing to delete the existing definition of “negotiated prices” at § 423.100 and to adopt a new definition for the term “negotiated price” at § 423.100, which we are proposing to define as the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor’s intermediary. Lastly, we are proposing to add a definition of “price concession” at § 423.100.	Requiring pharmacy price concessions in the negotiated price is expected to reduce beneficiary costs by \$21.3 billion over 10 years, or approximately 2 percent. In addition, the proposal is estimated to have \$40 billion in Part D costs for the government over 10 years due to increases in direct subsidy and low-income premium subsidy payments, which represents a 3 percent increase. Manufacturers would save about \$14.6 billion over 10 years. We expect a one-time cost to plan sponsors of \$0.1 million to update systems.

## Major Sections of the Proposal

### A. Improving Experiences for Dually Eligible Individuals (Page 19)

Overall, this is an extremely long section, some 125 pages, and represents more than a third of the proposal.

CMS provides the following table that summarizes how its proposals relate to Medicare and Medicaid Plan (MMP) policies. (Page 33)

Proposals that Would Apply MMP Features into D-SNPS

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

**Proposal for D-SNP Enrollee Advisory Committees** (Page 38)

CMS proposes at § 422.107(f) that any MA organization offering one or more D-SNPs in a State must establish and maintain one or more enrollee advisory committees to solicit direct input on enrollee experiences. CMS also propose at § 422.107(f) that the committee include a reasonably representative sample of individuals enrolled in the D-SNP(s) and solicit input on, among other topics, ways to improve access to covered services, coordination of services, and health equity for underserved populations.

**Standardizing Housing, Food Insecurity, and Transportation Questions on Health Risk Assessment (HRAs) (§ 422.101)** (Page 44)

CMS proposes to amend § 422.101(f) (1)(i) to require that all SNPs (chronic condition special needs plans, D-SNPs, and institutional special needs plans) include one or more standardized questions on the topics of housing stability, food security, and access to transportation as part of their HRAs.

**Refining Definitions for Fully Integrated and Highly Integrated D-SNPs (§§ 422.2 and 422.107)** (Page 52)

(a). CMS proposes to amend the definition of “fully integrated dual eligible special needs plan” at § 422.2 with a new paragraph (5) that requires for 2025 and subsequent years, that all FIDE SNPs have exclusively aligned enrollment.

(b). CMS proposes to specify in § 422.2 that FIDE SNPs are required to cover Medicare cost sharing as defined in section 1905(p)(3) (B), (C) and (D) of the Act, without regard to how section 1905(n) limits that definition to qualified Medicare beneficiaries (QMBs), as part of the FIDE SNP's coverage of primary and acute care; this means that the proposed amendment would require FIDE SNPs to cover Medicare cost-sharing for both QMB and non-QMB full-benefit dually eligible FIDE SNP enrollees.

(c). CMS proposes to require that, effective beginning in 2025, each FIDE SNP must cover additional Medicaid benefits to the full extent that those benefits are covered by the State Medicaid program. CMS is proposing to add home health services, as defined in § 440.70, and durable medical equipment (DME) services, as defined in § 440.70(b)(3).

CMS proposes to establish in a new paragraph (2)(iii) in the FIDE SNP definition at § 422.2 requiring that, for 2025 and subsequent years, the capitated contract with the State Medicaid agency must include coverage of Medicaid behavioral health services.

(d). CMS proposes to update the HIDE SNP definition at § 422.2 consistent with proposed changes to the FIDE SNP definition to more clearly outline the services HIDE SNPs must include in their contracts with State Medicaid agencies.

(e). CMS proposes to codify at § 422.107(g) and (h), respectively, current CMS policy allowing limited carve-outs from the scope of Medicaid LTSS and Medicaid behavioral health services that must be covered by FIDE SNPs and HIDE SNPs.

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

***Additional Opportunities for Integration through State Medicaid Agency Contracts (§ 422.107) (Page 82)***

CMS proposes a new paragraph (e) at § 422.107 to describe conditions under which CMS would facilitate compliance with certain contract terms that States require of D-SNPs that operate in the State. Proposed paragraph (e)(1) provides that CMS will take the steps described in proposed paragraphs (e)(2) and (3) when a State Medicaid agency's contracts with D-SNPs require exclusively alignment enrollment and require the D-SNPs to request MA contracts that only include one or more State-specific D-SNPs and that such D-SNPs use integrated member materials. CMS says it does not believe that proposed paragraph (e)(1), in and of itself, creates or limits opportunities already available to States to contract with D-SNPs. The primary purpose of proposed paragraph (e)(1) is to establish a pathway for States with parameters for how CMS will work with the State when the State wishes to require D-SNPs with exclusively aligned enrollment in that State to operate under D-SNP-only MA contracts and use specific integrated enrollee materials.

***Definition of Applicable Integrated Plan Subject to Unified Appeals and Grievances Procedures (§ 422.561) (Page 107)***

CMS proposes to expand the universe of D-SNPs for which the unified appeals and grievance processes apply.

***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)) (Page 109)***

CMS proposes 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;

*continued*

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.

**Requirements to Unify Appeals and Grievances for Applicable Integrated Plans (§§ 422.629, 422.631, 422.633, and 422.634) (Page 116)**

CMS proposes to revise § 422.629(d) to require that, as part of its responsibilities pertaining to an enrollee's presenting evidence for an integrated grievance or appeal, an applicable plan provide an enrollee with information on how evidence and testimony should be presented to the plan.

CMS proposes to revise paragraph (l)(1)(i) to list the enrollee and to revise paragraph (l)(1)(ii) to list the enrollee's representative, including any person authorized under State law.

**Attainment of the Maximum Out-of-Pocket (MOOP) Limit (§§ 422.100 and 422.101) (Page 127)**

CMS is proposing to specify that the MOOP limit in an MA plan (after which the plan pays 100 percent of MA costs) is calculated based on the accrual of all Medicare cost-sharing in the plan benefit, whether that Medicare cost-sharing is paid by the beneficiary, Medicaid, or other secondary insurance, or remains unpaid because of state limits on the amounts paid for Medicare cost-sharing and dually eligible individuals' exemption from Medicare cost-sharing. CMS projects that the change would save state Medicaid agencies \$2 billion over ten years while increasing payment to providers serving dually eligible beneficiaries by \$8 billion over ten years.

***B. Special Requirements during a Disaster or Emergency (§ 422.100(m)) (Page 141)***

CMS is proposing to revise and clarify timeframes and standards associated with disasters and emergencies. Current regulations have special requirements for MA plans during disasters or emergencies, including requirements for plans to cover services provided by non-contracted providers and to waive gatekeeper referral requirements. The proposal would require a MA plan to comply with the special requirements when there is a declaration of disaster or emergency (including a public health emergency) and disruption in access to health care.

***C. Amend MA Network Adequacy Rules by Requiring a Compliant Network at Application (§ 422.116) (Page 158)***

CMS is proposing to require that plan applicants demonstrate they have a sufficient network of contracted providers to care for beneficiaries before CMS will approve an application for a new or expanded MA plan. CMS says it believes that requiring applicants to demonstrate compliance with network adequacy standards as part of the application process will strengthen oversight of an organization's ability to provide an adequate network of providers to deliver care to MA enrollees. This change would also provide MA organizations with information regarding their network adequacy ahead of bid submissions, mitigating current issues with late changes to the bid that may affect the bid pricing tool. Due to the proposed changes in the timing of the network adequacy reviews and potential difficulties MA organizations may face with building a full network almost one year in advance of the contract year, CMS also proposes to allow a 10-percentage point credit toward the percentage of beneficiaries residing within published time and distance standards for new or expanding service area applicants.

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Once the coverage year start (January 1), the 10-percentage point credit would no longer apply and plans would need to meet full compliance.

#### ***D. Part C and Part D Quality Rating System*** (Page 164)

CMS is proposing a technical change to enable CMS to calculate 2023 Part C Star Ratings for the three Healthcare Effectiveness Data and Information Set (HEDIS) measures collected through the Health Outcomes Survey (HOS): Monitoring Physical Activity, Reducing the Risk of Falling, and Improving Bladder Control. Without this technical change, CMS would be unable to calculate 2023 Star Ratings for these measures for any MA contract since all contracts qualify for the extreme and uncontrollable circumstances adjustment for COVID-19.

CMS proposes to amend § 422.166(i) to specifically address the 2023 Star Ratings, for measures derived from the 2021 health outcomes survey (HOS), by adding § 422.166(i)(12) to remove the 60 percent rule for affected contracts.

#### ***E. Past Performance*** (§§ 422.502, 422.504, 423.503, and 423.505) (Page 168)

CMS is proposing additional bases for denying a new contract or service area expansion of an existing contract based on past performance. The current regulations permit CMS to deny applications from organizations under sanction or failing CMS' net worth requirements during the performance period.

The proposed rule adds Star Ratings (2.5 or lower), bankruptcy or bankruptcy filings, and exceeding a CMS designated threshold for compliance actions as bases for CMS denying a new application or a service area expansion application.

#### ***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) (Page 177)

CMS is proposing changes to marketing and communications requirements that “will protect Medicare beneficiaries” by ensuring they receive accurate and accessible information about Medicare coverage. These include strengthening oversight of third-party marketing organizations to detect and prevent the use of deceptive marketing tactics to enroll beneficiaries in MA and Part D plans, reinstating the inclusion of a multi-language insert in specified materials to inform beneficiaries of the availability of free language and translation services, codifying enrollee ID card standards, requirements related to a disclaimer for limited access to preferred cost sharing pharmacies, plan website instructions on how to appoint a representative, and website posting of enrollment instructions and forms.

#### ***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) (Page 187)

CMS is proposing to reinstate MLR reporting requirements that were in effect for contract years 2014 – 2017. The current regulations require that MA organizations and Part D sponsors report to CMS the percentage of revenue spent on patient care and quality improvement and the amount of any remittance that must be paid to CMS for failure to meet the 85 percent minimum MLR requirement. This proposal would require MA organizations and Part D sponsors to report the underlying cost and revenue information needed to calculate and verify the MLR percentage and remittance amount, if any. In addition, CMS proposes to require that MA organizations report the amounts they spend on various types of supplemental

*continued*

Analysis provided for MHA  
by Larry Goldberg,  
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benefits not available under original Medicare (e.g., dental, vision, hearing, transportation).

#### ***H. Pharmacy Price Concessions in the Negotiated Price (§ 423.100) (Page 212)***

CMS is proposing a policy that would require Part D plans to apply all price concessions they receive from network pharmacies to the point of sale, so that the beneficiary can also share in the savings. Specifically, CMS is proposing to redefine the negotiated price as the baseline, or lowest possible, payment to a pharmacy, effective January 1, 2023. “This policy would reduce beneficiary out-of-pocket costs and improve price transparency and market competition in the Part D program.”

#### **Requests for Information (Page 238)**

The proposal is seeking comments on:

Prior Authorization for Hospital Transfers to Post-Acute Care Settings during a Public Health Emergency  
Building Behavioral Health Specialties within MA Networks  
Data Notification Requirements for Coordination-Only D-SNPs (§ 422.107(d))

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#### **FINAL THOUGHTS**

**This proposal’s regulatory and regulation text extend nearly 80 pages.**

**CMS appears to suggest that the changes being proposed would be minimally invasive. However, the extensiveness of the material suggests otherwise. For those potentially impacted, the need for in-depth review is obvious.**

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