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CMS Proposes CY 2026 Changes to Medicaid Advantage and Part D to Allow Access to Anti-Obesity Medications, Enhance Patient Care, and Promote Health Equity

On November 26th, the Centers for Medicare & Medicaid Services (CMS) released its Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly proposed rule, which contains proposed policies for Medicare Advantage (MA) and Medicare Part D plans in contract year (CY) 2026. See the press release here and the fact sheet here. In this rule, CMS proposes to:

- Reinterpret existing policies to allow Medicare Part D coverage of Anti-Obesity Medications (AOMs) for beneficiaries diagnosed with obesity. This reinterpretation would also extend to Medicaid coverage,
- Codify Part D provisions in the Inflation Reduction Act (IRA) eliminating cost-sharing for adult vaccines and restricting cost-sharing for a one-month supply of insulin,
- Implement regulatory changes to codify agency guidance implementing the Medicare Prescription Payment Plan,
- Establish new Part D policies to promote pharmacy transparency and minimize disruptions in care,
- Modify regulations governing internal coverage criteria to improve patient access to care under MA,
- Implement guardrails for use of artificial intelligence to prevent inequitable care and/or bias in MA,
- Update MA plans' health equity analyses of utilization management policies in alignment with feedback received in response to the CY 2025 proposed rule,
- Modify behavioral health cost-sharing standards for MA and Cost Plans to ensure equitable access to behavioral health benefits,
- Change MA and Part D medical loss ratio (MLR) requirements to align with commercial and Medicaid MLR requirements,
- Implement policies aimed at integrating care for dually-eligible individuals, and

- Establish requirements for the proper administration of supplemental benefits coverage.

Additionally, CMS clarifies that Part D plans must provide beneficiaries with broad access to generics, biosimilars, and other low-cost drugs to remain compliant with statutory requirements. The agency seeks feedback on how manufacturer rebates affect formulary decisions that restrict access to these drugs and whether additional measures are needed to prevent Part D formularies from excluding or disadvantaging them.

This proposed rule is scheduled to be published in the *Federal Register* on December 10, 2024. Comments are due January 27, 2025.

CMS PROPOSES REINTERPRETATION OF STATUTORY WEIGHT LOSS EXCLUSION TO ALLOW PART D COVERAGE OF ANTI-OBESITY MEDICATIONS

CMS proposes a reinterpretation of the statutory exclusion from coverage of "agents when used for weight loss" to allow Medicare Part D coverage of Anti-Obesity Medications (AOMs) for individuals diagnosed with obesity. Currently, AOMs are excluded from Part D because they are classified as weight loss drugs, which do not meet the statutory definition for coverage. However, CMS recognizes that obesity is a chronic disease, and its understanding of obesity has evolved since the inception of Part D. This reinterpretation aims to align Part D coverage with modern medical understanding, recognizing that AOMs are not merely for weight loss but are critical in managing a chronic disease with wide-ranging health implications.

The proposed change would allow AOMs to be covered under Part D when prescribed for the treatment of obesity, defined by a Body Mass Index (BMI) of 30 or greater, regardless of the underlying causes of the condition. This is a shift from the current policy, which only covers AOMs when prescribed for other FDA-approved uses, such as for diabetes or cardiovascular disease. To ensure that these medications are accessible to individuals with obesity and are not restricted by overly stringent utilization management policies, CMS is also proposing to review Part D plan sponsors' prior authorization (PA) criteria.

This reinterpretation would also apply to the Medicaid program, meaning that state Medicaid programs would no longer have the discretion to exclude AOMs from Medicaid drug coverage when used for weight loss or to maintain weight loss to treat obesity. If the agency's reinterpretation is finalized as proposed, states that are not already covering AOMs for weight loss or to maintain weight loss would be required to do so to treat obesity in Medicaid enrollees with obesity.

CMS CLARIFIES THAT PART D PLANS MUST PROVIDE BROAD ACCESS TO GENERICS, BIOSIMILARS, AND OTHER LOW-COST DRUGS TO BE COMPLIANT WITH STATUTE

Section 1860D-49(c)(1)(A) of the Social Security Act requires plan sponsors to have a cost-effective drug utilization management program that includes incentives to reduce costs when medically appropriate, such as through the use of generics and biosimilars. This requirement is codified in regulation at 42 CFR § 423.153(b). CMS has identified multiple recent reports, actions, and findings published or taken by external entities that indicate Part D sponsors, and their pharmacy benefit managers (PBMs), engage in practices that favor, either intentionally or unintentionally, higher-cost brand-name drugs and reference biologics over generics, biosimilars, and other lower-cost drugs in terms of formulary placement. CMS specifically cites a March 2022 HHS Office of Inspector General OIG report, "Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions with Increased Biosimilar Use,"[1] the July 2024 Federal Trade Commission (FTC) report, "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies,"[2] and the September 2024 Administrative Complaint from the FTC against PBMs and other related entities[3].

Based on these findings, CMS is concerned about the potential for higher out-of-pocket (OOP) costs for Medicare beneficiaries and non-compliance with Part D requirements and clarifies that plans must provide beneficiaries with broad access to generics, biosimilars, and other lower-cost drugs to be compliant with statute. CMS states that broad access refers to tier placements and utilization management requirements, not only formulary inclusion. CMS also plans to add an additional step to its formulary review process, where the agency will confirm that Part D sponsors provide broad access to generics, biosimilars, and other lower costs drugs. CMS will also monitor and assess plans' inclusion of these products on formularies.

The agency seeks feedback on two topics: 1) the prevalence of manufacture rebates and the extent to which these rebates impact formulary decisions that reduce Part D beneficiaries' access to generics, biosimilars, and other lower cost drugs; and 2) whether programmatic actions within CMS's existing statutory authority are needed to Prevent Part D formularies from excluding or disfavoring generic, biosimilar, and other lower cost drug coverage. Based on stakeholder input, CMS may take additional steps in future rulemaking or guidance to promote broader access to these drugs.

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[1] https://oig.hhs.gov/reports/all/2022/medicare-part-d-and-beneficiaries-could-realize-significant-spending-reductions-with-increased-biosimilar-use/

[2] https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf

[3] https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices

AGENCY PROPOSES CODIFICATION OF IRA PROVISIONS ELIMINATING COST-SHARING FOR ADULT VACCINES UNDER PART D

CMS proposes to implement and codify provisions from the IRA that eliminate cost-sharing for adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) under Medicare Part D starting in 2026 and for each subsequent plan year. These vaccines must be licensed by the Food & Drug Administration (FDA) for use by adults and administered in accordance with ACIP recommendations. Enrollees will not have any OOP costs for such vaccines, including associated fees like sales tax, dispensing fees, or administration charges. CMS clarifies that cost-sharing rules apply regardless of whether vaccines are in-network or out-of-network, newly recommended midyear, or obtained through formulary exceptions. Part D sponsors must reimburse beneficiaries fully for OOP payments for these vaccines, using the full cash price for reporting purposes.

CMS defines "ACIP-recommended adult vaccine" comprehensively to include vaccines listed on the ACIP Adult Immunization Schedule or recommended under separate guidelines for specific populations or circumstances, such as travel vaccinations. Part D sponsors can place these vaccines on any formulary tier and use utilization management strategies to ensure appropriate usage aligned with ACIP recommendations, but the agency emphasizes that these strategies must not affect the statutory zero-cost-sharing requirement.

Since the cost-sharing limits for vaccines have been in place since 2023 under program instruction authority, and CMS has annually reviewed cost-sharing in plan benefit package submissions, the agency believes the proposed codification of these requirements will have minimal impact on Part D sponsors and beneficiaries.

AGENCY PROPOSES TO CODIFY IRA PROVISIONS RESTRICTING PART D COST-SHARING FOR A ONE-MONTH SUPPLY OF INSULIN

CMS proposes to codify the requirements related to cost-sharing for covered insulin products under Medicare Part D, as required by the IRA, for 2026 and each subsequent plan year. Effective for plan years beginning on or after January 1, 2023, the Medicare Part D deductible will not apply to covered insulin, and the cost-sharing for a one-month supply of a covered insulin product will be capped at $35 for 2023, 2024, and 2025.

For 2026 and beyond, CMS proposes that the cost-sharing for a one-month supply of insulin will be limited to the lesser of $35, 25 percent of the maximum fair price (MFP) established for the product, or 25 percent of the negotiated price. These cost-sharing limits will apply separately to each prescription fill. For prescriptions longer than one month, cost-sharing will be calculated on a cumulative basis, using the smallest number of one-month increments.

A "covered insulin product" is defined as an FDA-licensed insulin product, including those that combine multiple types of insulin or combine insulin with non-insulin drugs. However, compounded insulin products are not covered under these regulations.

CMS PROPOSES CODIFICATION OF PROGRAM GUIDANCE FOR THE IRA'S MEDICARE PRESCRIPTION PAYMENT PLAN WITH SOME MODIFICATIONS

Section 11202 of the IRA establishes the Medicare Prescription Payment Plan (MPPP) which requires each PDP sponsor offering a prescription drug plan and each MA organization offering an MA-PD plan to offer enrollees, including those eligible for subsidies, the option to pay their cost-sharing in monthly capped amounts for each plan year. After considering public comments on its draft guidances, CMS issued two final guidance documents to implement the MPPP for 2025. The first[4], released on February 29, 2024, focused on operational requirements, while the second[5], issued on July 16, 2024, addressed Part D enrollee education, outreach, and communications. CMS now proposes to codify the requirements from these two guidance documents for 2026 and beyond. In addition, CMS makes several proposed modifications to its guidance, such as:

- **Grace Period and Notice of Non-Payment:** Under the final Part One guidance[4], CMS stated that the grace period would begin either on the first day of the month in which the balance is unpaid or the first day of the month following the payment request, whichever is later. In this proposed rule, CMS proposes to adjust the start date for the grace period to the first day of the month following the date the initial notice is sent.
- **Adjustments to Part D Claims:** In the final Part One guidance[4], CMS required plans to work with participants to either refund overpayments or apply them to remaining OOP costs. In this proposed rule, the agency proposes to modify that requirement to allow a plan to follow its normal processes for adjustments and issuing refunds. Additionally, CMS proposes that when adjustments increase the amount owed by the participant, plans "must" include the additional costs in the revised OOP balance, rather than "should" as previously stated.

CMS also proposes several new requirements:

- **Renewal Process and Notice:** CMS proposes an automatic renewal system in which participants will be automatically renewed in the MPPP unless they choose to opt out, eliminating the need for new paperwork each year. Additionally, CMS proposes to require that sponsors send renewal notices at the end of the Annual Election Period (no later than December 7th) informing enrollees that their participation will continue unless they opt out for the upcoming year.

[4] https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-one-guidance.pdf
[5] https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-two-guidance.pdf

- **Effective Date of Voluntary Terminations:** CMS proposes to maintain the requirement for Part D sponsors to send the notice of voluntary termination within 10 calendar days of receipt. However, the agency proposes to require that the effective date of termination must be within 24 hours of receipt of the voluntary termination request.
- **Pharmacy Access to Part D Enrollee's OOP Costs:** CMS proposes requirements for Part D sponsors to ensure that pharmacies can easily access information on a Part D enrollee's OOP costs for the MPPP for prescriptions processed under the program at the point of sale (POS). Specifically, CMS proposes that these costs be included in the paid claim billing response of the MPPP Coordination of Benefits (COB) transaction. Additionally, Part D sponsors must ensure that pharmacies are equipped to provide this information to participants at the POS.

CMS invites comments on these proposed changes concerning the MPPP.

CMS PROPOSES POLICIES TO PROMOTE TRANSPARENCY FOR PHARMACIES AND MINIMIZE DISRUPTIONS IN CARE

CMS proposes two new provisions in an effort to prevent instability in pharmacy networks and to promote better service to Part D beneficiaries. These provisions focus on increasing transparency in pharmacy network contracts and requiring Part D sponsors to allow pharmacies to terminate network contracts without cause if sufficient notice is given.

The first provision would require Part D plans (including first tier, downstream, or related entities, such as PBMs, acting on the Part D sponsors' behalf) to notify network pharmacies which plans the pharmacies will be in-network with for a given plan year by October 1 of the year prior to that plan year. Additionally, CMS proposes to require sponsors to provide pharmacies with a list of these plans to network pharmacies on request after October 1.

The second provision would require Part D sponsors, including those acting on the Part D sponsors' behalf, to allow pharmacies to terminate their network contracts without cause after providing the same notice that the contract requires the sponsor to provide the pharmacy.

CMS solicits comment on these proposals and notes that it does not expect that these proposals to have an economic impact on the Medicare Trust Fund.

TO IMPROVE PATIENT ACCESS, CMS PROPOSES TO ENHANCE RULES ON INTERNAL COVERAGE CRITERIA

In the CY 2024 MA and Part D final rule, CMS codified regulations at 42 CFR at § 422.101(b)(2) clarifying that the statute and regulations defining the scope of coverage in fee-for-service (FFS) Medicare also apply to MA organizations when setting their coverage benefits. To align more closely with FFS Medicare, CMS also established guardrails focused on MA organizations' development and use of internal coverage criteria, which is used when Traditional Medicare coverage criteria are not fully established. CMS codified requirements that determine when

MA organizations may use internal coverage criteria, what the criteria must be based on, and rules for making this coverage criteria accessible to the public. Since these rules went into effect on January 1, 2024, CMS has received many questions, indicating confusion related to some of the internal coverage criteria policies. As such, CMS is proposing changes to the definition of the phrase "internal coverage criteria", the addition of guardrails for patient access, and more specific rules regarding the posting of MA internal coverage criteria content on plan websites.

Defining Internal Coverage Criteria

In the CY 2024 Final Rule, CMS identified instances where using internal coverage criteria is appropriate. CMS intended for this to mean that MA organizations could supplement or interpret the plain language of existing and applicable Medicare coverage and benefit criteria when needed, but only if the additional criteria prioritize patient safety and outweigh any potential risks. However, noting that further clarification is needed, CMS proposes to add language to the regulatory text to make it clear that internal coverage criteria may only be used to supplement or interpret already existing content in Medicare coverage and benefit rules. This internal coverage criteria cannot be used to add new, unrelated coverage criteria for an item or service with existing but not fully established coverage policies.

CMS did not define "internal coverage criteria" in the CY 2024 Final Rule and has since found that MA organizations are interpreting this term differently. To provide clarity, CMS proposes to define internal coverage criteria as "any policies, measures, tools, or guidelines, whether developed by an MA organization or a third party, that are not expressly stated in applicable statutes, regulations, NCDs, LCDs, or CMS manuals and are adopted or relied upon by an MA organization for purposes of making a medical necessity determination at § 422.101(c)(1)." CMS also provides further clarifications, including a non-exhaustive list of types of internal coverage criteria it has observed being used, and distinctions for aspects of MA plan coverage that do not qualify as internal coverage criteria under the proposed definition.

Guardrails to Protect Patient Access

CMS proposes two requirements that prohibit the use of internal coverage criteria as guardrails for patient access. Under the first proposal, a coverage criterion would be prohibited when it does not have any clinical benefits, and therefore, exists to limit utilization. Internal clinical criteria would be required to have a value that contributes to the determination of whether a benefit is reasonable and necessary under statute. Under the second proposal, use of an internal coverage criterion to automatically deny coverage of basic benefits without an individual medical necessity determination would be prohibited. For example, certain blanket policies that automatically deny access to a covered benefit in every circumstance would violate this rule.

Making Internal Coverage Policies Publicly Accessible

As finalized in the CY 2024 Final Rule, MA organizations using internal coverage policies must provide the internal coverage criteria in use, a summary of evidence that was considered during the development of the criteria, a list of sources of evidence, and an explanation of the rationale supporting internal coverage criteria use. This information must be publicly

accessible, but CMS has not specified how MA organizations must meet these requirements beyond noting that it could be posted on plan websites. In this rule, CMS proposes additional public accessibility requirements to make it easier to understand and locate this information.

TO INCREASE EQUITABLE ACCESS TO MA SERVICES, CMS PROPOSES GUARDRAILS FOR ARTIFICIAL INTELLIGENCE USE

In October 2023, the Biden-Harris Administration released an Executive Order (EO), "Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence."[6] This EO directs agencies to ensure that artificial intelligence (AI) tools do not impede the advancement of equity and civil rights, and that their use within health care organizations does not deny equal opportunities and justice. Citing the growing use of AI in the healthcare sector, including AI-based patient care decision-support tools, vision transformed-based AI methods for lung cancer imaging applications, and AI and machine learning based decision-support systems in mental health care settings, CMS believes it is necessary to ensure that AI use does not result in inequitable treatment and/or bias, and is instead used to enhance access to care and person-centered care. CMS specifically cites instances where AI has the potential to exacerbate inequities. As such, CMS proposes to revise current regulations to require MA plans to ensure their services are provided equitably, regardless of whether the services are provided by humans or automated systems. CMS also reiterates that if an MA plan uses AI or automated systems, it must comply with existing relevant laws and regulations related to ensuring equitable access to services and non-discrimination.

CMS PROPOSES CHANGES TO PLANS' HEALTH EQUITY ANALYSES OF UTILIZATION MANAGEMENT POLICIES, ALIGNED WITH FEEDBACK ON CY 2025 PROPOSED RULE

In the CY 2025 MA and Part D Final Rule, CMS finalized policies requiring MA plans to conduct an annual health equity analysis of their use of PA, based on specific metrics outlined in the rule.[7] The analysis assesses the impact of PA on enrollees with at least one specified social risk factor (SRF), at the plan level, comparing metrics related to the use of PA for enrollees with specified SRFs to those without. Currently, metrics are reported in the aggregate for all items and services. Drugs are excluded from this analysis.

Comments on the CY 2025 MA and Part D Proposed Rule noted concerns that aggregated metrics would not provide an adequate level of detail and could allow plans to hide disparities. When the rule was issued, CMS believed that establishing baseline data was valuable because there was limited publicly available data on the use of PA and its impact on specific

[6] https://www.federalregister.gov/documents/2023/11/01/2023-24283/safe-secure-and-trustworthy-developmentand-use-of-artificial-intelligence

[7] See pages 245-246 of the unpublished proposed rule for the list of metrics.

populations. CMS now proposes to require the metrics to be reported by each item and service, rather than in the aggregate, which will allow CMS and MA organizations to better identify trends related to the use of PA and address the impacts on enrollees with the specified SRFs. The agency seeks feedback on alternative ways to group items and services for the purposes of reporting these metrics, while still allowing for meaningful disaggregation. Additionally, while CMS does not anticipate privacy issues, out of an abundance of caution, CMS seeks feedback on including a provision to allow for suppression of certain data points if disaggregation may pose concerns for enrollee privacy (e.g., small data sets).

Plans are required to make their health equity analyses publicly available. To increase the public's understanding of this data, CMS proposes requiring these analyses to include executive summaries with specific elements intended to improve understanding of key information. CMS also seeks feedback on how data produced in analyses could be formatted to foster usability by the public and enrollees.

Lastly, CMS seeks feedback on whether to add "having a mental health or substance use disorder diagnosis" to the list of SRFs that MA plans must use when conducting analyses.

CMS PROPOSES STANDARDS TO ENSURE EQUITABLE ACCESS TO BEHAVIORAL HEALTH BENEFITS

In an effort to improve access to behavioral health care, CMS proposes to require MA and Cost Plans' in-network cost sharing for behavioral health services be no greater than that in Traditional Medicare. These proposed behavioral health cost-sharing standards strike a balance between improving affordability in a timely manner and minimizing disruption to enrollees' coverage options and access to care. These proposed standards include:

- A 20 percent coinsurance or an actuarially equivalent copayment limit for outpatient substance abuse services, partial hospitalization/intensive outpatient services, psychiatric services, and mental health specialty services,
- Zero cost sharing for opioid treatment program services, and
- Coverage of 100 percent of estimated FFS Medicare cost sharing for inpatient hospital psychiatric services (current standard is 100 to 125 percent of estimated Medicare FFS cost sharing).

CMS is seeking comment on implementation of these proposals, including:

- Whether CMS should enact these proposed changes beginning in CY 2026 or 2027,
- The need for a transition period from existing behavioral health cost-sharing standards to the proposed standard for certain behavioral health service categories, and
- The length of time needed for any transition.

CMS assumes, from an aggregate perspective, that this proposal will not result in significant losses for MA organizations nor additional out of pocket costs for MA enrollees, compared to

Traditional Medicare beneficiaries, due to the requirement for MA organizations to submit bids that are at least actuarially equivalent to Traditional Medicare coverage.

CMS PROPOSES POLICIES TO ENCOURAGE COMMUNITY-BASED SERVICES AND IMPROVE TRANSPARENCY OF IN-HOME SERVICE CONTRACTORS

CMS highlighted concerns that some entities providing covered benefits may not be included in an MA organization's provider directory. To support increased individual protections and transparency regarding such supplemental benefit service providers, CMS proposes to:

- Codify definitions of community-based organizations (CBOs) and in-home or at-home supplemental benefit providers, and direct furnishing entities,
- Require plans to identify, within the provider directory, which providers and direct furnishing entities meet the proposed definition of a CBO,
- Require plans to identify in-home or at-home supplemental benefit providers and direct furnishing entities, including those that provide a hybrid of services (both in-home or at-home, and in-office services), either through a subset list within the provider directory or through a separate list comprising in-home or at-home supplemental benefit providers and direct furnishing entities, and
- Require all direct furnishing entities to be included within the provider directory.

The agency does not anticipate that the proposed policies will have an impact on the Medicare Trust Fund.

CMS PROPOSES CLARIFICATIONS TO MA ORGANIZATION DETERMINATIONS IN THE INPATIENT SETTING

CMS proposes four modifications to strengthen existing regulations related to the requirement that MA organizations cover and provide all reasonable and necessary Medicare Part A and B benefits, focusing on determinations for the inpatient setting. Specifically, CMS proposes to:

- Clarify that a determination regarding services for which an enrollee has no further liability to pay for services are not subject to CMS's administrative appeals process. An enrollee's further liability to pay for services cannot be determined until an MA organization has made a determination or requested payment.
- Modify the definition of an organization determination to clarify that a coverage decision made by an MA organization that occurs during the provision of such services is an organization determination subject to appeal and other current requirements.
- Strengthen the notice requirements to ensure a provider receives notice of an MA organization's decision when the provider has made a standard organization determination or integrated organization request on an enrollee's behalf.

- Eliminate the discretion of an MA organization to reopen an approved authorization for an inpatient hospital admission.

TO IMPROVE OVERSIGHT AND ALIGNMENT WITH EXISTING COMMERCIAL AND MEDICAID MLR REQUIREMENTS, CMS PROPOSES CHANGES TO MA AND PART D MLR REQUIREMENTS

CMS proposes several changes to the MLR requirements for MA and Part D to improve meaningfulness and comparability of the MLR across plan contracts and align MA and Part D MLR requirements with commercial and Medicaid MLR requirements. MLR represents the percentage of revenue spent on patient care rather than for other items such as administrative expenses or profit. Thus, for each MA and Part D contract, MLR reflects the ratio of costs (numerator) to revenues (denominator) for all enrollees under the contract.

CMS proposes to make the following changes to MLR:

- Establish clinical and quality improvement standards for provider incentives and bonus arrangements included in the MA MLR numerator to align bonus payments with care outcomes and avoid excess premium transfer to providers,
- Prohibit administrative costs from being included in quality improvement activities in both the MA and Part D MLR numerator,
- Codify additional requirements for allocating expenses in the MLR to align Medicare MLR regulations with commercial and Medicaid MLR requirements and with current Medicare MLR reporting practices,
- Establish new audit and appeals processes for MLR compliance including setting forth standards for selecting contracts for audit examinations, clarifying compliance actions that will be taken as a result of audit findings, and outlining an appeals process,
- Amend the Medicare MLR regulations authorizing the release of Part C and Part D MLR data to add exclusions,
- Codify the rules established in the CY 2025 Part D Redesign Program Instructions for 2026 and subsequent years to exclude Medicare Prescription Payment Plan unsettled balances from the MLR, and
- Collect additional detailed information regarding plan expenditures categorized by different provider payment arrangements as part of Medicare MLR reporting.

In response to concerns raised by policymakers, the Medicare Payment Advisory Commission (MedPAC), and other researchers about increasing vertical integration among large MA organizations, CMS is issuing a request for information on potential changes to how MA and Part D MLRs are calculated to enable policymakers to address these concerns. CMS seeks public input on the following:

- Establishing parameters in MLR reporting that limit the amount of transfer payments that are incurred between related parties that can be included in the numerator, such as capping amounts included in the numerator to be under a relative benchmark,

- Revising the definition of incurred claims to include profits earned by related parties as indirect remuneration to a Part D sponsor or MA organization and not allowable for inclusion in the MLR numerator,
- Revising the definition of "incurred claims" to include payments net of direct or indirect remuneration by or to the Parent Organization, in addition to the Part D sponsor,
- Establishing a framework to assess transfer payments made to or by related parties by expanding related-party reporting requirements in the MLR and the kind of information CMS could collect about transfer payments to be able to assess what portions of such payments should be reported in the MLR numerator,
- The type of information CMS could collect to better define types of vertical integration or related party relationships that exist in the health insurance market, and
- Other frameworks or policies not enumerated in the rule.

CMS estimates that the MLR proposals to prohibit administrative costs from being included in quality improving activities could result in annual remittances paid by MA organizations to the government of approximately $101 million. The agency also estimates the audit process could result in annual remittances paid back to the government by MA organizations and Part D sponsors of approximately $32 million.

CMS PROPOSES POLICIES AIMED AT INTEGRATING CARE FOR DUALLY ELIGIBLE ENROLLEES

Aimed at addressing dually eligible enrollees' current experiences with fragmented health care, CMS proposes policies to better integrate Medicare and Medicaid services. These policies aim to enhance person-centered care coordination, mitigate cost-shifting incentives between the programs, and create a seamless healthcare experience.

CMS proposes new Federal requirements for dual eligible special needs plans (D-SNPs) that qualify as applicable integrated plans (AIPs), including 1) using integrated member identification (ID) cards that serve as identification for both the Medicare and Medicaid plans in which an enrollee is enrolled; and 2) conducting a single integrated health risk assessment (HRA) covering both programs instead of separate HRAs.

The agency also proposes codifying timeframes for all SNPs to conduct HRAs and individualized care plans (ICPs) and prioritize the involvement of the enrollee or the enrollee's representative, as applicable, in the development of the ICPs.

While CMS anticipates that the integrated HRA requirement may involve upfront administrative costs for AIPs, it does not expect the proposed ID card and ICP policies to have financial impacts.

CMS PROPOSES REQUIREMENTS ON THE PROPER ADMINISTRATION OF SUPPLEMENTAL BENEFITS COVERAGE

CMS has received numerous inquiries from stakeholders, including Medicare enrollees, requesting clarity on the use of debit cards. To address these inquiries, CMS proposes to:

- Describe the ways and manner in which debit cards can be used by an MA organization and enrollee,
- Introduce disclosure requirements to increase transparency, including disclosure rules regarding supplemental benefits and plan debit cards,
- Require MA organizations to permit an enrollee to receive covered benefits through a different process if there is a problem with a plan debit card,
- Ensure debit cards are linked electronically to plan covered services through a real-time identification mechanism, and
- Clarify what types of over the counter (OTC) products are allowable.

Furthermore, CMS proposes to forbid MA organizations from marketing the financial value of a supplement benefit or the method by which it is administered, including the use of a debit card by the enrollee to issue the plan's payment to the provider for the covered service or item.

CMS solicits comments on all aspects of this proposal and will take comments under consideration when finalizing revisions to their policies. CMS does not expect these proposals to have an economic impact on the Medicare Trust Fund.

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This Applied Policy® Summary was prepared by Caitlyn Bernard with support from the Applied Policy team of health policy experts. If you have any questions or need more information, please contact her at CBernard@appliedpolicy.com or at (202) 558-5272.