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CMS Finalizes CY 2026 Changes to Medicare Advantage and Part D Without Key Provisions Related to Access to Anti-Obesity Medications and Health Equity

On April 4, 2025, 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 final rule, which contains finalized policies for Medicare Advantage (MA) and Medicare Part D plans in contract year (CY) 2026. See the fact sheet here. CMS initially proposed these policies under the Biden Administration and has finalized them under the Trump Administration with significant changes.

In this rule, CMS finalizes proposals to:

- 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, with some modifications,
- Establish a shortened prescription drug event (PDE) submission timeline for drugs selected for negotiation under the Medicare Drug Price Negotiation Program,
- Clarify MA organization determinations in the inpatient setting, and
- Implement policies aimed at integrating care for dually eligible individuals.

Additionally, the agency reaffirms that its clarification from the proposed rule requiring Part D plans to ensure broad access to generics, biosimilars, and other low-cost drugs to comply with statutory requirements remains in effect. While the agency requested input on how manufacturer rebates may influence formulary decisions that limit access to these drugs and whether further action is needed to prevent their exclusion or disadvantage, it did not address stakeholder feedback on these issues in the final rule.

The agency is not moving forward with several policies previously proposed under the Biden Administration, including those that would:

- Reinterpret existing policies to allow Medicare Part D coverage of Anti-Obesity Medications (AOMs) for beneficiaries diagnosed with obesity,
- Implement guardrails for the use of artificial intelligence (AI) to prevent inequitable care and/or bias in MA, and
- Update MA plans' health equity analyses of utilization management policies in alignment with feedback received in response to the CY 2025 proposed rule.

Although CMS is not finalizing certain proposals at this time, it indicates that some may be considered in future rulemaking, including:

- Revisions to regulations governing internal coverage criteria to improve patient access to care under MA, and
- Updates to behavioral health cost-sharing standards for MA and cost plans to promote equitable access to behavioral health benefits.

Proposals related to establishing new Part D policies to promote pharmacy transparency and minimize disruptions in care, as well as reforming MA and Part D medical loss ratio (MLR) requirements to align with commercial and Medicaid MLR requirements, are not addressed in this final rule.

The provisions in this final rule are applicable to coverage beginning January 1, 2026, except as otherwise noted.

AGENCY TO CODIFY IRA PROVISIONS ELIMINATING COST-SHARING FOR ADULT VACCINES UNDER PART D

Beginning in 2026 and beyond, CMS will implement and codify IRA provisions eliminating cost-sharing under Medicare Part D for adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP). These vaccines must be licensed by the Food & Drug Administration (FDA) for use by adults and administered in accordance with ACIP recommendations. Enrollees will have no out-of-pocket (OOP) costs, including sales tax, dispensing fees, or administration charges. Cost-sharing rules apply regardless of network status, timing of recommendation, or formulary exceptions. Part D sponsors must reimburse beneficiaries fully for OOP payments for these vaccines, using the full cash price for reporting.

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.

CMS notes that similar cost-sharing protections have been in effect since 2023 and expects minimal impact from this formal codification.

CMS CODIFIES IRA PROVISIONS RESTRICTING PART D COST-SHARING FOR A ONE-MONTH SUPPLY OF INSULIN

The agency finalizes its proposal to codify cost-sharing requirements 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 does not apply to covered insulin, and the cost-sharing for a one-month supply is capped at $35 for 2023, 2024, and 2025.

In line with statute, for 2026 and beyond, CMS 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 under the Medicare Drug Price Negotiation Program, 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 an FDA-licensed insulin product, including combinations of different insulins or insulin with non-insulin drugs. Compounded insulin products are excluded.

PROGRAM GUIDANCE FOR THE IRA MEDICARE PRESCRIPTION PAYMENT PLAN CODIFIED 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[1], released on February 29, 2024, focused on operational requirements, while the second[2], issued on July 16, 2024, addressed Part D enrollee education, outreach, and communications.

CMS proposed to codify the requirements from these two guidance documents for 2026 and beyond, with a few modifications, including:

- **Grace Period and Notice of Non-Payment:** Under the final Part One guidance[1], 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. CMS finalizes its proposal 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[1], CMS required plans to work with participants to either refund overpayments or apply them to remaining OOP

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

costs. CMS finalizes its proposal to modify that requirement to allow a plan to follow its normal processes for adjustments and issuing refunds. Additionally, CMS finalizes its proposal 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 addresses several new requirements:

- **Renewal Process and Notice:** CMS finalizes 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. CMS modifies its proposed timing requirement for the renewal notice to be sent out. Under the final policy, the renewal notice must be sent after the end of the annual coordinated election period but before the beginning of the plan year.
- **Effective Date of Voluntary Terminations:** CMS finalizes its proposal to maintain the requirement for Part D sponsors to send the notice of voluntary termination within 10 calendar days of receipt. CMS proposed to require that the effective date of termination must be within 24 hours of receipt of the voluntary termination request but finalizes a 3-calendar day requirement instead.
- **Pharmacy Access to Part D Enrollee's OOP Costs:** CMS does not finalize requirements for Part D sponsors to ensure that pharmacies can provide information on a Part D enrollee's OOP costs for the MPPP for prescriptions processed under the program at the point of sale (POS).

CMS FINALIZES SHORTENED PDE SUBMISSION TIMELINE FOR DRUGS SELECTED FOR NEGOTIATION

CMS finalizes its proposal to require that for drugs selected for negotiation under the Medicare Drug Price Negotiation Program, Part D sponsors must submit initial PDE records within seven calendar days from the date the Part D sponsor receives the claim.

AGENCY REITERATES THAT PART D PLANS MUST CONTINUE TO PROVIDE BROAD ACCESS TO GENERICS, BIOSIMILARS, AND OTHER LOW-COST DRUGS

Section 1860D-4g(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). In the proposed rule, CMS noted it 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.[3,4,5] Based on these findings, CMS expressed concerned about the potential for higher 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 stated that broad access refers to tier placements and utilization management requirements, not only formulary inclusion. In the proposed rule, CMS stated it planned to add an additional step to its formulary review process, where the agency would confirm that Part D sponsors provide broad access to generics, biosimilars, and other lower costs drugs. **CMS will no longer implement this additional step in formulary review but states that the clarifications in the proposed rule still apply. CMS will also consider codifying additional requirements regarding formularies in future rulemaking if needed.**

The agency sought feedback on two topics in the proposed: 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. **CMS does not address stakeholder feedback on these topics in the final rule.**

CMS FINALIZES CLARIFICATIONS TO MA ORGANIZATION DETERMINATIONS IN THE INPATIENT SETTING

CMS finalizes 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 finalizes, with some modifications, its proposals 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. CMS modifies the proposal by making the enrollee's payment liability be contingent on the resolution of a provider's request for 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.

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

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

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

- Eliminate the discretion of an MA organization to reopen an approved authorization for an inpatient hospital admission. CMS also adds a limit for determinations regarding favorable inpatient hospital admissions after the initial decision.

CMS FINALIZES POLICIES AIMED AT INTEGRATING CARE FOR DUALLY ELIGIBLE ENROLLEES

Aimed at addressing dually eligible enrollees' current experiences with fragmented health care, CMS finalizes 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 finalizes two new Federal requirements for dual eligible special needs plans (D-SNPs) that qualify as applicable integrated plans (AIPs), including:

- The use of integrated member identification (ID) cards that serve as proof of enrollment in both the Medicare and Medicaid programs, and
- The implementation of a single integrated health risk assessment (HRA) covering both programs, with two modifications: 1) implementation is now set for January 1, 2027, and 2) managed care organizations (MCOs) will be required to make an effort to conduct an initial screening of each enrollee's needs.

The agency also finalizes its proposal to codify 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. CMS does extend the timelines in the final rule to within 90 days of conducting a comprehensive HRA.

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

CMS DEFERS ACTION ON KEY EQUITY AND AI PROVISIONS IN FINAL RULE

The final rule does not address or finalize several provisions from the proposed rule, which CMS states remain under review in alignment with Executive Order 14192, "Unleashing Prosperity Through Deregulation."[6]

Specifically, CMS is not finalizing proposals to:

- Enhance rules on internal coverage criteria to align with fee-for-service (FFS) Medicare, including by:

[6] https://www.federalregister.gov/d/2025-02345

    - Defining "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).",
    - Implementing two safeguards to prevent misuse of internal coverage criteria: prohibiting criteria without clinical benefit used solely to limit utilization, and banning blanket denials of basic benefits without individualized medical necessity determinations, and
    - Requiring MA organization to implement changes to make it easier to understand and locate internal coverage criteria policies.
- Require MA and cost plans to align in-network cost sharing for behavioral health services with Traditional Medicare, including capped coinsurance for outpatient services, zero cost sharing for opioid treatment program services, and full coverage of inpatient psychiatric cost sharing.

CMS notes it may address these proposals in subsequent rulemaking.

Additionally, the agency states it does not intend to finalize proposals to:

- Reinterpret the statutory exclusion on weight loss drugs to allow Medicare Part D and Medicaid coverage of anti-obesity medications (AOMs) for individuals diagnosed with obesity (BMI ≥30).
- Require MA plans to report health equity analyses of prior authorization (PA) by individual item or service, rather than in aggregate, to better identify disparities.
- 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, such as AI.

While these provisions will not move forward at this time, CMS acknowledges strong stakeholder interest in AI regulation and indicates it will consider the extent to which it may be appropriate to engage in future rulemaking in this area.

Proposals to enhance pharmacy network transparency or to reform MA and Part D MLR requirements, including changes to provider incentives, expense reporting, and oversight processes, are not addressed in this final rule.

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