

Summary of the Final Rule for CY2026 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

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Prepared by:

Wakely Consulting Group, an HMA Company



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Final Rule Summary April 2025



Executive Summary

On April 4, 2025, the Centers for Medicare and Medicaid Services (CMS) released the Final Rule for the "CY2026 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".

Most of the policies in the Proposed Rule were finalized; however, there were some notable exceptions.

This report summarizes the financial and actuarial aspects of the Final Rule. It is not intended to be a comprehensive description of all portions of the Rule.

Policies Finalized as Proposed or with Minor Modifications

The following policies described in the Proposed Rule were finalized as written or with minor modifications:

- No cost sharing can be charged for vaccines recommended by the Advisory Committee on Immunization Practices (ACIP).
- Insulin beneficiary cost sharing must be no greater than the lesser of \$35, 25% of the Medicare negotiated price, and 25% of the plan's negotiated price.
- Various operational requirements related to the Medicare Prescription Payment Program (MPPP).
- Prescription Drug Event (PDE) submission timeline requirements for non-select and select drugs.
- Requirements for certain drug manufacturers to participate in the Medicare Transaction Facilitator (MTF) system.
- Enhancement of enrollee protections related to organization determinations for inpatient services.
- Clarifications related to county and service area definitions.
- Disallowed services covered under special supplemental benefits for the chronically ill.
- Additional restrictions for Applicable Integrated Dual Special Needs Plans (D-SNPs) regarding member identification cards and the administration of health risk assessments.

Proposed Policies not Finalized



The following policies in the Proposed Rule were not finalized:

- Coverage of weight loss medications under Part D for beneficiaries with obesity.
- Cost sharing for behavioral health services cannot exceed traditional Medicare.
- Public disclosure of plans' internal coverage determination process.
- Requirement to ensure that pharmacies inform Part D enrollees of the actual out of pocket (OOP) cost of a Part D prescription processed under the program at the pharmacy point of sale (POS).

The remainder of this report provides brief summaries of CMS's decisions and responses to public comments.

Attachment II. Implementation of IRA provisions for PDP program

Section A. Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices (ACIP under Medicare Part D (§§423.100 and 423.120)

CMS finalized the rule as proposed. Both the definition of vaccines and the cost-sharing rules as specified in the Inflation Reduction Act (IRA) and described in the September 26, 2022, memorandum were codified. The only notable discussion centered on the lack of complete prohibition of utilization management (UM) strategies for vaccines. CMS affirmed that UM strategies will continue to be allowed, but only in certain circumstances detailed in the Final Rule.

Section B. Cost Sharing for Covered Insulin Products under Medicare Part D (§§423.100 and 423.120)

CMS finalized the rule as proposed. For 2026 and all subsequent years, the copayments for covered insulin products are the lesser of (1) \$35 for a 1-month supply, (2) 25% of the Maximum Fair Price (MFP) for CMS negotiated drugs, or (3) 25% of the negotiated price of the insulin product.

Section C. Medicare Prescription Payment Plans (§§423.137, 423.2265, 423.2267, 423.2536)

CMS is codifying the requirements established in the final part one guidance and final part two guidance, with some modifications.



- The MPPP will be added to list of Part D requirements waived for the limited income newly eligible transition (LI NET) program.
- CMS is not finalizing requirements for real-time election or for Part D plans to provide pharmacies with easily accessible information on a Part D enrollee's costs incurred under the program.
- All Part D plans, except those offering \$0 copays, need to offer the MPPP to their beneficiaries, including EGWP plans.
 - D-SNPs, even with a nominal member cost sharing, are required to offer MPPP to their beneficiaries, but CMS is exempting D-SNPs from the requirement to provide a MPPP election request form and additional education information on the program in a hard copy mailing.
- Part D enrollee participation in MPPP will rollover into subsequent years, if within same PBP, until optout. Plan sponsors are required to communicate continued enrollment in the MPPP program to their beneficiaries after annual enrollment periods (AEPs) but before plan year commencements.
- Members that are already enrolled in MPPP are exempt for receiving "Medicare Prescription Payment Plan Likely to Benefit Notices. "Likely to Benefit" thresholds continue to be (1) \$600/script in OOP expenses or (2) \$2,000 in OOP expenses within the first 9 months of the year.
- CMS extended the deadline to complete work on voluntary terminations to three calendar days compared with the previous 24-hour requirement. Plan sponsors will still have only 24 hours to process election forms.
- The monthly calculation of expenses will remain as proposed, as will the billing requirements that monthly premiums are billed separately from MPPP balances.
- Unsettled MPPP balances will continue to be excluded from the numerator in the medical loss ratio (MLR) calculation. Unsettled balance estimates are included in administrative expenses in the bid pricing tools (BPTs), so they must be excluded from the numerator as to not incentivize Part D plan sponsors to avoid collecting unsettled balances.



Section D. 'Timely Submission Requirements for Prescription Drug Event (PDE) Records (§423.325)

TABLE 1A. PROPOSED PDE SUBMISSION TIMELINES FOR NON-SELECTED AND SELECTED DRUG CLAIMS

Submission Timeframe	Non-Selected Drugs	Selected Drugs
Initial PDE	30 calendar days following date claim received by Part D plan sponsor or its contracted first tier, downstream, or related entity	7 calendar days following date claim received by Part D plan sponsor or its contracted first tier, downstream, or related entity
Resolution of Rejected Records	90 calendar days following receipt of rejected record status from CMS	
Adjustment and Deletion	90 calendar days following discovery of issue requiring change	

Selected Drugs are those that have an MFP through negotiations with CMS, starting in CY2026.

CMS has finalized that the 30-day and 90-day requirements will be defined as calendar days, calculated from the date claims are received. No additional reporting requirements are being imposed for drugs outside of the selected drug categories. The established "7-day timeliness requirement" underscores the importance of ensuring prompt payment of MFP refunds to dispensing entities, while also maintaining a submission timeline for PDE data that remains operationally feasible for Part D sponsors.

Section E. Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements

CMS finalized proposed requirements requiring applicable drug manufacturers to participate in the MTF system.

A "Primary Manufacturer" of a selected drug that is participating in the Medicare Drug Price Negotiation Program and has an agreement to provide a MFP to eligible individuals, and Medicare Part D drug dispensaries (pharmacies, mail order services, etc.) must provide access to the MFP in one of two ways:

1. prospective pricing (ensuring the price paid by the dispensing entity is no higher than the MFP), or



- 2. retrospectively reimbursing the cost difference.
 - a. In the case of retrospective reimbursement, the obligation must be met within 14 days of when certain claim level data is sent to the Primary Manufacturer by the Medicare Transaction Facilitator Data Module (MTF DM).

The MTF has two distinct modules:

- The MTF DM facilitates the exchange of certain claim-level data elements to support the verification that the selected drug was dispensed to an MFP-eligible individual. Membership in the MTF DM is mandatory for Primary Manufacturers.
 - Further, as part of the Medicare Drug Price Negotiation Program, CMS requires that pharmacies that contract with Part D Sponsors' networks (or first tier, downstream, or related entities, such as PBMs, acting on the sponsors' behalf) be enrolled in the Medicare Drug Price Negotiation Program's MTF DM.
- 2. Medicare Transaction Facilitator Payment Module (MTF PM), which is a voluntary option to pass payment for MFP refunds from Primary Manufacturers to dispensing entities. Membership in the MTF PM is voluntary for Primary Manufacturers.

The two modules combine data and payment facilitation functionalities. The combination of the data module (DM) and payment module (PM) attempts to address the interest expressed by dispensing entities and manufacturers to have a single platform for transmitting the data necessary for program administration

Attachment III. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies

Section A. Clarifying MA Organization Determinations to Enhance Enrollee Protections in Inpatient Settings

CMS proposed four modifications to existing regulations at 42 CFR part 422, subpart M, to clarify and strengthen existing rules related to organization determinations.

- 1. Clarifying When a Determination Results in No Further Financial Liability for the Enrollee (§ 422.562)
 - a. CMS proposed to clarify the rule that if an enrollee has no further liability to pay for services furnished by a MA organization, a determination regarding these services is not subject to appeal.



- b. To eliminate potential confusion related to identifying when organizations' determinations may not be appealable due to the lack of enrollee financial liability, CMS proposed modifying § 422.562(c)(2) to clarify that the provision is only applicable to contract provider payment disputes from a claim payment decision in which the enrollee has no additional financial liability.
- c. CMS is finalizing a modified version of their proposal that conditions the applicability of § 422.562(c)(2) on the submission and adjudication of a contract provider's request for payment.
- d. The language of the proposed text is also being finalized as "If a contract provider's request for payment has been adjudicated and the enrollee is determined to have no further liability to pay for the services furnished by the Medicare Advantage (MA) organization, the claim payment determination is not subject to the appeal process in this subpart."
- 2. Clarifying the Definition of an Organization Determination to Enhance Enrollee Protections in Inpatient Settings (§§ 422.138 and 422.566)
 - a. CMS proposed revising the definition of an "organization determination" to clarify that coverage decisions made by an MA organization at the time services are being provided—including decisions about the appropriate level of care (such as inpatient vs. outpatient)—qualify as organization determinations and are therefore subject to appeal and other existing requirements.
 - b. The proposed revisions were finalized with no modification.
- 3. Strengthening Requirements Related to Notice to Providers (§§ 422.568, 422.572, and 422.631)
 - a. CMS proposed to strengthen the notice requirements to ensure that a provider who has made a standard organization determination or integrated organization determination request on an enrollee's behalf, or when it is otherwise appropriate, receives notice of the MA organization's decision.
 - b. The proposed revisions were finalized with no modification.
- 4. Modifying "Reopening" Rules Related to Decisions on an Approved Hospital Inpatient Admission (§§ 422.138 and 422.616)
 - a. CMS proposed to change the reopening rules to curtail MA organizations' authority to reopen and modify an approved authorization for an inpatient hospital admission the basis of good cause for new and material evidence.



- b. After considerations of the comments received, CMS finalized the amendment to § 422.616(a) to state that the reopening provisions are subject to the rules at § 422.138(c) and finalized the addition of new paragraph (e) to § 422.616, placing a limitation on reopening determinations related to favorable inpatient hospital admissions without modification.
- c. CMS is omitting the unitalicized heading that was included in the proposed rule to paragraph (e) of § 422.616.
- d. CMS is also finalizing the technical amendment to the parenthetical text in paragraph (c) of § 422.138 to add a cross reference to the rules at § 422.616 with a minor modification to fix an editorial error that was inadvertently made in the proposed regulation text revision (specifically, reinstating "or" between "prior authorization" and "preservice determination").

Section B. Clarifying the Definition of "County" (§ 422.116)

This policy codifies CMS's longstanding approach of using the term "county" to refer to geographic areas as defined by the U.S. Census Bureau—that is, the primary political and administrative divisions of states, including county-equivalents such as boroughs, certain designated cities, parishes, municipalities, and the District of Columbia. Accordingly, CMS is formally adopting its established practice of treating county-equivalents the same as counties for purposes of network adequacy by defining "county" in § 422.116. Additionally, CMS is finalizing its proposals to revise the definition of "service area" in § 422.2 and to add a definition of "county" in § 422.116 to explicitly include county-equivalents for network adequacy standards.

Section C. Non-allowable Special Supplemental Benefits for the Chronically III (SSBCI) (§ 422.102)

As was also stated in the Final Rule issued in April 2024, plans must still submit a bibliography that provides evidence that SSBCI services offered by the plan "[have] a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee". CMS may decline any proposed benefit if substantial evidence has not been provided. Furthermore, plan marketing in all forms (physical, digital, etc.) must continue to comply with the rules outlined in the April 2024 Rule. This includes (but is not limited to) the listing of all qualifying chronic conditions as well as specific font and reading speeds.

CMS also produced a non-exhaustive list of items that do not meet the "reasonable expectation" requirement above and their corresponding reasons:

• Soley Cosmetic Procedures: not explicitly health related.



- Tobacco and Alcohol: Not considered nutritional, thus not "healthy food".
- Marijuana and Derivates: Illegal under Federal Law.
- Funeral Expenses and Life Insurance: Applicable after death, thus "do not improve or maintain" health.
- Hospital Indemnity: Shifts payments to a third-party.
- Membership Programs (Amazon, Costco, etc.): Can be used to purchase items not approved as SSBCI and can potentially be used to give cash to an enrollee.

Items not listed as either approved or un-approved must still be submitted to CMS for approval.

Section D. Risk Adjustment Data Updates

CMS will modify the definition of Hierarchical Condition Categories (HCC) to exclude mentioning any specific International Classification of Diseases (ICD) version (currently ICD-9-CM) in favor of generally referencing ICD. This is to ensure that only the valid ICD codes are used in the respective year. Since this involves no change in meaning or use of HHCs, CMS predicts this will not result in any change to cost, savings, or administrative burden.

Additionally, CMS is officially codifying payment procedures for Program for All-Inclusive Care for the Elderly (PACE) and Cost plans. A new paragraph [42 CFR 460.180(b)(3)] will be added to require that PACE payment submissions be in accordance with the submission requirements for risk adjustment data. A similar measure has been taken for Cost plans: to amend § 417.486(a) to add a new § 417.486(a)(3) to explicitly require the collection and mandatory submission of risk adjustment data. Since both alterations are codifying what has already been done in practice, no change to savings or cost are anticipated.

Section E. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.166 and 423.186)

- The updated Breast Cancer Screening (Part C) measure with an expanded age range was finalized to be included in the 2029 Star Ratings.
- The Proposed Rule proposed several other policies that were not addressed in the final rule. Those other proposals may be addressed in a future rule.



Attachment IV. Improving Experiences for Dually Eligible Enrollees

Dually eligible individuals face fragmentation in many different areas of the current health care system, including their experiences enrolling in managed Medicare and Medicaid plans. Implementing new policies will help deal with this fragmentation.

Section A. Member ID Cards, Health Risk Assessments, and Individualized Care Plans (§§ 422.101, 422.2267, 423.2267)

CMS emphasized how Integrated care is a strategic priority for CMS, defined as approaches that: (1) maximize person-centered coordination of Medicare and Medicaid services, (2) mitigate cost-shifting incentives between programs, and (3) create a seamless experience for dual-eligible individuals.

 Approximately 992,000 dual-eligible individuals were enrolled in integrated care plans using integrated materials as of January 2025, representing a significant market segment.

CMS is systematically incorporating Medicare-Medicaid Plan (MMP) features into D-SNP requirements, creating operational consistency for organizations serving this population.

CMS is now requiring Applicable Integrated Plans (AIPs) to provide enrollees with a single integrated member ID card that serves both Medicare and Medicaid functions, effective January 1, 2027 (with marketing beginning October 2026).

- The integrated ID cards must comply with existing Medicare requirements (§§ 422.2267(e)(30) and 423.2267(e)(32)) and applicable Medicaid requirements (§ 438.3(s)(7)), without substantive changes to current content requirements.
- This requirement will affect AIPs in three additional jurisdictions (District of Columbia, New York, and Puerto Rico) beyond the 13 states that already require integrated ID cards, plus any new AIPs formed in the future.
- CMS also limited this requirement to AIPs rather than extending it to all Highly Integrated Dual Eligible Special Needs Plans (HIDE SNPs), citing operational complexity in situations where a plan has both aligned and non-aligned enrollees.

CMS is proposing changes to State Medicaid Agency Contracts that will make the State Medicaid Agency Contracts (SMACs) publicly available, creating greater transparency around state-specific requirements that affect D-SNP operations and costs.



The new final regulations proposed by CMS requires SNPs to develop Individualized Care Plans (ICPs) within 90 days of conducting a Health Risk Assessment (HRA) or 90 days after enrollment (whichever is later), which extends the timeline from the originally proposed 30 days.

Stakeholders strongly support person-centered ICPs that engage enrollees and their representatives, which could impact how plans allocate resources for care management.

• States can impose stricter ICP timelines through SMACs, creating market-specific variations that actuaries must account for in resource planning

Section B. Clarifying Highly Integrated Dual Eligible Special Needs Plan Definition Relative to Oregon's Coordinated Care Organization Structure (§ 422.2)

CMS is finalizing the proposed definition change to HIDE SNPs, making minor edits to paragraph (1) and add a new paragraph (1)(iii) to the definition to explicitly describe a scenario in which there is a capitated contract between the State Medicaid agency and a local nonprofit public benefit corporation of which the MA organization is a founding member.

Attachment V – Technical Changes

Section A. Technical Change to the Specific Rights to Which a PACE Participant is Entitled (§ 460.112)

- § 460.112(a)(1) and (2) redesignated as § 460.112(b)(1) and (2) due to more appropriate alignment in section (b) ("right to treatment").
- § 460.112(b)(1) through (8) redesignated as § 460.112(a)(1) through (8) due to more appropriate alignment with section (a) ("respect and nondiscrimination").

Section B. Technical Change to PACE Contracted Services (§ 460.70(e)(2))

 Updated the cross-reference § 460.98(c) to § 460.98(d) to affirm the connection between § 460.70(e)(2) and the "Minimum services furnished at each PACE center" requirements at the redesignated § 460.98(d).