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CMS CY2026 Proposed Rule

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Executive Summary

On November 26, 2024, the Centers for Medicare and Medicaid Services (CMS) released 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". The deadline to submit comments is January 27, 2025.

The Proposed Rule includes numerous suggested regulations for the contract year 2026 and beyond affecting Part D, provider network requirements, minimum loss ratio calculations, and plan determinations of coverage applicability.

Please note that this summary is primarily focused on the financial and actuarial aspects of the Proposed Rule and is not intended to be a comprehensive description of all portions of the Rule.

Below is a brief summary of the more consequential proposals in the Rule.

- Coverage of weight loss medications under Part D for beneficiaries with obesity (in addition to previously covered diagnoses such as Type 2 Diabetes and Cardiovascular disease).
- Insulin beneficiary cost sharing to be the lesser of $35, 25% of the Medicare negotiated price, and 25% of the plan's negotiated price.
- Cost sharing for behavioral health services cannot exceed traditional Medicare.
- Descriptions of plans' internal coverage determination process must be disclosed publicly.
- Enhancement of enrollee protections regarding organization determinations for inpatient services.
- Minimum loss ratio calculation to include Medicare Prescription Payment Plan (M3P) balances in the numerator, and expanded reporting related to provider settlements.
- Additional restrictions for Applicable Integrated Dual Special Needs Plans (D-SNPs) regarding member identification cards and administration of health risk assessments.
- Several changes to the Quality Rating System, including changes to the health equity index reward eligibility for D-SNPs.
- Changes in provider network requirements related to network adequacy (including testing at a Plan Benefit Package level), attestations for the accuracy of network directories, increased pharmacy rights, and required disclosures for supplemental benefit providers.

- Part D operational changes, including formulary requirements to ensure low-cost drug availability, timely submission of prescription drug event records, and restrictions related to the application of medication therapy management programs according to member's chronic conditions.

The remainder of this report provides brief summaries of the sections in the Proposed Rule.

Attachment II. Implementation of IRA Provisions for the Medicare Prescription Drug Benefit Program

Section A. Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices under Medicare Part D

CMS clarifies their definition of a vaccine covered under the IRA as one that is:

- Licensed by the FDA for use by adult populations and
- Administered appropriately to an adult.

Coverage of a vaccine that meets these requirements must start with the effective date of the Advisory Committee on Immunization Practices (ACIP) recommendation. If ACIP were to narrow their recommended uses for a particular vaccine, plan sponsors may apply prior authorization to ensure it is administered only for covered use-cases. If it is not used for a covered use, the plan is allowed to apply cost sharing.

Section B. Appropriate Cost-Sharing for Covered Insulin Products under Medicare Part D

For the years 2023-2025, cost-sharing for insulin products was capped at a maximum of $35 for a 30-day fill. For 2026 and beyond, this copay will be the lowest of the following:

1) $35
2) 25% of the Medicare Negotiated Price (meaning, the price determined by CMS for a selected drug)
3) 25% of the Plan Negotiated Price (meaning, the price after incorporating plan-specific discounts)

For example, Novolog is a selected insulin drug for 2026, with a Medicare Negotiated Price of $119 for a 30-day fill. 25% of this amount is $29.75. Since this is lower than the current $35 copay, the member would pay $29.75 for this drug.

Additionally, many insulins have recently seen significant price decreases that may result in 25% of the Plan Negotiated Price being lower than the original $35 copay amount.

CMS also clarifies that insulin copays do not need to be pro-rated for fills less than 30-days. The same is also true of extended fills. In other words, a 7-day fill of insulin would generate a $35 copay, and a 45-day fill would generate a $70 copay (assuming that the Plan or Medicare Negotiated Price rules do not apply).

CMS estimates that these changes will result in additional costs to the federal government of $1.2B over a 10-year span.

Section C. Medicare Prescription Payment Plan

This section reviews and proposes to codify the previously released guidance for the M3P program. In addition, CMS proposes the following changes meant to streamline the member election process, lessen administrative burden, and ensure member comprehension:

- Auto-enrolling members who have previously elected M3P into the program for the next enrollment year
- Ensuring members receive information about the costs they will have to pay under the M3P program at the point of sale
- Seeking feedback on how to allow members to elect into the M3P program at the point of sale

CMS estimates that there will not be any associated costs for these policy changes.

Attachment III. Strengthening Current MA, PDP, and Medicaid Program Policies

Section A. Part D Coverage of Anti-Obesity Medication

Medicare has not historically covered drugs for weight loss without other diagnoses. However, CMS proposes to re-interpret existing laws to allow Part D to cover popular medications, like Ozempic for obesity. Currently, these types of drugs are only covered for those with diabetes or other qualifying conditions. CMS believes this re-interpretation is needed due to the evolving medical view of treating obesity as a metabolic disease instead of a solely cosmetic issue. CMS data indicate that approximately 22% of all Medicare beneficiaries have already been diagnosed with obesity, but states that this number is likely higher (other sources indicate ~42% in 2022).

CMS defines anti-obesity medications (AOMs) that would be newly eligible for Part D coverage very broadly – coverage would "encompass any drugs that are indicated for weight loss or chronic weight management for the treatment of obesity". Coverage will not be extended to those who are overweight but not obese (except with another qualifying condition, like diabetes), potentially resulting in an incentive to *gain* unhealthy weight to meet the criteria for obesity.

Plan sponsors will be allowed to define obesity for prior authorization criteria if the requirements are not more restrictive than the FDA labeling for the drug. CMS cites multiple sources that use a BMI over 30 as a standard definition. They also mention that Prior Authorization criteria for AOMs will be reviewed similarly to other chronic conditions. CMS cautions that plans with excessively restrictive prior authorization protocols may not comply with regulations if these requirements significantly hinder the enrollment of individuals with obesity.

This change will be implemented in the Medicare program on the first of the year after the final rule is published. If finalized, this change would be in effect January 1, 2026.

These coverage changes would also apply to state Medicaid programs, which would now be required to cover AOMs for weight loss. If finalized, this change would be implemented 60 days after the final rule is published.

Section B. Network Transparency for Pharmacies

Proposal: Part D sponsors must notify network pharmacies for which plans the pharmacy will be in-network for by October 1st of the year prior to the plan year. Sponsors will be required to provide this in-network plan list to pharmacies (on request) after October 1st. This would allow pharmacies to effectively provide customers accurate information about their plan's network status before the Annual Enrollment Period starts on Oct 15th. Sponsors would also be required to provide pharmacies with this information upon request after October 1st. The details must include the contract number, plan ID, and marketing name of each plan the pharmacy participates in and can be provided either in paper or electronic form.

Currently pharmacies do not have the ability to negotiate or demand information from the PBM's. Congress and the Federal Trade Commission (FTC) have started to investigate PBM practices (including pharmacy contracting). The FTC has already determined that large PBMs use "lopsided and unfair contracting prices" which prevents smaller pharmacies from having any negotiating power. The FTC pointed out that Pharmacy Benefit Managers (PBMs) often change contract terms without clearly notifying pharmacies. Instead of requiring pharmacies to agree to new terms, they make pharmacies "opt out." This practice makes it hard for pharmacies to know which terms are currently in place and can lead to sudden changes in the networks' pharmacies are included.

Section C. Part D Medication Therapy Management (MTM) Program Eligibility Criteria (§ 423.153(d)(2))

For a beneficiary to be targeted for MTM they must have multiple chronic diseases, with three chronic diseases being the maximum a Part D sponsor may require for targeted enrollment. Effective January 1st, 2025, CMS established improved targeting criteria for the program to ensure consistency, equitability, and expanded access to MTM services (already confirmed in 2024 Final Rule). Specifically, Part D sponsors must include all 10 core chronic diseases in their targeting criteria, listed as follows: (1) Alzheimer's disease; (2) Bone disease-arthritis (including osteoporosis, osteoarthritis, and rheumatoid arthritis); (3) Chronic congestive heart failure (CHF); (4) Diabetes; (5) Dyslipidemia; (6) End-stage renal disease (ESRD); (7) Human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS); (8) Hypertension; (9) Mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions); and (10) Respiratory disease (including asthma, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders).

The proposed change also changes "Alzheimer's disease" to now include "Alzheimer's disease and dementia" and would be effective January 1st, 2026. This would help to improve medication adherence and to reduce the risk of adverse events.

Section D. Part D Sponsors Must Provide Network Pharmacies Reciprocal Rights to Terminate Contracts Without Cause and Request for Information on Access to Pharmacy Services and Prescription Drugs

1. Terminating Contracts without Cause. CMS is proposing a change to require Part D sponsors to allow pharmacies to terminate their network contracts without cause after the same notice period the sponsor is required to give for termination without cause. This rule would only apply if the contract already allowed sponsors to terminate without cause. Currently, some sponsors allow pharmacies to terminate with long notice periods (sometimes over a year) but can terminate pharmacies with much shorter notice. This proposal aims to make contract terms fairer and prevent disruptions in service for beneficiaries if a pharmacy decides to leave the network. Additionally, CMS proposes that if a contract allows sponsors to end a pharmacy's participation in only certain networks, pharmacies should be able to similarly terminate their participation in those networks with the same notice. This change would ensure more balanced and consistent contracting practices in Part D pharmacy networks and downstream entities.

2. Request for Information on Access to Pharmacy Services and Prescription Drugs. CMS is concerned with the sustainability of small and independent pharmacies. Their potential closures may eliminate convenient access to pharmacy services, especially in rural and underserved areas, which goes against the assurance of this access in section 1860D-4(b)(1)(C) of the Act and § 423.120(a). CMS is seeking comments on what additional information or data

should be considered - such as reimbursement rates, underlying costs, steering, contracting terms, and other elements which may affect pharmacies' ability to continue providing Part D drugs to beneficiaries, and continue to improve the protection of a members convenient access to Part D drugs.

Section E. Modifying the definition of "Service area" (§ 422.2)

CMS is proposing to update the current definition of "service area" in § 422.2: "a geographic area that for local MA plans is a county or multiple counties", to align with a new definition of "county". In §422.116, this would include "county-equivalents," which are areas recognized by the U.S. Census Bureau for economic purposes. The goal is to make sure the term "county" is used consistently in both service area and network adequacy rules, and to formalize CMS's long-standing policy of treating county-equivalents the same as counties in these contexts. Thereby proposing to amend § 422.2 to state "a geographic area that for local MA plans is one or more counties, as defined in § 422.116(a)(1)".

Section F. Administration of Supplemental Benefits Coverage through Debit Cards

The August 1, 2022, RFI focused on ways to improve transparency of supplemental benefits.

Starting in 2025, CMS is implementing two new requirements.

1. Reporting requirements for usage of supplemental benefits
2. SSBCI requirements to establish bibliography to show benefit will improve or maintain overall health

Proposal includes:

- Codifying existing guidelines and add new guardrails to ensure that beneficiaries are fully aware of covered supplemental benefits and how to access those benefits.
- Requiring MA plan to have a process for delivering all supplemental benefits (including those administered through a debit card) to enrollees that ensure compliance with the Act. MAO may contract with vendor or provider to administer supplemental benefit and require beneficiary to use third party.
- Guardrails for Debit Cards:
    - Ensuring the supplemental benefit or SSCBI is available and accessible to all beneficiaries.

  - Requiring MAOs to disclose all benefits, including conditions and limitations in the evidence of coverage (EOC) (Including supplemental benefits and the use of debit cards).
  - Requiring MAOs to send an explanation of benefits (EOB) to an enrollee that summarizes all debit card claims activity during that reporting period.

- Debit cards should be used to reduce beneficiary cost for a service that is paid for 100% by the MA plan. (I.e. instead of reimbursing beneficiary, service is paid for via debit card at the point of sale.)
  - Proposing to require MAO to provide debit cards that are electronically linked to plan covered benefits through a real-time identification mechanism to verify eligibility of plan covered benefits at the point of sale. Needs to include checks to ensure the enrollee may only receive covered benefits they are eligible for.
  - Proposing requirements that MAOs provide instructions and customer service support for how to use the debit card.
  - Proposing use of the debit card be limited to the specific plan year.
  - Plans should be required to have an alternative method to reimburse enrollees if there is an issue with the debit card of contracted vendor.
  - PPOs should be required to provide reimbursement regardless of whether the services are provided within the network of providers.
- A list of OTC items that cannot be covered as MA supplemental benefits.
- Prohibiting MAOs from marketing the dollar value or administration of the supplemental benefit.

Section G. Non-allowable SSBCI

2024 Rule finalized bibliography requirement and codified that CMS may decline to approve an MAO's bid if it determines that the MAO has not demonstrated that the SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the enrollee. It also finalized marketing guidelines to provide more transparency.

Currently proposing to:

- Codify a non-exhaustive list of examples of items or services that do not meet supplemental benefit standards and requirements. (e.g. cosmetic procedures, alcohol tobacco, marijuana, cash). CMS is soliciting comments on items to include in this list.

Section H. Eligibility for Supplemental Benefits for the Chronically Ill (SSBCI) and Technical Changes to the Definition of Chronically Ill Enrollee

The number of plans that offer SSBCI and scope of benefits offered have significantly increased over last five years. There are current requirements that MA plans must have written policies for making SSBCI enrollment determination. However, there is a lack of transparency to the enrollees making it difficult for them to review and determine whether they are eligible for certain SSBCI benefits.

CMS is clarifying that having a chronic condition by itself is not enough to qualify for SSBCI eligibility. Proposing to revise the language to specify that a chronically ill enrollee is an individual who meets the following:

1. One or more comorbid and medically complex chronic condition that is life threatening or significantly limits the overall health or function of enrollee.
2. Has high risk of hospitalization or other adverse health outcomes.
3. Requires intensive care coordination

CMS is further requiring plans to have an established plan for determining if enrollee meets all three criteria. Plans must also publish how they plan to determine if an enrollee qualifies for the SSBCI benefit.

Section I. Risk Adjustment Data Updates (§§ 422. 2)

CMS proposes to:

- remove language that references International Classification of Disease (ICD) revision numbers,
- refer to “disease codes” as “diagnoses codes”, and
- codify the requirement that PACE and 1876 Cost organizations must submit risk adjustment data.

Section J. Ensuring Equitable Access to Medicare Advantage (MA) Services – Guardrails for Artificial Intelligence (§§ 422.112)

CMS is concerned that learning models that had trained artificial intelligence algorithms (AI) lacked data on all populations and as such observations reported by artificial intelligence may inaccurately represent traditionally unserved populations.

The Biden Administration has released an Executive Order "Advancing Racial Equity for Underserved Communities Though the Federal Government" (E.O. 13985) to ensure equity principles, policies and approaches are not undermined by AI.

It will be an MA plans' responsibility to ensure that all tools that assist in decision making processes follow CMS regulations. Decisions to use AI to influence outcomes can be reviewed during a program audit.

In the evolving landscape of AI, CMS is proposing to formalize definitions of what are "automated systems" and "patient care decision support tools".

Section K. Promoting Community-Based Services and Enhancing Transparency of In-Home Service Contractors (§§ 422.2 and 422.111)

CMS is concerned that plans' provider directories may not include supplemental services, especially those that are non-traditional (e.g. transportation, adult day care, in-home support, meal delivery, and home modifications) and may not provide direct patient care. CMS proposes to codify a "direct furnishing entity" (DFE) as any individual or entity that provides benefits. These DFEs fall under the umbrella of any entity that is first tier, downstream, or related (FDR).

CMS encourages MA plans to engage with community-based organizations (CBO).

CMS proposes to add filtering to provider directories to show if a provider's services include at-home support.

Section L. Ensuring Equitable Access to Behavioral Health Benefits Through Section 1876 Cost Plan and MA Cost Sharing Limits (§§ 417.454 and 422.100)

Beneficiaries that receive behavioral health benefits are more likely to be low-income and the cost sharing on these services typically exceeds traditional Medicare cost sharing. CMS is proposing that cost sharing for these services do not exceed traditional Medicare. This change would begin in Contract Year 2026 or 2027.

Opioid treatment program services are proposed to have zero cost sharing.

There is indication that all member out-of-pocket (MOOP) levels will have the same limits on cost sharing. Bid Pricing Tools (BPTs) would include actuarial equivalent cost sharing checks.

This rule would affect PPOs such that out-of-network (OON) cost sharing is the same as in-network cost sharing.

Section M. Ensuring Equitable Access – Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures (§§ 422.137)

Research presented in the 2024 Final Rule indicates the historically underserved populations receive more bias in prior authorization decisions.

CMS required during the 2024 Final Rule that the Utilization Management (UM) committee must 1) include at least one member with social equity expertise, 2) conduct an annual prior authorization review, and 3) post results by service category every year on July 1st beginning 2025.

In the CY2025 Proposed Rule, CMS is proposing to revise health equity analysis metrics to require the following:

1) Percentage of prior authorizations approved
2) Percentage of prior authorizations approved after appeal
3) Percentage of prior authorizations denied
4) Percentage of prior authorization decisions with extended timelines
5) Percentage of expedited prior authorizations approved
6) Percentage of expedited prior authorizations denied
7) Average and median times for expedited and standard prior authorizations.

Section N. Medicare Advantage Network Adequacy (§§ 422.137)

Current regulatory guidelines seek to limit network exceptions but leaves the door open for “use of Original Medicare telehealth providers, mobile providers, specific patterns of care in a community”. Specific patterns of care could indicate beneficiaries are unable to receive care in

their counties and travel to specific locations, thus putting those locations under a carriers' network. CMS is proposing to codify existing standards or network adequacy exceptions.

Original Medicare telehealth providers refer to entities that offer currently approved Medicare telehealth services. Mobile service providers must be qualified and furnish services through scheduled appointments.

Inability to contract with providers is not a reason for an exception to network adequacy.

CMS is considering testing network adequacy at a PBP-level and not a contract-level. Current regulations note that it already has the authority to do so. CMS seeks comment on whether SNPs should be tested at this level.

Section O. Promoting Informed Choice– Expand Agent and Broker Requirements regarding Medicare Savings Programs, Extra Help, and Medigap (§§ 422.2274 and 423.2274)

– may lead to higher enrollment in LIS MSP and Medigap plans.

Currently sections 422.2274(c)(12) and 423.2274(c)(12) require that MA and Part D sponsors must guarantee that agents and brokers are asking specified list of questions and discussing important topics with a potential beneficiary before an enrollment can be completed. CMS is proposing to add three topics (low-income subsidy (LIS), Medicare Savings Program (MSP) and Medigap) and require agents to pause to ask the beneficiary of they have any outstanding questions to the specified criteria.

To be eligible for LIS or partial LIS an individual must be below 150 percent of the Federal Poverty Line which went into effect January 1st, 2024. This edit to eligibility criteria has increased the number of potential beneficiaries who could use it. Agents and brokers now must include the updated LIS eligibility criteria as a mandatory topic of discussion. Additionally, they will have to inform the beneficiary about the option of MSP and where the resources can be found. Lastly, they will be required to discuss potential impacts that enrolling in a MA plan could have on Medigap Federal rights (Medicare supplemental insurance). Technical changes: The list will now be changed to be read individually to be clearer and more concise for the beneficiary and for tracking/data purposes.

Section P. Format Medicare Advantage (MA) Organizations' Provider Directories for Medicare Plan Finder (§§ 422.111 and 422.2265)

To make the beneficiary process more informative and easier to manage, CMS is looking to include MA provider directories that can be easily viewed on Medicare Plan Finder (MFP) for the 2026 enrollment period. To ensure the accuracy of the data, it is proposed that MA organizations

will have to attest to the accuracy of what is submitted. If this is approved the process for submitting provider and formulary information would closely mirror the Qualified Health Plan (QHP) issuers on the federally facilitated exchange (FFE). CMS would require directory data for testing starting in summer of 2025.

Section Q. Promoting Informed Choice– Enhancing Review of Marketing & Communications (§§ 422.2260 and 423.2260)

CMS is proposing to expand its oversight of marketing materials for Medicare Advantage (MA) and Part D plans by removing certain content standards. Currently, only materials that discuss plan benefits, costs, or rankings are considered "marketing" and subject to review. However, CMS has seen a rise in complaints about misleading ads, including TV ads that were not submitted for review because they did not meet the existing content standards. By expanding these content requirements, CMS aims to ensure that all materials intended to influence beneficiaries' decisions—whether related to plan selection or retention—are reviewed for accuracy and transparency, protecting beneficiaries from misleading marketing.

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

Background: The Inflation Reduction Act of 2022 established a Negotiation Program aimed at setting maximum fair prices (MFPs) for certain high-cost, single-source drugs. The program's guidance specifically addresses the implementation of Sections 1191-1198 of the Social Security Act, focusing on the initial price applicability for 2027 and how manufacturers will implement the MFP in 2026 and 2027. Under this program, drug manufacturers must provide the MFP to eligible individuals, pharmacies, and dispensing entities during a specified price applicability period.

The program is unique because it requires manufacturers to ensure the MFP is applied at the point of sale through two potential methods:

1. Ensuring the dispensing entity pays no more than the MFP when acquiring the drug, or
2. Reimbursing the dispensing entity for the difference between their acquisition cost and the MFP.

This approach differs from previous Part D drug programs (Coverage Gap Discount Program, Manufacturer Discount Program) by mandating a specific pricing mechanism that directly impacts the cost at the point of dispensing.

Figure 1. 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	

Requirements – General PDE Submission Timelines: CMS is proposing to codify and specify the existing 30-day and 90-day general PDE submission time frames with these changes.

1) The 30-day and 90-day requirements will now specifically refer to calendar days and not business days.
2) Clarifying the verbiage surrounding timing of the initial PDE record submission to state that the records must be submitted within 30 calendar days of when the Part D sponsor (or contracted first-tier, downstream or related entities) receive the claim, given that the claim may be received by the sponsor after the date of service (DOS).

Requirements – Selected Drugs PDE Submission Timelines: CMS is proposing that for selected drugs, the initial PDE record time frame will shorten from 30 days to 7 calendar days from the date the Part D sponsor (or contracted first-tier, downstream or related entities) receive the claim. It will be referred to as the "Selected Drugs PDE Submission Timeliness Requirement".

Section S. Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements

CMS proposes to require pharmacies that are contracted with Part D plan sponsors or PBMs to be enrolled and maintain enrollment in the Medicare Transaction Facilitator Data Module (MTF DM).

The MTF DM will allow pharmacies to:

- Receive, audit, and reconcile MFP refund payments from manufacturers
- Submit complaints and disputes about payment

- Flag potential cash flow issues caused by the Medicare Negotiated Price program in advance
- View the status of MFP refunds for cash flow/financial planning
- Facilitate direct financial relationships b/w pharmacies and manufacturers

This is intended to facilitate additional financial clarity around the Medicare Negotiated Price program between all involved parties.

Section T. Proposed Regulatory Changes to Medicare Advantage (MA) and Part D Medical Loss Ratio Standards (§§ 422.2401, 422.2420, 422.2430, 422.2450, 422.2452, 422.2454, 422.2460, 422.2480, 422.2490, 422.2401, 422.2420, 422.2430, 422.2450, 422.2452, 422.2454, 422.2480, 422.2490)

General goal is to further align MA MLR reporting with commercial and Medicaid. CMS would further seek to codify standards for clinical or quality improvement standards around provider incentives and bonus arrangement adjustments to MLR numerators. CMS would seek to strengthen audit processes of MLR reporting and proposes to exclude M3P balances from MLR numerators. Lastly, CMS proposes to expand reporting around provider settlements.

Regarding MLR reporting and provider settlements, CMS is concerned that vertical integration is resulting in higher numerator reporting. MLR reporting could limit transfer payments included in the numerator.

Section U. Enhancing Rules on Internal Coverage Criteria

In the Rule, CMS proposes that by January 1, 2026, MA organizations must publicly display on the organization's website a list of all Medicare items and services where the MA organization uses internal coverage criteria when making medical necessity decisions.

CMS clarifies that criteria developed by vendors/third-parties or criteria built into software/algorithms would qualify as internal coverage criteria. Additionally, CMS adds specific requirements for where and how these criteria need to be posted to make them accessible to the public.

CMS does not believe this change will significantly alter utilization patterns, and notes that the majority of plans are using internal coverage criteria that is consistent with the above definition. As a result, they do not anticipate an impact to the Medicare Trust Fund.

Section V. Clarifying MA Organization Determinations to Enhance Enrollee Protections in IP Settings

CMS seeks to ensure enrollees have the right to appeal all relevant organization determinations that impact their care and coverage. The current rule limits appeals when an enrollee has "no further liability to pay" for services. Some MA organizations misapply this, excluding appeals for coverage decisions (like inpatient denials) even if the enrollee still has some cost-sharing responsibility. CMS seeks to clarify that this limitation only applies to payment determinations where the enrollee has no remaining financial liability after the determination. This ensures enrollees can appeal coverage decisions that impact their care, even if their out-of-pocket costs are limited.

Some MA organizations incorrectly exclude certain decisions, such as "concurrent reviews" (decisions made while an enrollee is receiving inpatient care), from the definition of "organization determination." This prevents enrollees from appealing these decisions.

CMS proposes to broaden the definition of "organization determination" to explicitly include:

- Pre-service decisions: Decisions made before an enrollee receives services (e.g., prior authorization requests).
- Concurrent decisions: Decisions made while an enrollee is receiving services (e.g., inpatient level of care decisions, denials of inpatient coverage).
- Post-service decisions: Decisions made after an enrollee receives services but before a payment request is submitted (e.g., retrospective denials of inpatient coverage).

Additionally, CMS wants to ensure all organization determinations comply with notice and appeal requirements and that enrollees and providers are aware of the decision and have the right to appeal.

Section W. Formulary Inclusion and Placement of Generics and Biosimilars

CMS is seeing issues where Pharmacy Benefit Managers (PBMs) and Part D sponsors are not giving broad access to biosimilars and are favoring more expensive brand drugs instead of other generic, biosimilar, or other lower cost drugs. High-cost product alternatives are still being used at a significantly higher rate than compared to biosimilars. Had biosimilars been used more frequently Part D spending on biologics (with already available biosimilars) could have decreased by $84 million in 2019. CMS has found cases where generic drugs or biosimilars are either excluded from formularies or placed on the same or higher formulary tiers as the more expensive brand-name drugs. These practices raise concerns because they could lead to higher out-of-pocket costs for Medicare beneficiaries. CMS believes that such formulary decisions may indicate

the use of utilization management (UM) programs that are not cost-effective and may be out of compliance with Part D requirements.

In September 2024, the FTC filed a complaint against certain PBMs and related entities, accusing them of violating the FTC Act. The complaint claims that these PBMs favor higher-priced insulin products with large rebates and fees over lower-cost insulin products (including some biosimilars). This practice allegedly inflates the perceived value of their formularies and allows them to offer higher rebate guarantees, to the detriment of cheaper alternatives. Given the concerns of CMS from the reports, actions, and findings, they want to further clarify that formularies MUST include a broad scope of generics, biosimilars and other low-cost drugs to be compliant with the current Part D requirements. A reasonable drug utilization management program should be cost-effective and when medically appropriate, includes incentives to reduce costs.

Access to generics, biosimilars and other low-cost drugs is not only in regards to formulary inclusion, but also tier placement. CMS currently conducts an in-depth formulary review process, and moving forward will be adding a formal check for this accessibility. CMS plans to review whether Part D formularies apply fewer restrictions on brand-name drugs and reference products compared to lower-cost alternatives, like generics and biosimilars. If a plan's formulary does not provide broad access to these lower-cost options, CMS may use its authority to negotiate the terms of the plan's bid to ensure better access for beneficiaries and compliance with Part D requirements.

CMS is seeking feedback on these topics: (1) how manufacturer rebates influence formulary decisions that may limit access to these drugs, and (2) whether additional actions are needed to prevent Part D formularies from excluding or limiting these lower-cost options. Based on the feedback, CMS may take further steps in the future to improve access to generics and other affordable medications for beneficiaries.

Attachment IV. MA/PDP Quality Rating System

Section A-B. Measure Changes

- Two measures were proposed to be added for Star Ratings Year (SY) 2028:
    - Initiation and Engagement of Substance Use Disorder Treatment (Part C)
    - Initial Opioid Prescribing for Long Duration (Part D)
- Three measures were proposed to be updated for SY 2029:
    - Breast Cancer Screening (Part C)
    - Plan Makes Timely Decisions about Appeals (Part C)

  - Reviewing Appeals Decisions (Part C)

- CMS is working to align the Universal Foundation measures with the Medicare Star Ratings. As a reminder, all Universal Foundation measures are expected to eventually become a part of the Part C and D Star Ratings. Three Part C measures have been submitted to the "2024 Measures under Consideration" list as a step toward adding these measures in the future:
  - Adult Immunization Status
  - Depression Screening and Follow-Up for Adolescents and Adults
  - Social Need Screening and Intervention

Section C-D-E. HEI Reward Changes

Beginning in SY 2029, there is a proposed change to the Health Equity Index (HEI) reward determination for contracts that are required by a state Medicaid agency to move D-SNP plans to a D-SNP only contract. Currently, MAOs operating in these states would not be eligible for the HEI reward since fewer enrollees with social risk factors (SRFs) would remain in the original ("legacy") contract creating misaligned incentives between these state-mandated D-SNP separations with the HEI reward goal for integrated care. As additional SRFs are eventually added to the HEI reward, it is anticipated that this adjustment will no longer be necessary. The proposed series of rules described below would make it more likely for these contracts to retain HEI reward eligibility.

1. Follow unmodified methodology for contracts that continue to meet either of the SRF enrollment thresholds based on their own enrollment.
2. Determine whether the legacy MA contract can reliably have the rating-specific HEI score calculated based on its own enrollment. If not, the contract does not qualify for an HEI reward.
3. If the D-SNP only contract cannot have the rating-specific HEI score reliably calculated, then the legacy MA contract does not qualify for an HEI reward.
4. If the legacy MA contract's performance using its own enrollment 1) does not meet the minimum index score of greater than zero or 2) is less than the performance of the D-SNP only contract, then the legacy MA contract does not qualify for an HEI reward.
5. If the contract is not excluded due to one of the criteria, then:

a. The enrollment threshold will be calculated based on the combined enrollment from the legacy MA contract and the D-SNP only contract from the most recent measurement year used in calculating the HEI.

b. The legacy MA contract would qualify for an HEI reward calculated using the HEI score for the D-SNP only contract.

Other proposed changes beginning in SY 2027 include:

- I-SNP-only contracts must have data for at least half the measures included in the HEI measure set only for the subset of measures that I-SNP-only contracts are required to report.
- In the second year of a consolidation, the combined enrollment from the consumed and surviving contracts from the most recent year of data used in calculating the HEI will be used to assess whether the surviving contract meets one of the enrollment thresholds.

Other proposed changes beginning in SY 2029 include:

- If a contract's HEDIS measure score across all enrollees for a measure that is calculated by CMS using submitted patient-level detail (PLD) data does not match the contract's summary-level score submitted to NCQA for either of the two measurement years, the contract would receive -1 points for that measure in the calculation of the HEI Score.
- Contracts that do not provide PLD data for a measure for which it has provided summary-level HEDIS data to NCQA would receive -1 points for that measure.

Section F. Other Methodological Changes

- CMS is considering finalizing the December 2022 proposal to remove cut point guardrails for SY 2028.
- The improvement measure Hold Harmless provision will be determined based on the rounded Star Rating before the addition of the HEI reward.
- In the case of a contract consolidation, "missing" measure scores for any contract involved in the consolidation will be treated as missing in the enrollment-weighted measure score in both the first and second years of consolidation.

Attachment V – Improving Experiences for Dually Eligible Enrollees

CMS finalized several significant changes in the CY2025 Final Rule designed to increase the percentage of dual eligible beneficiaries enrolled in "integrated" D-SNPs, where the health plan provides the coverage for both Medicare and Medicaid. These changes included a new monthly special enrollment period for duals that allowed beneficiaries to choose to enroll in a new or different D-SNP provided the plan is the Medicare and Medicaid carrier and the reduction of the dual percentage threshold at which point general enrollment plans would be disapproved. These changes along with other benefit and operational provisions in the CY2025 rule signaled a strong push from CMS to encourage aligned enrollment in D-SNPs.

In the Proposed CY2026 rule, further provisions are described along these same lines; although, they are not as dramatic as the CY2025 rule. The following federal requirements for Applicable Integrated Plans were proposed:

1. Plans must issue integrated member ID cards for Medicare and Medicaid plans, effective January 1, 2027.
2. Health Risk Assessments must be conducted in an integrated manner across Medicare and Medicaid products.
3. Other operational and qualitative items:
    a. Promoting person-centeredness in SNP Integrated Care Plans (ICPs) and timeliness of HRAs and ICPs
    b. Improvement in the timeliness of HRAs
    c. Requirement that integrated care plans be updated as enrollee's health status changes
    d. Potential requirement that plans post State Medicaid Agency Contracts publicly.

The CY2026 Rule also addressed in several subsections how Highly Integrated Dual Eligible (HIDE) D-SNPs fit within the proposed rules and the expansion of the HIDE Definition to include other ownership structures, such as the Oregon Coordinated Care Organization Structure.