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Special Bulletin

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CMS Issues Final Rule for CY 2025 Medicare Advantage, Prescription Drug Plans

The final rule includes consumer and beneficiary protections, policies promoting access to behavioral health, advancing health equity and streamlining certain operational processes

The Centers for Medicare & Medicaid Services (CMS) April 4 released its final Policy and Technical Changes to the Medicare Advantage (MA) and Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, and Health Information Technology Standards for contract year (CY) 2025 (CMS-4205-F). The final rule includes a series of changes intended to strengthen beneficiary protections, promote access to behavioral health care providers, advance equity in coverage, and improve supplemental benefits in the MA program.

Specifically, the rule finalizes requirements that:

- Strengthen network adequacy standards for certain behavioral health provider types.
- Streamline the appeals process for enrollees if the MA plan terminates coverage for certain post-acute care services.
- Lay the groundwork for increasing data collection and reporting from Part C and D plans.
- Annually review MA utilization management policies for health equity considerations.
- Provide new guardrails for plan compensation to agents and brokers to prevent undue influence on beneficiary enrollment decisions.
- Ensure that MA plans offer appropriate supplemental benefits.
- Simplify enrollment for individuals dually eligible for Medicare and Medicaid.
- Standardize the appeals process for MA Risk Adjustment Data Validation audit findings.
- Limit out-of-network patient cost sharing for certain plans serving dually eligible enrollees.
- Give Part D plans more flexibility to substitute biosimilars for reference drug products.

AHA TAKE

The AHA is increasingly concerned about certain MA plan policies that restrict or delay patient access to care, which also add cost and burden to the health care system. Last year, CMS finalized important policies in the CY 2024 MA rule that greatly increased

health plan accountability and oversight, while creating greater alignment between coverage policies and access under Traditional Medicare and MA, as intended. The AHA strongly supports those rules, which went into effect Jan. 1, 2024.

While the CY 2025 MA rule does not include greater direction or clarity around enforcement and compliance policies for the 2024 rules, which AHA has encouraged the agency to adopt (including in a recent letter), we appreciate CMS' continued efforts to improve the Medicare program and advance important consumer and beneficiary protections. The new rule contains several helpful provisions, including a required annual health equity analysis of MA plan utilization management policies and their impact on underserved populations, provisions to address access gaps for behavioral health services, more streamlined mechanisms for enrollees to appeal MA plan decisions to terminate coverage of certain post-acute care services, and policies laying the groundwork for increased data collection on MA coverage decisions, appeals and decision rationales.

We urge the agency to rigorously enforce and ensure plan compliance with the new rules finalized in this policy, as well as in the CY 2024 MA final rule, to ensure the important beneficiary protections included in both rules achieve their intended effects.

HIGHLIGHTS OF THE FINAL RULE

Behavioral Health Access

CMS finalizes several updates to network adequacy standards designed to improve behavioral health services access for Medicare enrollees. Specifically, the rule creates a new facility type of "Outpatient Behavioral Health," for which CMS can set MA plan network adequacy standards. The range of behavioral health providers under this category will include marriage and family therapists and mental health counselors (services rendered by these qualified professionals were established as a new statutory Medicare benefit category through separate rulemaking in 2023), as well as Opioid Treatment Program providers, Community Mental Health Centers, addiction medicine physicians and other providers who furnish addiction medicine and behavioral health counseling or therapy services.

In addition, CMS finalizes the addition of the Outpatient Behavioral Health facility type to the list of specialties that qualifies MA plans for a 10% network adequacy credit if their contracted network includes one or more telehealth providers of that specialty type.

Enrollee Rights to Appeal an MA Plan Decision to Terminate Coverage for Certain Post-acute Care Services

CMS finalizes requirements to streamline the process for an enrollee to appeal an MA plan's decision to terminate coverage for certain post-acute care services, including expanding the rights of MA beneficiaries to access an expedited appeal and aligning the process for an expedited review with Traditional Medicare procedures. Under current

regulations, MA enrollees do not have the same procedural access to a fast-track appeal as Traditional Medicare beneficiaries, who have the right to an appeal by an Independent Review Entity (IRE) through a Quality Improvement Organization (QIO) when their covered skilled nursing facility (SNF), home health agency (HHA) or comprehensive outpatient rehabilitation facility (CORF) services are being terminated.

In this final rule, CMS requires an independent QIO (instead of the MA plan) to review untimely fast-track appeals of a MA plan's decision to terminate services provided by a HHA, SNF or CORF. This change aligns MA enrollees' rights with those of Traditional Medicare enrollees. Second, CMS fully eliminates an existing provision which requires forfeiture of an enrollee's right to appeal a termination of services decision once they leave the facility.

Data Collection and Reporting on Parts C and D

CMS finalizes technical updates to the reporting requirements for MA plans and Part D sponsors to affirm the agency's authority to collect detailed information from plans in specified areas and to broaden existing requirements to include reporting on "the procedures related to and utilization of services and items." CMS notes that the updates are intended to authorize CMS in the future to require more detailed data collection about MA and Part D sponsor procedures related to coverage and utilization (in both the aggregate and at the beneficiary-level), including the steps beneficiaries may need to take to access covered benefits. The finalized technical changes will lay the groundwork for new program-wide data collection requirements for MA and Part D sponsors to be established through the Paperwork Reduction Act process, which requires advance notice to interested parties and will be subject to public comment.

CMS provides specific examples of areas the agency has an interest in greater data collection and transparency including "service level data for all initial coverage decisions and plan level appeals, such as decision rationales for items, services, or diagnosis codes to have a better line of sight on utilization management and prior authorization practices, among many other issues." The agency also notes that "such information will ensure that CMS may better understand under what circumstances plans choose whether to provide or pay for a service or item."

Complaints Tracking Module Resolution Timelines

CMS maintains the Complaints Tracking Module (CTM) as a central repository for complaints received by CMS about MA and Part D plan sponsors from a variety of sources including patients, providers, contractors, and other advocates or stakeholders. In the final rule, CMS codifies existing guidance for the timeliness of complaint resolution by plans in the CTM to include Cost plans and PACE plans (in addition to MA plans and Part D sponsors as required by current regulation). The agency also codifies existing priority levels for complaints based on the urgency of a beneficiary's need to access care or services, including definitions of "immediate need" and "urgent" complaints. It also includes a new requirement for plans to attempt first contact with

individuals filing non-immediate need complaints within seven days, in addition to codifying timeframes for resolving Part D and non-Part D complaints in the CTM: within two calendar days for immediate need complaints; seven calendar days for urgent complaints; and within 30 days of receipt for all other complaints.

Health Equity Analysis of MA Plan Utilization Management Policies

CMS notes in the final rule that it recognizes "prior authorization policies and procedures may have a disproportionate impact on underserved populations and may delay or deny access to certain services." Accordingly, the agency finalized new requirements for MA plans to conduct an annual health equity analysis of their prior authorization and utilization management policies and procedures from a health equity perspective (using specified metrics) through their required Utilization Management Committee (UMC). The agency also will require that a member of the UMC have expertise in health equity and that the results of the annual health equity analysis be made publicly available on the MA plan's website.

Guardrails for Plan Compensation to Agents and Brokers

CMS expresses concern that "excessive compensation, and other bonus arrangements, offered by plans to agents and brokers can result in individuals being steered to some Medicare Advantage and Part D plans over others based on the agent or broker's financial interests, rather than the prospective enrollee's health care needs." In response, CMS finalizes new guardrails to govern plan compensation for agents and brokers, including standardized compensation structures, with a stated goal of ensuring that compensation is used in a way that incentivizes individuals to enroll in the plan that best meets their health care needs.

Specifically, CMS redefines "compensation" to a set a clear, fixed amount that agents and brokers can be paid regardless of the plan in which the beneficiary enrolls. The final rule also prohibits contract terms between MA plans and marketing middlemen that could impede an agent or broker's ability to objectively assess and recommend plan options that best meet a beneficiary's health needs, such as volume-based bonuses for enrollment into certain plans.

Protection of Personal Beneficiary Data

In response to CMS' concerns about third party marketing organizations (TPMO) selling and reselling personal beneficiary data without awareness or consent of the individual, CMS finalizes a series of policies to protect personal information of prospective or enrolled Medicare beneficiaries. Specifically, CMS will require that personal beneficiary data collected by a TPMO for marketing and enrollment purposes can only be shared with another TPMO with explicit prior written consent of the individual. CMS also sets guardrails for the process of obtaining such written consent through a transparent process and requires that one-to-one consent be provided for each TPMO that receives a beneficiary's personal information.

Supplemental Benefits

CMS notes that an increasing share of Medicare dollars are going toward MA plan rebates that are linked to a wide variety of supplemental benefits, which account for $337 billion in spending over the last 10 years. These can include vision, hearing, fitness and dental, among many others, with MA plans offering an average of 23 supplemental benefits from which to choose. While CMS discusses the value of these benefits in addressing potentially unmet health and social needs, it notes that utilization of these benefits is low and will require MA plans to engage in certain outreach efforts to enrollees, so they are aware of the benefits available to them. CMS specifically notes it's intent in doing so is to "ensure the large federal investment of taxpayer dollars in supplemental benefits is actually making its way to enrollees and is not primarily used to market benefits that individuals rarely use."

Specifically, CMS finalizes requirements that a "Mid-Year Enrollee Notification of Unused Supplemental Benefits" be issued annually (between June 30 and July 31 of the plan year) and personalized to each enrollee. The plan is required to provide a list of any supplemental benefits not accessed during the first six months of the year. The notification would also need to include information about the scope of the benefit, cost-sharing, any network information for each available benefit, instructions on how to access the benefit and a customer service number to call if needed.

In addition, CMS finalizes new requirements for MA plans to demonstrate that special supplemental benefits for the chronically ill (SSBCI) are items and services that meet the legal threshold of having a reasonable expectation of improving the health or overall function of chronically ill enrollees and are supported by research. Under this requirement, MA plans will need to establish and maintain bibliographies of relevant research studies or other data to demonstrate that SSBCI meets these requirements. CMS also finalized new marketing standards to ensure SSBCI are not being advertised in misleading ways that suggest they are available to everyone.

Risk Adjustment Data Validation Appeals Process

CMS finalizes a series of operational changes intended to standardize the MA Risk Adjustment Data Validation (RADV) appeals process for MA plans. Specifically, the rule requires MA plans to exhaust all three levels of appeal for medical record review determinations in a RADV audit before initiating an appeal through the payment error calculation appeals process. This means these processes will no longer be able to take place concurrently. This change is intended to ensure adjudication of the medical record review determination is final before a recalculation of a payment error is completed and subject to appeal (as the payment error calculation is based on the outcome of the medical record review determination). CMS also includes several other technical revisions and clarifications regarding the RADV appeals process related to this change. Finally, CMS codifies that if the CMS administrator does not elect or decline to review a

timely request for review of a RADV appeal within 90 days of receipt, the hearing officer's decision becomes final.

Enrollment in Integrated Plans

CMS finalizes several policies designed to increase the percentage of dually eligible beneficiaries who are enrolled in integrated care plans that coordinate both Medicare and Medicaid benefits. Specifically, the rule creates more opportunities for dually eligible individuals to enroll in integrated plans, including:

- Replacing the current quarterly special enrollment period (SEP) with a one-time-per-month SEP for dually eligible individuals (and others enrolled in Part D low-income subsidy program) to elect a standalone Part D prescription drug plan.
- Creating a new integrated care SEP to allow dually eligible individuals to elect an integrated Dual Eligible Special Needs Plan (D-SNP) monthly if they also receive Medicaid services through an affiliated managed care plan.

The rule also limits enrollment in certain D-SNPs to those individuals who are also enrolled in an affiliated managed care organization and limits the number of D-SNP plan benefit packages an MA plan or its parent company can offer in the same service area as an affiliated Medicaid managed care plan.

Overpayments

The CY 2024 MA proposed rule included a provision that would change the legal standard for identifying an overpayment from "reasonable diligence" to the "knowing" and "knowingly" standard in the False Claims Act. The AHA interprets that this proposed change would have the effect of eliminating the six-month investigation period that providers currently have to quantify overpayments before the obligation to repay is triggered. The AHA urged the agency not to impose an unrealistically strict 60-day deadline on hospitals and health systems to return overpayments once they are on notice of an overpayment from the government and provided detailed comments describing why a quantification period is necessary to investigate the cause of the overpayment and identify the exact amount owed.

This concerning provision was ultimately not finalized in the CY 2024 MA rule, but the agency has indicated in subsequent rulemaking that it intends to address this topic in future regulations. In the CY 2025 final rule, CMS summarizes the previously proposed overpayment provisions from 2024 and provides a status update, noting that the agency "has received inquiries regarding this proposal and want[s] to be clear that it remains under consideration and that CMS intends to issue a final rule to revise the definition of 'identified' in the overpayment rules as soon as is reasonably possible." The AHA will continue to reinforce the concerns that hospitals and health systems have raised with respect to the previously proposed change and urge CMS not to impose an unrealistically strict 60-day deadline on providers to return overpayments without appropriate time for investigation and quantification.

Other Key Provisions

CMS also finalized several other changes including:

- Permitting Part D sponsors to treat formulary substitutions of biosimilar biological products other than interchangeable biological products for their reference products as "maintenance changes" that would not require CMS prior approval.
- Providing additional flexibility for Part D sponsors to immediately substitute a new interchangeable biological product for a reference product (with required notice to affected enrollees) if the product was not on the market at the time the Part D sponsor submitted their initial formulary for CMS approval.
- Modifying the eligibility criteria for the Medicare Part D Medication Therapy Management Program to ensure more consistent, equitable and expanded access.
- Lowering the threshold for identifying D-SNP look-alike plans from 80% to 70% in 2025 and to 60% in 2026 to help encourage the proliferation of MA plans that are serving a high percentage of dually eligible individuals but may not otherwise meet the requirements to be a D-SNP.
- Limiting out-of-network patient cost sharing for D-SNP preferred provider organizations for specific services beginning in 2026.

Finally, CMS reminds stakeholders of the agency's open request for information on Medicare Advantage data and encourages responses by the May 29 deadline.

FURTHER INFORMATION

For additional detail, the CMS Fact Sheet on the final rule summarizes key provisions.

Unless otherwise noted, the rule is applicable to coverage beginning Jan. 1, 2025. The marketing-related provisions are applicable for all CY 2025 marketing and communications beginning Oct. 1, 2024.

If you have further questions, please contact Michelle Millerick, AHA's director of health insurance and coverage policy, at mmillerick@aha.org.