Summary of Contract Year 2024 Medicare Advantage and Part D Final Rule

Executive Summary

On April 5, the Centers for Medicare & Medicaid Services (CMS) released the Contract Year (CY) 2024 Medicare Advantage and Part D <u>final rule</u>, which confirmed technical changes to the Medicare Advantage and Part D programs.

In Medicare Advantage, CMS finalized several provisions as proposed, including adding a health equity index (HEI) to the Star Ratings program, increasing network access requirements for behavioral health providers, adopting stricter requirements on the use of prior authorization, and tightening restrictions on marketing activities.

In Part D, CMS finalized its proposed definition of "gross covered prescription drug costs" and expanded eligibility for people receiving the low-income subsidy (LIS), consistent with the Inflation Reduction Act (IRA). CMS did not finalize proposals to limit midyear formulary changes or modify the Medication Therapy Management (MTM) program, which may be addressed in future rulemaking.

Implementation of Provisions in the Bipartisan Budget Act of 2018; Consolidated Appropriations Act, 2021; and Inflation Reduction Act

The provisions included in this section implement or clarify provisions in previously passed legislation that have implications for the Part D or Medicare Advantage program. CMS finalized provisions to clarify terminology and procedures used in legislation to ensure implementation. These areas include:

- Adapting the regulations to limit contracting with dual-eligible special needs plan (D-SNP) look-alike plans to ensure full implementation of D-SNP requirements in the Bipartisan Budget Act and Medicare Improvements for Patients and Providers Act of 2008
- Modifying the provision of the Consolidated Appropriations Act codifying the timing of the special enrollment period (SEP) for Part B and Part D enrollment as well as Medicare Advantage enrollment.
 - The SEP for individuals who enroll in Part B will align with either Part B entitlement or application submission dates, with their effective date of Part D enrollment being the first of the month after the month of submission.
 - If the Medicare premium Part A and/or Part B exceptional condition SEP is used, there will be a SEP to enroll in Medicare Advantage or a Part D Prescription Drug Plan (PDP).
- Establishing the Limited Income (LI) Net Program as a permanent program within Part D as directed by the Consolidated Appropriations Act. The LI NET program will begin no later than January 1, 2024 and eligible beneficiaries will be provided transitional Part D coverage under an open formulary. One Part D sponsor will serve as the sole contractor administrator and will be selected based on pharmacy access,

past performance, administrative ability, and experience covering low-income beneficiaries.

• Implementing the expanded low-income subsidy (LIS) eligibility from the IRA amendment to provide the full LIS subsidy to those who currently qualify for the partial subsidy.

Medicare Advantage and Part D

Medicare Advantage Policies

Health Equity / CMS finalized several regulatory changes to advance health equity, including listing language capabilities in provider directories, assessing digital health literacy of beneficiaries, and requiring plans add at least one activity in their quality improvement programs aimed at reducing health disparities.

Behavioral Health / CMS finalized behavioral health-related changes intended to strengthen network adequacy requirements for Medicare Advantage plans and encourage access to telehealth providers. Clinical psychology and clinical social work providers will be subject to network adequacy evaluation. CMS did not finalize the proposed addition of prescribers of MOUD as a provider specialty type.

To ensure the availability of behavioral health services for Medicare Advantage enrollees, CMS added the phrase "behavioral health services" to services that must have a coordinated care program in place. CMS also finalized the addition of language clarifying that emergency medical conditions can be physical or mental, in order to ensure access to care for enrollees and require Medicare Advantage organizations (MAOs) to reimburse providers regardless of prior authorization or contractual requirements. Finally, CMS codified appointment wait times to reduce access barriers to both behavioral health services and primary care.

Enrollee Notification Requirements / CMS will require specific enrollee notifications for nocause and for-cause provider contract terminations, with more strict notification requirements for the termination of primary care and behavioral health providers. CMS finalized its proposal to remove the "good faith effort" timing for no-cause terminations, limiting the use to only for-cause terminations.

Utilization Management /

- Coverage Criteria for Basic Benefits
 - CMS finalized its proposal to remove the reference to "original Medicare manuals and instructions" from current regulations and require MAOs to comply with general coverage and benefit conditions included in traditional Medicare laws. CMS finalized its proposal referring to specific Medicare regulations that include example coverage criteria for Part A inpatient admissions, skilled nursing facility care, home health services, and inpatient rehabilitation facilities.
 - CMS finalized the requirement for MAOs to make medical necessity determinations based on coverage and benefit criteria specified in traditional Medicare regulations. Per the final rule, MAOs cannot deny coverage for basic

benefits on criteria that are not specified in the regulation (e.g., internal, proprietary, or external clinical criteria not found in traditional Medicare coverage policies). CMS modified its proposal to include that when coverage criteria is not fully established, MAOs may use internal coverage criteria but must make such criteria publicly available.

- CMS finalized its proposal requiring MAOs to publicly issue summaries of evidence considered for the development of internal coverage criteria for medical necessity determinations when coverage criteria is not found in traditional Medicare coverage policies. CMS finalized its proposal requiring internal coverage criteria to be based on current evidence in widely used treatment guidelines or clinical literature.
- CMS finalized its proposal to restrict MAOs' ability to limit when and how a covered benefit is furnished when traditional Medicare will cover different provider settings. Under the proposed changes, MAOs could still choose who provides Part A and Part B benefits through contracted networks.
- Appropriate Use of Prior Authorization: CMS finalized its proposal to add a new section (§ 422.138(b)(1)–(3)) to limit the use of prior authorization only to confirm the presence of a diagnosis or other medical criteria needed to ensure that the basic benefit is medically necessary, or the supplemental benefit is clinically appropriate. CMS also finalized its proposal to codify sub-regulatory guidance (section 10.16 of Chapter 4 of the Medicare Managed Care Manual), which states that when a plan approves a pre-service determination, it cannot later deny coverage or payment based on medical necessity.
- Continuity of Care: CMS finalized its proposal to require that the approval of a prior authorization request for a course of treatment be valid for as long as medically necessary for coordinated care plans in continuity and coordination of care requirements. Further, CMS prohibits coordinated care plans from disrupting or requiring prior authorization for any active course(s) of treatment for at least 90 days when an enrollee has enrolled in a Medicare Advantage plan after starting a course of treatment.
- Mandated Annual Review of Utilization Management Policies by Committee: CMS finalized its proposal requiring MAOs to establish a utilization management (UM) committee by January 1, 2024 to review UM policies and procedures at least once a year. The committee will be required to document its rationale for developing UM policies. The rule outlines the criteria to be reviewed by the committee, and notes that the group will be led by a medical director and be composed primarily of practicing physicians.

Review of Medical Necessity Decisions / MAOs are currently required to have a procedure for determining an enrollee's entitlement to a health service and how much the individual must pay for the service. CMS narrowed the coverage determination reviewer description to state that the reviewer must have expertise specific to the service that is being requested in cases where the MAO or applicable integrated plan expect to issue a restrictive medical necessity decision or deny the request.

Key Part D Policies

Clarifying the Definition of Gross Covered Prescription Drug Costs in Part D / CMS finalized its proposal to modify the definition of gross covered prescription drug costs (GCPDC) in regulation to remove the phrase "actually paid" and clarify that GCPDC do not reflect all direct and indirect remuneration (i.e., rebates). Because the IRA references "gross covered prescription drug costs" as it relates to selection of drugs to be negotiated by the Secretary of Health and Human Services, CMS noted that this change will remove ambiguity between the IRA and the regulatory definition of GCPDC. CMS specified that the revision to the definition is consistent with current policy and operations (e.g., payment calculations and reporting requirements) under Part D.

Eligibility for Low-Income Subsidies / CMS will implement LIS income and resource requirement changes to provide the full LIS subsidy for those who currently qualify for the partial subsidy as required by the IRA. Beginning on or after January 1, 2024, CMS will implement the following provisions:

- Eligibility for the partial subsidy will require an income below 150% of the federal poverty level (FPL), applicable to plan years beginning before January 1, 2024
- The resource standards that currently apply to the partial subsidy will apply to beneficiaries eligible for the full LIS subsidy, enabling partial LIS enrollees to access the full LIS

CMS plans to conduct direct-to-consumer outreach to promote LIS enrollment in 2024 and is contemplating sending notices in the fall of 2023 to individuals with the partial LIS to notify them of the increased assistance they will receive in 2024.

Star Rating System

Measure Weights / The rule lowered the measure weight of the patient experience/complaints and access measures from 4 to 2 for the 2026 Star Ratings/2024 measurement period. These measure weights were increased from 1.5 to 2 in the 2021 Star Ratings, and from 2 to 4 in the 2023 Star Ratings. CMS proposed treating measures with substantive updates as new for weighting purposes and giving them a weight of 1 for the first year but the final rule did not address this proposal.

Guardrails / CMS will retain the guardrails (caps in either direction) of non-Consumer Assessment of Healthcare Providers and Systems (non-CAHPS) measures, and the removal as proposed will be addressed in a later final rule.

Health Equity Index Reward / This rule added an HEI, as proposed, to the Star Ratings program to replace the reward factor. The HEI is intended to address disparities in care by rewarding contracts that can achieve high measure-level scores for enrollees with social risk factors. The HEI will augment (not replace) the categorical adjustment index (CAI) in the 2027 Star Ratings.

CMS will use dual eligibility or disability (similar to the CAI) to create the HEI initially. CMS also explored the Area Deprivation Index but decided against its inclusion because the analysis found that this index did not explain additional variation in quality of care beyond LIS/dual eligibility and disability.

HEI Calculation: Measure-level scores for enrollees who are dual eligible, receive a low-income subsidy, or who have a disability are combined over the 2 most recent measurement years. The final rule clarified that measure-level scores will only be used for contracts with data from the most recent of the 2 years and not for those with data from only the first of those years. Measures that are typically case-mix adjusted will continue to be so adjusted (excluding social risk factor-related adjusters). Measures are only included if they are focused on an individual (rather than a plan) and if they have reliability of at least 0.7 and meet any denominator criteria within the social risk factor subset. The HEI score will then be assigned to a contract according to the distribution of HEI contract performance for the measure with the top third of plans receiving 1 point, the middle receiving 0 points, and the bottom receiving -1 point. The final HEI score will be the weighted average calculated using the weights assigned to the measure.

Extreme and Uncontrollable Circumstances / Starting with the 2024 Star Ratings, CMS finalized a standard statistical model to remove extreme outliers from measure scores. It will also remove the 60% rule that adjusts plan measures in extreme and uncontrollable circumstances, beginning with the 2026 Star Ratings.

Improvement Measure Hold Harmless / CMS did not finalize its proposed modification to only apply the hold harmless provision to contracts with five stars for their highest rating to encourage improvement across all measures. Under the hold harmless provision, the highest rating for contracts with four or more stars will not be reduced by the addition of improvement measures into the calculation. This proposed modification will be addressed in a later final rule.

Quality Bonus Payment Rules / The proposed rule included provisions to clarify the quality bonus payment appeals process. Under the proposed rule, CMS would prohibit MAOs from requesting administrative reviews based on data accuracy from numerous listed sources because they have already been validated or audited or have come from CMS itself. Additionally, the proposed rule would have prevented MAOs from appealing measures based on feedback or surveys from enrollees. CMS did not address these proposals in the final rule.

Marketing

Overview / CMS finalized most provisions from the proposed rule to change Medicare communication and marketing to ensure that beneficiaries are not misled by inaccurate marketing materials. The final rule limits the use of the Medicare name, logo, and products or information in MAO or Part D sponsors' marketing materials to prevent beneficiaries from associating non-Medicare-related materials with Medicare. One minor modification from the proposed rule permits the use of the Medicare card image with CMS authorization.

Another change finalized as proposed is an increase in CMS authority to review marketing materials, develop marketing standards, and prohibit certain marketing activities. The prohibition of benefits marketed in service areas where the benefits are not available was finalized as proposed and codifies previous CMS guidance.

CMS finalized the proposed prohibition on marketing potential savings to enrollees under certain conditions. The proposal to prohibit marketing that does not clearly identify the name of the MAO/Part D sponsor and the product being advertised was modified in the final rule to require the marketing names be read or displayed at the same pace or in the same font as other contact information in the advertisement. MAOs and Part D sponsors must increase their oversight and

monitor agent/broker activities by developing an oversight plan to ensure compliance with CMS standards, as outlined in the proposed rule.

One provision from the proposed rule that would prohibit third-party marketing organizations (TPMOs) from distributing beneficiary contact information was not addressed in the final rule.

Policies Not Addressed in the Final Rule

CMS did not finalize several policies included in the proposed rule but did note that they will be addressed in future rulemaking. These provisions include:

- Clarification of the definition of "cash equivalent," as its use in regulation has been questioned (MAOs are currently prohibited from rewarding cash or cash equivalents to enrollees under Reward and Incentive programs)
- Updated policies related to incorrect collections of premiums and cost-sharing payments
- Alteration and codification of certain SEPs (e.g., clarifying language regarding SEPs for government-declared disasters or other emergencies, altering the SEP end date for state or local emergencies, and codifying SEPs and disenrollment changes for changes in residence)
- Allowing CMS to terminate a contract with an MAO or levy immediate enrollment and marketing sanctions if there is a change in ownership while under contract.
- Midyear formulary changes (e.g., allowing plans to substitute new interchangeable biological products for corresponding reference products and authorized generics for corresponding brand equivalents)
- Changes to MTM programs to reduce minimum eligibility requirements
- Updated standards for electronic prescribing and adoption of health IT standards
- Changes to Part D PDP requirements, including prohibiting PDP sponsors and all subsidiaries from offering plan benefit packages under more than one contract in a Part D region, and to plan crosswalk requirements
- Codification of chronic condition special needs plan (C-SNP) scope and enrollment eligibility based on an updated list of chronic conditions and combinations
- Definition of institutional special needs plan (I-SNP) and codification of current policies regarding contract requirements with institutions
- Codification of several policies in current guidance including: (1) prohibitions on changes to plan benefits between October 1 and the end of the plan year, (2) midyear formulary changes, (3) grace periods for failure to pay, (4) reinstatement of enrollment for good cause, (5) policies related to disenrollment, (6) formulary coverage for drug shortages, (7) transition fill requirements, (8) automatic shipment policies, (9) single-tier benefit structure requirements for Part D plans offering defined standard coverage, and (10) retroactive transaction processes for employer/union group health plan members
- Modifying policies related to "global reopenings" and "targeted reopenings"
- Updates to requirements for Part D sponsor contracts with first tier, downstream or related entities as they relate to contract termination

- Clarification that the 2-year prohibition on reentering Part D following non-renewal only applies at the regional level
- Removing discretionary language regarding Part D plan sponsors' responsibility for establishing drug management programs for at-risk beneficiaries
- Updates to the settlement process and final settlement appeals process for organizations consolidating, non-renewing, or terminating a contract
- Prohibition of TPMOs from distributing beneficiary contact information
- Removal of guardrails when determining measure-specific thresholds for non-CAHPS measures
- Modifications to the improvement measure hold harmless policy
- Clarifications for Quality Bonus Payment appeals and weighting measures with substantive changes