Issue Brief

FEDERAL ISSUE BRIEF

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

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CMS Issues Final Rule Regarding Contract Year 2025 Medicare Advantage and Part D Final Rule

The Centers for Medicare & Medicaid Services (CMS) have released a final rule regarding Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2025.

The rule will revise the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), Medicare cost plan, and Programs of All-Inclusive Care for the Elderly (PACE) regulations to implement changes related to Star Ratings, marketing and communications, agent/broker compensation, health equity, dual eligible special needs plans (D-SNPs), utilization management, network adequacy, and other programmatic areas. The rule also codifies existing sub-regulatory guidance in the Part C and Part D programs.

The rule is effective June 3, 2024.

A copy of the 1,327-page document is available at: https://public-inspection.federalregister.gov/2024-07105.pdf. Publication is scheduled for April 23.

CMS provides the table summarizing the changes being made.

Summary of Costs, Transfers, and Benefits

Provision	Description	Financial Impact
1. Part D Medication Therapy Management (MTM) Program: Eligibility Criteria	CMS is finalizing changes to the MTM eligibility requirements to (1) codify the 9 core chronic diseases currently identified in sub-regulatory guidance and adding HIV/AIDS for a total of 10 core chronic diseases; (2) require Part D sponsors to include all core chronic diseases in their MTM targeting criteria, and to include all Part D maintenance drugs when determining the number of drugs an enrollee is taking; and (3) revise the methodology for the MTM cost threshold to calculate the dollar amount based on the average annual cost of 8 generic drugs.	The revisions to the MTM targeting criteria have an estimated annual administrative cost of $192.7 million. CMS says it is unable to score this provision largely due to challenges with estimating Part A/B savings.
2. Improving Access to Behavioral Health Care Providers	CMS is finalizing changes to add a new facility- specialty type called "Outpatient Behavioral Health" to the network adequacy standards under § 422.116(b)(2). For purposes of the network adequacy requirements, the new facility- specialty type will be evaluated using time and distance and minimum number standards adopted in this rule. The new facility type will include MFTs, MHCs, OTP or other behavioral health and addiction medicine specialists and facilities. Based on comments from stakeholders CMS is also finalizing how an organization will determine when certain providers (NP, PA, CNS) may be utilized to meet network adequacy.	The new provision adds requirements for a new facility specialty type, which include providers some of which CMS has data for and some which are new and for which CMS lacks data. Therefore, CMS cannot quantify the effects of this provision though CMS expects it may increase access which may qualitatively increase utilization.
3. Distribution of Personal Beneficiary Data by Third Party Marketing Organizations (TPMOs)	CMS is codifying that personal beneficiary data collected by a TPMO for marketing or enrolling the beneficiary into an MA or Part D plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Further, CMS is codifying that prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained separately for each TPMO that receives the data through a clear and conspicuous disclosure.	CMS does not expect any cost impact to the Medicare Trust Fund.

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Provision	Description	Financial Impact
4. Enhance Guardrails for Agent/Broker Compensation	CMS is modifying agent/broker compensation requirements to further ensure payment arrangements and structure are aligned with CMS's statutory obligation to set limits on compensation to ensure that the use of compensation creates incentives for agents and brokers to enroll prospective enrollees in plans that best fit their needs.	This provision has no costs because CMS is transferring funds the MA plans are already paying Marketing Agencies directly to the agents and brokers with some reductions due to some funds possibly being used inconsistent with the requirements of the regulation.
5. Special Supplemental Benefits for the Chronically Ill (SSBCI)	CMS is finalizing changes to require MA organizations to establish bibliographies for each SSBCI they include in their bid to demonstrate that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. This will shift the burden from CMS to the MA organizations to demonstrate compliance with this standard and help ensure that SSBCI items and services are offered based on current, reliable evidence. In addition, CMS is finalizing new policies to protect beneficiaries and improve transparency regarding SSBCI so that beneficiaries are aware that SSBCI are only available to enrollees who meet specific eligibility and coverage criteria. CMS is modifying and strengthening the current requirements for the SSBCI disclaimer that MA organizations offering SSBCI must use whenever SSBCI are mentioned.	The requirements for SSBCI are not expected to have any economic impact on the Medicare Trust Fund.
6. Mid-Year Enrollee Notification of Available Supplemental Benefits	CMS is finalizing requirements for MA plans to issue notices to enrollees who, by June 30th of a given year, have not utilized supplemental benefits, to ensure enrollees are aware of the availability of such benefits and ensure appropriate utilization.	Although these changes may result in increased utilization and ultimately create a savings to the Medicare Trust Fund, CMS cannot currently quantify this provision because it is new, and lacks data. See the Regulatory Impact Analysis for further discussion. The provision has an administrative cost of $23.7 million.
7. Annual Health Equity Analysis of Utilization Management Policies and Procedures	CMS is finalizing changes to the composition and responsibilities for the Utilization Management committee, to require: a member of the UM committee have expertise in health equity; the UM committee conduct an annual health equity analysis of prior authorization used by the MA organization using specified metrics; and require MA organizations to make the results of the analysis publicly available on its website.	CMS does not expect any cost impact to the Medicare Trust Fund.
8. Amendments to Part C and Part D Reporting Requirements	CMS is affirming its authority to collect detailed data from MA organizations and Part D plan sponsors under the Part C and D reporting requirements and finalizing the proposed regulatory revisions to be consistent with the broad scope of the reporting requirements.	CMS does not expect any cost impact to the Medicare Trust Fund.
9. Enhance Enrollees' Right to Appeal an MA Plan's Decision to Terminate Coverage for Non-Hospital Provider Services	CMS is finalizing regulations to (1) require Quality Improvement Organizations (QIOs) to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF and (2) eliminate the provision requiring the forfeiture of an enrollee's right to appeal to the QIO a termination of services decision when they leave the facility.	The revisions to this provision have an estimated annual administrative cost of $683,910. This is a transfer from MA plans to QIOs; MA plans have a reduced cost while QIOs have a corresponding increased cost.
10. Changes to an Approved Formulary—Including Substitutions of Biosimilar Biological Products	CMS is finalizing regulations to permit Part D sponsors to immediately substitute authorized generics for corresponding brand name drug products, interchangeable biological products for their reference products, and unbranded biological products marketed for the brand name biological product marketed under the same biologics license application. CMS also is finalizing regulations to permit substitutions of all biosimilar biological products with 30 days advance notice.	CMS does not expect any cost impact to the Medicare Trust Fund.

Provision	Description	Financial Impact
11. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services from the Same Organization	CMS is finalizing, with some modifications, policies to (a) replace the current dual/LIS quarterly SEP, (b) create a new integrated care SEP for full-benefit dually eligible individuals, limit enrollment in certain D-SNPs to those full-benefit dually eligible individuals who are also enrolled in an affiliated Medicaid MCO, and (c) limit the number of D-SNPs an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, can offer in the same service area as an affiliated Medicaid MCO.	Over a 10-year horizon, CMS estimates a $1.3 billion savings to the Trust Fund for Part D plans and an additional $1 billion savings to the Trust Fund for Part C plans.
12. For D-SNP PPOs, Limit Out-of- Network Cost Sharing	CMS is finalizing a limitation on D-SNP PPOs' out-of-network cost sharing for certain Part A and Part B benefits, on an individual service level.	CMS does not expect any cost impact to the Medicare Trust Fund.
13. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes	CMS is lowering the D-SNP look-alike threshold from 80 percent to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years.	CMS estimates this provision will have an average annual impact of less than $1M for plan years 2025-2027 due to non-SNP MA plans meeting the lower D-SNP look-alike threshold transitioning enrollees into other plans. CMS also estimates this provision will have an average annual impact of less than $1M on MA plan enrollees for plan years 2025-2027 due to enrollees choosing a different plan. CMS expects cumulative annual costs to non-SNP MA plans and MA plan enrollees beyond plan year 2027 to also be less than $1M per year.
14. Standardize the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) Appeals Process	CMS is revising when a medical record review determination and a payment error calculation appeal can be requested and adjudicated because RADV payment error calculations are based upon the outcomes of medical record review determinations. CMS is also finalizing other revisions to its appeals process to conform with these proposed changes. The changes could reduce burden on some MA organizations that, absent these revisions, will have otherwise potentially submitted payment error calculation appeals that could have been rendered moot by certain types of medical record appeals decisions. The potential reduction in burden to MA organizations cannot be quantified prior to the implementation of the new appeals process and until appeals have been fully adjudicated. While the MA RADV appeals regulations have been in place for a period of years, CMS did not issue RADV overpayment findings to MA organizations as it worked to finalize a regulation on its long-term RADV methodology. Therefore, any impact of these policies on MA organization behavior is further unquantifiable. The proposed changes do not impose any new information collection requirements.	The potential reduction in burden to MA organizations cannot be quantified prior to the implementation and execution of the appeals process pursuant to these changes.

The following material is from CMS' fact sheet accompanying this rule.

New Guardrails for Plan Compensation to Agents and Brokers to Stop Anti-Competitive Steering

CMS is finalizing requirements that redefine "compensation" to set a clear, fixed amount that agents and brokers can be paid regardless of the plan the individual enrolls in, addressing loopholes that result in commissions above this amount that create anti-competitive and anti-consumer steering incentives. The provisions of this final rule, which are applicable beginning with the upcoming Annual Enrollment Period, ensure that agent and broker compensation reflect only the legitimate activities required of agents and brokers, by broadening the scope of the regulatory definition of "compensation," so that it is inclusive of

all activities associated with the sales to/enrollment of an individual into a Medicare Advantage or Part D plan. In response to feedback from stakeholders, CMS is increasing the final national agent/broker fixed compensation amount for initial enrollments into a Medicare Advantage or Part D plan by $100, which is an amount higher than what was proposed ($31). CMS believes this increase will provide agents and brokers with sufficient funds to serve individuals with Medicare. This increase will eliminate variability in payments and improve the predictability of compensation for agents and brokers. This increase will be added to agent and broker compensation payments for the Annual Election Period in Fall 2024 and applied to all enrollments effective in CY2025 and future contract years.

Additionally, the final rule generally prohibits contract terms between Medicare Advantage organizations/Part D sponsors and middleman Third Party Marketing Organizations (TPMOs), such as field marketing organizations, which may directly or indirectly create an incentive to inhibit an agent or broker's ability to objectively assess and recommend the plan that is best suited to a potential enrollee's needs. In the final rule, CMS provides several examples of contract terms that will be impermissible under this prohibition, including provisions offering volume-based bonuses for enrollment into certain plans.

Limiting the Distribution of Personal Beneficiary Data by Third-Party Marketing Organizations

Some TPMOs have been selling and reselling personal beneficiary data, which can undermine existing rules that prohibit cold calling people with Medicare and result in other aggressive marketing tactics for Medicare Advantage and Part D plans. Individuals may be unaware that by placing a call or clicking on a generic-looking web link, they are unwittingly agreeing and providing consent for their personal beneficiary data to be collected and sold to other entities for future marketing activities. To curtail this practice, in this final rule, CMS is codifying the requirement that personal beneficiary data collected by a TPMO for marketing or enrolling the individual into a Medicare Advantage or Part D plan may only be shared with another TPMO when prior express written consent is given by the individual. Further, the TPMO must obtain this written consent through a transparent, and prominently placed, disclosure from the individual to share the information and be contacted for marketing or enrollment purposes, separately for each TPMO that receives the data; i.e., one-to-one consent, which is generally consistent with Federal Trade Commission (FTC) and Federal Communications Commission (FCC) regulations.

Improving Access to Behavioral Health Care Providers

CMS is taking steps to improve access to behavioral health care services for Medicare Advantage plan enrollees by finalizing important updates to network adequacy standards. The ***Consolidated Appropriations Act***, 2023 established a new statutory Medicare benefit category for services furnished by marriage and family therapists (MFTs) and mental health counselors (MHCs). Through separate rulemaking in the Calendar Year 2024 Physician Fee Schedule final rule, CMS implemented these new statutory requirements for MHCs so that they can enroll in Medicare. Many MFTs and MHCs practice within outpatient behavioral health facilities, such as mental health centers, substance use treatment centers, and hospitals. To help ensure that people with a Medicare Advantage plan have access to behavioral health providers, including these newly enrolled providers, CMS is adding network adequacy evaluation standards for a new facility-specialty provider category, called "Outpatient Behavioral Health," that will include a range of behavioral health providers under one category. Specialists in this new facility-specialty category include MFTs and MHCs, Opioid Treatment Program providers, Community Mental Health Centers, addiction medicine physicians, and other providers, like nurse practitioners (NPs), physician assistants (PAs), and Clinical Nurse Specialists (CNSs), who regularly furnish addiction medicine and behavioral health counseling or therapy services covered by Medicare. To address concerns from commenters that some NPs, PAs, and CNSs might lack the necessary skills, training, or expertise to effectively address the behavioral health needs of enrollees, CMS added specific criteria that MA organizations must use to determine when an NP, PA or CNS can be included in the Outpatient

Behavioral Health category to meet the new network adequacy standards for Outpatient Behavioral Health. Specifically, Medicare Advantage plans must independently verify that the provider they are adding to their network has furnished or will furnish such services to at least 20 patients within a 12-month period, using reliable information about services furnished by the provider, such as the Medicare Advantage plan's claims data, prescription drug claims data, electronic health records or similar data in order to make this determination.

In addition, while evaluating an MA organization's network, CMS is adding this Outpatient Behavioral Health facility specialty to the list of the specialty types that will receive a 10 percent credit toward meeting required time and distance standards. The Medicare Advantage organization's contracted network of providers must include one or more telehealth providers of that specialty type who provide additional telehealth benefits for covered services.

Mid-Year Enrollee Notification of Available Supplemental Benefits

An increasing share of Medicare dollars is going toward Medicare Advantage plan rebates, roughly $337 billion over the last 10 years, and the 2023 Trustees Report estimated $67 billion in 2024 alone. Medicare Advantage plans can use these rebate dollars to advertise a wide array of supplemental benefits, including special supplemental benefits for chronically ill enrollees. In 2022, over 99 percent of Medicare Advantage plans offered at least one supplemental benefit. The median was 23 supplemental benefits, and the most frequently offered benefits were vision, hearing, fitness, and dental. Some of these benefits address unmet social determinants of health needs, such as food insecurity or inadequate access to transportation. However, at the same time, some plans have indicated that enrollee utilization of many supplemental benefits is low. 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, the final rule requires Medicare Advantage plans to engage in outreach efforts so that enrollees are aware of the supplemental benefits available to them. CMS is requiring Medicare Advantage plans to issue a "Mid-Year Enrollee Notification of Unused Supplemental Benefits" annually, between June 30 and July 31 of the plan year, that is personalized to each enrollee, and that includes a list of any supplemental benefits not accessed by the individual during the first six months of the year. In addition, the notification will include the scope of the benefit, cost-sharing, instructions on how to access the benefit, any network application information for each available benefit, and a customer service number to call if additional help is needed.

New Standards for Supplemental Benefits for the Chronically Ill

The Bipartisan Budget Act of 2018 authorized Medicare Advantage plans to cover new special supplemental benefits for the chronically ill (SSBCI), which are benefits provided only to eligible chronically ill enrollees and that must have a reasonable expectation of improving or maintaining health or overall function of the enrollee. CMS is finalizing new requirements for Medicare Advantage plans to demonstrate, with support from research by the time they submit bids, that SSBCI items and services meet the legal threshold of having a reasonable expectation of improving the health or overall function of chronically ill enrollees. Medicare Advantage plans must establish and maintain bibliographies of relevant research studies or other data to demonstrate that an SSBCI meets these requirements. Additionally, CMS updated SSBCI marketing and communications requirements to prevent misleading marketing and communications related to these benefits that may make it appear that the benefits are available to everyone.

Annual Health Equity Analysis of Utilization Management Policies and Procedures

Prior authorization policies and procedures may have a disproportionate impact on underserved populations and may delay or deny access to certain services. The final rule ensures that Medicare Advantage organizations analyze their utilization management (UM) policies and procedures from a

health equity perspective. CMS is updating the composition of, and responsibilities for, the UM committee to require: 1) at least one member of the UM committee has expertise in health equity, 2) the UM committee conducts plan-level annual health equity analysis of prior authorization policies and procedures used by the Medicare Advantage plan, and 3) the results of the analysis be made publicly available on the plan's website. The goal of the health equity analysis is to create additional transparency and identify disproportionate impacts of UM policies and procedures on enrollees who receive the Part D low-income subsidy, who are dually eligible, or who have a disability.

Enhance Enrollees' Rights to Appeal a Medicare Advantage Plan's Decision to Terminate Coverage for Non-Hospital Provider Services

Currently, enrollees in a Medicare Advantage plan do not have the same access to Quality Improvement Organization (QIO) review of a fast-track appeal as individuals in Traditional Medicare. CMS is revising regulations to (1) require the QIO, instead of the Medicare Advantage plan, to review untimely fast-track appeals of a Medicare Advantage plan's decision to terminate services in a skilled nursing facility, comprehensive outpatient rehabilitation facility or by a home health agency; and (2) fully eliminate the provision requiring forfeiture of an enrollee's right to appeal a termination of services from these providers when they leave the facility. These changes will bring Medicare Advantage plan regulations in line with the parallel reviews available to individuals Traditional Medicare and expand the rights of Medicare Advantage plan enrollees to access the fast-track appeals process.

Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services From the Same Organization

Dually eligible individuals face a complex assortment of enrollment options. The rule will improve experiences and outcomes for dually eligible individuals by increasing the percentage of dually eligible Medicare Advantage enrollees who are in affiliated Medicaid managed care plans, as opposed to Medicare Advantage plans that differ from the enrollee's Medicaid plan. To achieve this, the rule (a) revises the current Part D quarterly special enrollment period (SEP) for dually eligible, and other Part D low-income subsidy (LIS) enrolled individuals, to a once-per-month SEP to enroll in a standalone prescription drug plan and (b) creates a new integrated care SEP to allow dually eligible individuals to elect an integrated dual eligible special needs plan (D-SNP) when the individual also receives Medicaid services through an affiliated managed care plan. Further, this rule (c) limits enrollment in certain D–SNPs to those individuals who are also enrolled in an affiliated Medicaid managed care organization (MCO), and (d) limits the number of D–SNP plan benefit packages an MA organization, its parent organization, or entity that shares a parent organization with the MA organization, can offer in the same service area as an affiliated Medicaid MCO.

Increasing the percentage of dually eligible Medicare Advantage enrollees who are in plans that also cover Medicaid will expand access to integrated materials, unified appeal processes across Medicare and Medicaid, and continued Medicare services during an appeal for those individuals. By reducing the number of plans that can enroll dually eligible individuals outside of the annual election period, the rule will also reduce aggressive, confusing marketing tactics toward dually eligible individuals throughout the year.

For D-SNP PPOs, Limit Out-of-Network Cost Sharing

The rule limits out-of-network cost sharing for Medicare Advantage D-SNP preferred provider organizations (PPOs) for specific services beginning in 2026. The rule will reduce cost-shifting to

Medicaid, increase payments to safety net providers, expand dually eligible enrollees' access to providers, and protect dually eligible enrollees from unaffordable costs.

Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes

The rule will lower the Medicare Advantage D-SNP look-alike threshold from 80 percent to 70 percent in 2025 and to 60 percent in 2026. This policy will help to address the continued proliferation of Medicare Advantage plans that are serving high percentages of dually eligible individuals without meeting the requirements to be a D-SNP and promoting full implementation of requirements for D-SNPs, including minimum integration standards as required under section 1859(f)(8)(D)(i) of the Act, as added by the ***Bipartisan Budget Act*** of 2018.

Standardize the Medicare Advantage Risk Adjustment Data Validation (RADV) Appeals Process

The final rule addresses operational constraints in existing Risk Adjustment Data Validation (RADV) appeal regulations. CMS is finalizing revisions to the appeals process whereby Medicare Advantage organizations will not request both a medical record review determination appeal and a payment error calculation appeal at the same time. Medicare Advantage organizations that request a medical record review determination appeal may only request a payment error calculation appeal after the completion of the medical record review determination administrative RADV appeal process. Additionally, the final rule clarifies that a revised audit report containing a recalculated payment error calculation will not be issued by the Secretary at each level of appeal, but instead will be issued when a medical record review determination appeal or a payment error calculation appeal is final, as applicable. Finally, the final rule includes a requirement that if the CMS Administrator does not decline to review or does not elect to review within 90 days of receipt of either the Medicare Advantage organization's or CMS' timely request for review (whichever is later), the hearing officer's decision becomes final.

More Flexibility to More Quickly Substitute Lower Cost Biosimilar Biological Products for Their Reference Products

CMS is finalizing two changes to provide Part D sponsors with more flexibility to make midyear substitutions of biosimilars for their reference products on their formularies:

- All biosimilars may be substituted as formulary maintenance changes: Part D sponsors may treat formulary substitutions of all biosimilars for their reference products as "maintenance changes" that would not require explicit prior approval by CMS. This option has previously been available only for interchangeable biological products. Part D sponsors previously had to obtain explicit approval prior to substituting biosimilars other than interchangeable biological products, and these substitutions applied only to enrollees who began therapy after the effective date of the change — delaying enrollees' access to cheaper options. Treating all biosimilar substitutions as maintenance changes means that midyear formulary substitutions of biosimilars for their reference products would apply to all enrollees (including those already taking the reference product prior to the effective date of the change) following a 30-day advance notice to affected enrollees.
- *New interchangeable biological products may be immediately substituted:* CMS is finalizing additional flexibility for interchangeable biological products not on the market at the time that Part D sponsors submit their initial formulary for CMS approval. Part D sponsors meeting certain requirements have the additional option to immediately substitute a new interchangeable biological product for a reference product and provide notice of the change to affected enrollees after making such change.

These changes provide Part D sponsors with mechanisms to give enrollees access to equally effective — but potentially more affordable — options sooner than under the current policy.

Medicare Part D Medication Therapy Management (MTM) Program

CMS is finalizing improved targeting criteria for the Medicare Part D MTM program that will help ensure more consistent, equitable, and expanded access to MTM services. Specifically, CMS is finalizing changes to the MTM eligibility criteria to: (1) add HIV/AIDS to the list of core chronic diseases, requiring plan sponsors to include all ten core chronic diseases identified by CMS in their targeting criteria; (2) require plan sponsors to include all Part D maintenance drugs and expressly state that Part D sponsors retain the flexibility to include all Part D drugs in their targeting criteria; and (3) revise the methodology for calculating the MTM cost threshold to be commensurate with the average annual cost of eight generic drugs (set at $1,623 for CY 2025). CMS is not finalizing the proposal to reduce the maximum number of drugs a plan sponsor may require for targeting enrollees taking multiple Part D drugs and is retaining the maximum number of drugs as eight drugs.