MEMORANDUM

To: PQA Members

From: PQA

Date: May 29, 2024

Re: Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024--Remaining Provisions and Contract Year 2025 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 (PACE)

The Centers for Medicare & Medicaid Services (CMS) has issued "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 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 (PACE)."

The rule, CMS-4201-F3 and CMS-4205-F, was published in the Federal Register on April 23, 2024, and can be found here. An April 4 CMS press release and fact sheet provide additional information on the final rule.

PQA summarized points of interest in this final rule for our members, including updates to the Star Ratings program. Specifically, our summary is focused on the Part D Medication Therapy Management (MTM) Program [P. 22] and Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System [P. 180].

Summary Explanation

The page numbers listed in the following summary correspond to the Federal Register document. An executive summary is provided on pages 2-3 and focuses narrowly on items most relevant to PQA's work. A broader summary of points of interest to PQA, its members and medication use is provided on pages 4-15.

Our goal with this summary is to isolate for your convenience the most relevant sections within the 401-page final rule. **In the broad summary, the language used is almost entirely verbatim from the final rule, so that we do not introduce interpretations of CMS' language. We recommend reviewing the original, full text for clarity and context as needed.**

The bold language in our summary is for emphasis to draw attention to specific items within the text. Finally, the text boxes indicate areas where CMS addressed comments, with a focus on comments relevant to PQA and its work. Not all comments and responses are included in the PQA summary.

PQA Executive Summary: CMS-4201-F3 and CMS-4205-F

Section 1. General Information

A. Applicability Dates

The provisions in this rule are applicable to coverage beginning January 1, 2025, except as otherwise noted.

Section 2. Part D Medication Therapy Management (MTM) Program

1. MTM Eligibility Criteria

CMS performed an extensive analysis to identify potential disparities in MTM program eligibility and access, as discussed in the December 2022 proposed rule, and CMS identified the high cost threshold and increasingly restrictive plan criteria (e.g., targeting select core chronic diseases or specific drugs) as the main drivers of the eligibility gaps. In the December 2022 proposed rule, CMS proposed changes to the MTM program eligibility criteria to address these concerns and help ensure beneficiaries with more complex drug regimens who would benefit most from MTM services are eligible.

After consideration of the comments received, CMS is finalizing proposed changes to the Part D MTM program eligibility requirements with the modifications discussed. The changes are effective January 1, 2025 and are summarized below.

- Part D sponsors must include all core chronic diseases in their targeting criteria for identifying beneficiaries who have multiple chronic diseases.
    - CMS is codifying the nine core chronic diseases currently identified in guidance and adding HIV/AIDS.
- CMS is retaining the maximum number of drugs a plan sponsor may require for targeting beneficiaries taking multiple Part D drugs at eight.
    - Part D sponsors will maintain the flexibility to set a lower thresholder (a number between two and eight Part D drugs).
- Part D sponsors will be required to include all Part D maintenance drugs in their targeting criteria and have the flexibility to include all Part D drugs in their targeting criteria.
    - Sponsors will not be permitted to limit their MTM targeting criteria to specific Part D maintenance drugs or drug classes.
    - Plans must rely on information in a widely accepted, commercially or publicly available drug information database.
- The MTM cost threshold will be set at the average cost of eight generic drugs.
    - CMS will calculate the dollar amount of the MTM cost threshold based on the average daily cost of a generic drug using the PDE data.

The changes also take into consideration the burden a change in the MTM program size would have on sponsors, MTM vendors, and the health care workforce. With these changes, CMS estimates that the number and percent of Part D enrollees eligible for MTM will increase from 3.6 million (7% of Part D enrollees based on actual 2022 MTM enrollment data) to a total of 7.1 million (13% of Part D enrollees estimated using 2022 data), which is smaller than the estimated program size of 11 million beneficiaries in the December 2022 proposed rule.

2. Define ‘‘Unable to Accept an Offer to Participate’’ in a Comprehensive Medication Review (CMR)

In guidance issued annually, CMS has consistently stated that they consider a beneficiary to be unable to accept an offer to participate in a CMR only when the beneficiary is cognitively impaired and cannot make

decisions regarding their medical needs. In the December 2022 proposed rule, CMS proposed to codify this definition by amending the current regulation text to specify that in order for the CMR to be performed with an individual other than the beneficiary, the beneficiary must be unable to accept the offer to participate in the CMR due to cognitive impairment.

CMS is finalizing the definition of a “unable to accept an offer to participate” in a CMR to provide that a beneficiary must be unable to accept the offer to participate in the CMR due to cognitive impairment.

3. Requirement for In Person or Synchronous Telehealth Consultation

As discussed in the December 2022 proposed rule, CMS proposed to require that the CMR be performed either in person or via synchronous telehealth to clarify that the CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via telehealth. While the consultation must be conducted in real-time, under this proposal, plans would continue to have the discretion to determine whether the CMR can be performed in person or using the telephone, video conferencing, or another real-time method.

CMS is finalizing the proposed requirement for in person or synchronous telehealth consultation without modification.

Section 3. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System

B. Adding, Updating, and Removing Measures

2. Measure Updates

c. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) (Part D) - Substantive Change

After consideration of the comments received, CMS is finalizing the proposed update to move the MTM Program Completion Rate for CMR measure to the display page for at least two years before adding it to the Star Ratings. As discussed in the final rule, CMS is finalizing changes to the targeting criteria that will be effective on January 1, 2025. Therefore, the MTM Program Completion Rate for CMR measure will move to the display page entirely for the 2025 and 2026 measurement years and would return as a new measure to the Star Ratings program for the 2027 measurement year for the 2029 Star Ratings.

3. Measure Additions

a. Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS) (Part D)

CMS proposed to add the following three Part D measures to the 2026 Star Ratings (2024 measurement year), which are measures developed by the PQA: COB, Poly-ACH, and Poly-CNS. The new Part D measures are calculated from Prescription Drug Event (PDE) or CMS administrative data, so they do not require any new data collections.

Additionally, as announced in the Advance Notice of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies the added measures would include a non-substantive update to align with the PQA measure specifications by using continuous enrollment (CE) and no longer adjusting for member-years (MYs).

After considering the comments CMS received and for the reasons outlined in the proposed rule and CMS' responses to the comments, CMS is finalizing the addition of the Poly-ACH and COB measures in the Star Ratings program beginning with the 2025 measurement year for the 2027 Star Ratings. The Poly-CNS measure will remain on the display page and not be added to the Star Ratings.

In addition, CMS announced the non-substantive updates to the Poly-CNS, Poly-ACH, and COB measures to align with the PQA measure specifications to use CE and no longer adjust for MYs in the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. CMS will make the update to change from MYs to CE for the 2024 measurement year for all three measures.

PQA Summary: CMS-4201-F3 and CMS-4205-F

Section 1. General Information [P. 1]

A. Applicability Dates

The provisions in this rule are applicable to coverage beginning January 1, 2025, except as otherwise noted.

Section 2. Part D Medication Therapy Management (MTM) Program [P. 22]

1. MTM Eligibility Criteria

a. Background [P. 22]

CMS requires all Part D sponsors to have an MTM program designed to assure, with respect to targeted beneficiaries, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. Part D sponsors are required to target Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet a cost threshold for covered Part D drugs established by the Secretary. Part D sponsors are also required to target all at-risk beneficiaries in their Part D drug management program for MTM.

As CMS discussed in the December 2022 proposed rule, MTM eligibility rates have steadily declined over time to 8 percent in 2020. In addition, CMS has observed near-universal convergence among Part D sponsors to the most restrictive targeting criteria currently permitted.

CMS performed an extensive analysis to identify potential disparities in MTM program eligibility and access, as discussed in the December 2022 proposed rule, and CMS identified the high cost threshold and increasingly restrictive plan criteria (e.g., targeting select core chronic diseases or specific drugs) as the main drivers of the eligibility gaps. In the December 2022 proposed rule, CMS proposed changes to the MTM program eligibility criteria to address these concerns and help ensure beneficiaries with more complex drug regimens who would benefit most from MTM services are eligible.

The proposed changes included:

- Requiring plan sponsors to target all core chronic diseases identified by CMS, codifying the current nine core chronic diseases in regulation, and adding HIV/AIDS for a total of 10 core chronic diseases.
- Lowering the maximum number of covered Part D drugs a sponsor may require from eight to five drugs and requiring sponsors to include all Part D maintenance drugs in their targeting criteria.
- Revising the methodology for calculating the cost threshold ($5,330 in 2024) to be commensurate with the average annual cost of five generic drugs ($1,004 in 2020).

After consideration of the comments received, CMS is finalizing proposed changes to the Part D MTM program eligibility requirements with the modifications discussed. The changes are effective January 1, 2025 and are summarized below.

- Part D sponsors must include all core chronic diseases in their targeting criteria for identifying beneficiaries who have multiple chronic diseases.
    - CMS is codifying the nine core chronic diseases currently identified in guidance and adding HIV/AIDS.
    - The 10 core chronic diseases are:

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)
10. Respiratory disease (including asthma, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders)

- Sponsors retain the flexibility to target additional chronic diseases beyond those codified as core chronic disease.

- CMS is retaining the maximum number of drugs a plan sponsor may require for targeting beneficiaries taking multiple Part D drugs at eight.
  - Part D sponsors will maintain the flexibility to set a lower thresholder (a number between two and eight Part D drugs).
- Part D sponsors will be required to include all Part D maintenance drugs in their targeting criteria and have the flexibility to include all Part D drugs in their targeting criteria.
  - Sponsors will not be permitted to limit their MTM targeting criteria to specific Part D maintenance drugs or drug classes.
  - Plans must rely on information in a widely accepted, commercially or publicly available drug information database.
- The MTM cost threshold will be set at the average cost of eight generic drugs.
  - CMS will calculate the dollar amount of the MTM cost threshold based on the average daily cost of a generic drug using the PDE data.

[PP. 22-26]

The summarized comments and responses from CMS are found on PP. 22-26. Excerpts from the comments and CMS responses are found below.

- Many commenters expressed support of the proposed changes and cited many studies reinforcing the value of MTM and the need for more equitable access.
  - CMS response: CMS appreciates the support and adds that almost all of the chronic diseases targeted for MTM are more prevalent among minorities and lower income populations. As a result, CMS anticipates that these changes will increase eligibility rates among those populations by promoting more equitable access to MTM services and closing eligibility gaps.
- Many commenters opposed the proposed eligibility criteria changes partially or in whole, and several expressed significant concerns about the costs and resource burden associated with implementing such a large-scale expansion of the MTM program.
  - CMS response: CMS acknowledges the concerns raised regarding the cost and burden of the proposed expansion of MTM, and CMS understands the concerns about the impact on the quality of MTM. In light of these comments, CMS is finalizing the proposed changes with modifications that will ensure a more moderate program size increase, result in less burden and lower costs than initially estimated in CMS' December 2022 proposed rule, and promote the administration of high-value MTM programs. To continue to provide quality MTM services to an expanded population and better manage resources, CMS reminds sponsors that the delivery of MTM may be tailored to meet each enrollee's needs. For example, the length of the CMR consultation or number of follow-up interventions

needed following targeted medication reviews (TMRs) may vary between MTM enrollees with more complex drug regimens and those who are stable on their medication regimens as long as the minimum level of MTM services is met.

- Some commenters stated that a large increase in the MTM enrollee population would require significant resources and that there would be limited time to hire and train additional staff, implement the necessary processes, and upgrade clinical and administration infrastructures. Commenters estimated needing to double or triple their staffing to accommodate MTM enrollment increases of up to 60 percent in one year, and there may be pressure to use call centers, possibly employing customer service representative without clinical training, which may lead to lower quality of care or member experience.
    - CMS response: CMS is optimistic that the increase in demand for MTM services will incentivize plan sponsors to strengthen their hiring efforts. It is not clear what methodology the commenters used to estimate staffing needed to accommodate certain MTM program size increases. However, CMS believes that their plan to finalize the proposed changes with modifications that scale back MTM expansion may alleviate a portion of the staffing concerns raised by commenters.
- A few commenters, particularly commenters representing dual eligible special needs plans (D-SNPs), expressed concern that they will be disproportionately impacted by the changes in the MTM eligibility criteria and estimates that the majority of their plan enrollment would be eligible for the MTM program.
    - CMS response: CMS acknowledges that some Part D contracts may have actual MTM enrollment rates above or below the average rate for the program. This is also true under the current MTM requirements, and there is no evidence that higher than average MTM enrollment has increased administrative costs and thus premiums to the point of limiting Part D plans' offerings, including MA-PDs that are D-SNPs. However, CMS considered the varying impacts of the proposed eligibility changes and is finalizing those changes with modifications that CMS expects to decrease estimated program size relative to the proposed rule.
- Many commenters stated that the proposed eligibility criteria changes would result in a substantive update to the Part D Star Rating MTM Program CMR Completion Rate measure (MTM Star Rating Measure) due to the program size expansion and impacts to resources, and they urged CMS to move the measure to a display measure for at least 2 years to adjust to the new levels of program size.
    - CMS response: The MTM Program Completion Rate for CMR measure is being updated in this rule to align with the revised targeting criteria; the updated measure will move to the display page entirely for the 2025 and 2026 measurement years and will return as a new measure to the Star Ratings program no earlier than the 2027 measurement year for the 2029 Star Ratings. CMS will share the additional suggestions for specification changes with the Pharmacy Quality Alliance (PQA), the measure steward.
- A few commenters suggested that additional analyses are needed to assess the effectiveness of MTM programs, optimize current MTM programs, and review alternative medication management methods already being used by plan sponsors and their contracted providers.
    - CMS response: CMS routinely analyzes CMS and plan-reported data to oversee the Part D MTM programs. CMS appreciates the comments on potential research and analysis topics and agrees that the high degree of variability between MTM program targeting criteria has made it difficult to evaluate MTM programs. CMS is hopeful that standardizing the criteria as finalized in this rule will allow more research to be done on MTM outcomes. CMS will also engage with industry to develop additional consensus-based measures to evaluate the quality of MTM programs which may be considered for the Star Ratings program in the future, and CMS is encouraged by recent efforts by the PQA to convene MTM leaders on evidence-based priorities for measurement.
- Some commenters encouraged CMS to continue to examine policy options that expand access to MTM and improve patient outcomes and to collaborate with interested parties to leverage findings from the Enhanced MTM model and identify best practices in MTM to scale nationally, as well as to guide future reforms before taking action to change MTM.
    - CMS response: CMS will continue to examine policy options within their authority that

expand access to MTM and improve patient outcomes. CMS will also continue to review the results of the Enhanced MTM model and collaborate with interested parties to identify best practices and lessons learned that may help improve the traditional Part D MTM programs. CMS disagrees that they should leverage model findings or run additional analyses before making changes to the Part D MTM programs, as their disparities analysis discussed in the December 2022 proposed rule identified specific eligibility gaps that need to be addressed.

- Many commenters suggested that updated eligibility criteria should be implemented on a delayed or phased-in basis.
  - CMS response: CMS does not agree that such an approach is necessary because CMS is finalizing the proposed changes with modification. The reduced program size mitigates the need for a phased-in approach to accommodate the new MTM enrollees. Additionally, the changes will be effective in 2025 rather than 2024 as initially proposed, which will provide additional time for Part D plan sponsors to build up the necessary infrastructure to support the anticipated increase in MTM enrollment.

b. Multiple Chronic Diseases [P. 27]

To be targeted for MTM, beneficiaries must have multiple chronic diseases, with three chronic diseases being the maximum number a Part D sponsor may require for targeted enrollment. In the current CMS MTM guidance, CMS identifies nine core chronic diseases.

CMS proposed to require all Part D sponsors to include all core chronic diseases when identifying enrollees who have multiple chronic diseases. CMS also proposed to codify the nine core chronic diseases currently identified in guidance and to add HIV/AIDS, for a total of 10 core chronic diseases. CMS explained that the current flexibility afforded to plans to identify enrollees with multiple chronic diseases had led to variability across plans and was a main driver of eligibility gaps and inequitable beneficiary access to MTM services. Under CMS' proposal to codify the 10 core chronic diseases, plan sponsors would maintain the flexibility to target beneficiaries with additional chronic diseases that are not identified as core chronic diseases, or to include all chronic diseases in their targeting criteria.

[PP. 27-29]

The summarized comments and responses from CMS are found on PP. 27-29. Excerpts from the comments and CMS responses are found below.

- Many commenters supported the proposal to add HIV/AIDS to the list of core chronic diseases.
  - CMS response: CMS agrees with the commenters and adds that Part D enrollees with HIV/AIDS are more likely to be members of populations affected by health disparities. For these reasons and for the reasons discussed in the December 2022 proposed rule, CMS finalized the proposal to include HIV/AIDS in the core chronic diseases.
- Many commenters were opposed to including HIV/AIDS as a core chronic disease and expressed concerns regarding the potential of MTM programs disrupting current therapy; potential lack of specialized pharmacist training on HIV/AIDS; and lack of data availability, including lab values, for a successful CMR in this population.
  - CMS response: MTM services should be complementary, not disruptive, to services furnished by the beneficiary's care team. CMS acknowledges that Part D sponsors, especially PDPs, may not always have complete and up to date information at the time of a CMR, but the CMR may provide the opportunity to obtain additional information regarding an individual's current therapy.
- Many commenters supported the proposal to require Part D sponsors to include all core chronic diseases when identifying enrollees who have multiple chronic diseases. CMS received suggestions to expand the inclusion of Alzheimer's disease on the list of core chronic diseases to include neurodegenerative diseases (including multiple sclerosis) and/or other dementias such as

Lewy Body disease or frontotemporal lobar degeneration and pain as core chronic diseases.

- CMS response: CMS will continue to analyze chronic diseases that are highly prevalent in the Part D population, align with common targeting practices across sponsors, and are commonly treated with Part D drugs, where MTM services could most impact therapeutic clinical outcomes, including those suggested by the commenters, and may consider proposing additional core chronic diseases such as neurodegenerative diseases and/or other dementias in future rulemaking.

- Many commenters opposed the proposal to require Part D sponsors to include all core chronic diseases to identify beneficiaries who meet the targeting criterion of having multiple chronic diseases. Some commenters suggested that CMS limit core diseases to those that do not require specialized training or requested extra time to hire specialized staff. Other commenters wanted to limit the core chronic diseases to those that are easily identified using Part D claims only or to those associated with the Star Ratings medication adherence measures.
  - CMS response: Plan sponsors' flexibility to target select core chronic diseases was a main driver of inequitable access to MTM in the Part D program that CMS addressed in the December 2022 proposed rule. CMS strongly believes pharmacists or other qualified MTM providers with extensive knowledge and training of prescribed medications are in an excellent position to impact a beneficiary's medication use, regardless of the chronic diseases they have or the Part D drugs they take.
- Some commenters indicated that complex cancer treatment needs timely, on-going monitoring by specialists with expertise across Part B and Part D medications (for which data sets may or may not be available) and may not be best managed by Part D MTM programs through annual CMRs or by pharmacists without specialized training. Other commenters noted that specialty pharmacies already provide monitoring or counseling for their oncology patients.
  - CMS response: After consideration of the comments received, CMS does not believe it would be appropriate to add cancer to the core chronic diseases. While CMS is not adding cancer as a core chronic disease at this time, CMS emphasizes that some cancer patients may still be eligible for MTM based on meeting the eligibility criteria.

c. Multiple Part D Drugs [P. 29]

Targeted beneficiaries must be taking multiple covered Part D drugs, and the current regulation specifies that eight is the maximum number of Part D drugs a Part D plan sponsor may require for targeted MTM enrollment. Sponsors are permitted to include all Part D drugs, all part D maintenance drugs, or specific drug classes.

CMS proposed to decrease the maximum number of Part D drugs a sponsor may require for targeted enrollment from eight to five for plan years beginning on or after January 1, 2024. The proposed change would ensure the MTM program continues to focus on more individuals with complex drug regiments and increased risk of medication therapy problems. CMS also proposed to require all sponsors to include all Part D maintenance drugs in their targeting criteria. Under this proposal, sponsors would no longer be allowed to target only specific Part D drug classes but would be required to target all Part D maintenance drugs. Plans would retain the option to expand their criteria by targeting all Part D drugs.

CMS solicited public comment defining maintenance drugs and on the proposed revisions to the maximum number of covered Part D drugs a plan sponsor may require and their proposal to require sponsors to include all Part D maintenance drugs in their targeting criteria.

CMS is finalizing the proposed provision about multiple Part D drugs with modification as follows.

- Sponsors must include all Part D maintenance drugs.
  - Sponsors are not allowed to target only specific Part D drug classes.
  - Sponsors retain the flexibility to include all Part D drugs in their targeting criteria.
  - Sponsors must rely on information contained within a widely accepted, commercially or publicly available drug information database to identify Part D maintenance drugs.

These requirements will apply beginning on January 1, 2025. CMS is not finalizing the proposal to lower the maximum number of covered Part D drugs a sponsor may require from eight to five drugs at this time.

[P. 30]

The summarized comments and responses from CMS are found on P. 30. Excerpts from the comments and CMS responses are found below.

- Commenters were concerned that MTM would not be as useful for beneficiaries with less complex drug regimens and suggested that beneficiaries should quality for MTM enrollment based on higher pill burdens and more complicated medication regimens. One commenter stated that a typical enrollee with three or more chronic diseases takes between seven and 10 medications and recommended retaining the current maximum number of drugs at eight.
    - CMS response: CMS found that the beneficiaries identified as having 3 or more core chronic conditions and using 8 or more drugs who were not eligible for MTM took on average eight to nine Part D drugs, which suggests that the number of Part D drugs criterion is not a main driver of MTM eligibility disparities under their current policies. This change to CMS' proposal allows them to respond to commenters' concerns regarding the potential impact of reducing the maximum number of Part D drugs from eight to five, while still addressing the barriers to eligibility posed by the increasingly restrictive plan criteria (for example, by targeting select core chronic diseases or drugs) and the high cost threshold, which were identified in CMS' analysis as the main drivers of reduced eligibility rates for MTM.

d. Annual Cost Threshold [P. 30]

Beneficiaries targeted for MTM must be likely to incur costs for covered Part D drugs that exceed a threshold determined by CMS. The annual cost threshold for 2024 is $5,330. The cost threshold has increased substantially since it was established in regulation, while the availability of lower cost generics and the generic utilization rates have also increased significantly since the Part D program began. The cost threshold has been identified as a significant barrier to MTM access, and, in the past, interested parties have recommended that it be lowered.

CMS proposed to set the MTM cost threshold at the average cost of five generic drugs for plan years beginning on or after January 1, 2024. Under this proposal, CMS would calculate the dollar amount of the MTM cost threshold based on the average daily cost of a generic drug. The average daily cost for a drug would be based on the ingredient cost, dispensing fees, sales tax, and vaccine administration fees, if applicable, and would include both plan paid amounts and enrollee cost sharing. That cost would then be multiplied by 365 days for an annual amount.

CMS is finalizing a modified MTM cost threshold methodology based on the average annual cost of eight generic drugs. This new cost threshold methodology will be applicable beginning January 1, 2025. Based on analysis of 2023 PDE data, the MTM cost threshold will be $1,623 for 2025. The MTM cost threshold will be published in the annual Part D Bidding Instructions memo for future years.

[PP. 31-32]

The summarized comments and responses from CMS are found on PP. 31-32. Excerpts from the comments and CMS responses are found below.

- While many commenters agreed that the current MTM cost threshold is too high, they opposed CMS' proposal to base the MTM cost threshold on the average cost of five generic drugs due to the estimated impact on MTM program size. These commenters provided various suggestions and considerations, such as a less significant cost threshold reduction and that a key metric is the

number of drugs rather than their cost. Another commenter suggested that CMS consider increasing the annual cost threshold, instead of decreasing it, to better account for inflation in the prescription drug market and allow plans to have greater capacity to target MTM services to high need members.

    - CMS response: CMS is persuaded to finalize a modified MTM cost threshold methodology based on the average annual cost of eight generic drugs beginning January 1, 2025. This revised cost threshold methodology aligns with CMS' decision not to finalize their proposal to reduce the maximum number of covered Part D drugs a sponsor may require from eight to five drugs. Lowering the cost threshold removes a significant barrier to MTM enrollment, but setting the threshold at the cost of eight (instead of five) generic drugs yields a more moderate program size expansion, which will address commenters' concerns about cost and burden.

- Many commenters requested clarification regarding the MTM cost threshold calculation.
    - CMS response: The average daily cost of one generic drug was calculated as total gross drug cost divided by total days supply for all Part D covered generic drugs utilized by all Part D enrollees during the plan year. The average daily cost of one generic drug was then multiplied by eight drugs and 365 days to compute an average annual cost of eight generic drugs. The total gross drug cost used in this calculation is the sum of the ingredient cost, dispensing fees, sales tax, and vaccine administration fees, if applicable, during the relevant plan year and includes both plan paid amounts and enrollee cost sharing. This calculation does not include the cost of biologic products or authorized generics. Compound drug claims are also excluded.
- A few commenters asked if the proposed cost threshold would be expected to increase or decrease annually. Another commenter suggested that CMS reevaluate cost data for generic drugs, as costs of many generic drugs have increased since 2020 due to global supply chain issues after the COVID-19 pandemic. One commenter asked if enrollees would be required to receive the generic drugs only.
    - CMS response: The cost threshold may change annually given the methodology described in the proceeding sub-bullet. Although average costs for all Part D covered generic drug fills will be used to calculate the MTM cost threshold, a beneficiary would not be required to only take generic drugs to meet the eligibility criteria for MTM, and beneficiary-specific drug costs may vary from the averages.
- Beginning January 1, 2025, CMS will calculate the dollar amount of the MTM cost threshold based on the average daily cost of a generic drug as determined using PDE data from the plan year that ended 12 months prior to the applicable plan year, which is the PDE data -currently used to determine the specialty-tier cost threshold. CMS will analyze the PDE data for all Part D covered generic drugs utilized by all Part D enrollees during the plan year to calculate the average daily cost of one generic fill and multiply the average daily cost of one generic fill by 365 days to determine an annual amount.

e. Summary [P. 32]

CMS believes these final policies will allow them to address specific gaps identified in MTM program eligibility by reducing marked variability across plans and ensuring more equitable access to MTM services; better align with Congressional intent while focusing on beneficiaries with complex drug regimens; and keep the program size manageable.

The changes also take into consideration the burden a change in the MTM program size would have on sponsors, MTM vendors, and the health care workforce. With these changes, CMS estimates that the number and percent of Part D enrollees eligible for MTM will increase from 3.6 million (7% of Part D enrollees based on actual 2022 MTM enrollment data) to a total of 7.1 million (13% of Part D enrollees estimated using 2022 data), which is smaller than the estimated program size of 11 million beneficiaries in the December 2022 proposed rule.

2. Define ‘‘Unable to Accept an Offer to Participate’’ in a Comprehensive Medication Review (CMR) [P. 32]

In guidance issued annually, CMS has consistently stated that they consider a beneficiary to be unable to accept an offer to participate in a CMR only when the beneficiary is cognitively impaired and cannot make decisions regarding their medical needs. In the December 2022 proposed rule, CMS proposed to codify this definition by amending the current regulation text to specify that in order for the CMR to be performed with an individual other than the beneficiary, the beneficiary must be unable to accept the offer to participate in the CMR due to cognitive impairment.

CMS is finalizing the definition of a “unable to accept an offer to participate” in a CMR to provide that a beneficiary must be unable to accept the offer to participate in the CMR due to cognitive impairment.

[P. 33]

The summarized comments and responses from CMS are found on P. 33. Excerpts from the comments and CMS responses are found below.

- A few commenters opposed or voiced concerns about the proposal, stating that many beneficiaries who are not cognitively impaired request that their caregiver or a trusted family member participate in the CMR on their behalf. They argued that caregivers should be allowed to participate in the CMR as long as HIPAA Privacy Rule policies are not violated, and proper documentation is maintained.
    - CMS response: CMS’ proposal to codify the definition of “unable to participate” does not preclude beneficiaries from inviting other individuals to join them for the CMR. MTM enrollees may continue to include caregiver or family member participation during the MTM process, though CMS emphasizes that MTM is a beneficiary-centric program. Instead, this rule codifies the definition of “unable to participate,” which is different from a beneficiary requesting a CMR to be completed with another individual. Generally, CMS expects the beneficiary being “unable to participate” due to cognitive impairment to be an uncommon designation that should be reported through the Part D Reporting Requirements.

3. Requirement for In Person or Synchronous Telehealth Consultation [P. 33]

As discussed in the December 2022 proposed rule, CMS proposed to require that the CMR be performed either in person or via synchronous telehealth to clarify that the CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via telehealth. While the consultation must be conducted in real-time, under this proposal, plans would continue to have the discretion to determine whether the CMR can be performed in person or using the telephone, video conferencing, or another real-time method.

CMS is finalizing the proposed requirement for in person or synchronous telehealth consultation without modification.

[P. 33]

The summarized comments and responses from CMS are found on P. 33. Excerpts from the comments and CMS responses are found below.

- A few commenters expressly stated that their support for the proposal was conditioned on "telehealth" including a telephone option. Another commenter expressed concern regarding lower levels of engagement due to fewer people wanting in-person interactions in a pharmacy setting and fewer people answering their phone, even when it is their local pharmacy calling.
    - CMS response: CMS confirms that telephonic communication meets the definition of

synchronous telehealth. CMS believes updating the regulation to clarify that a CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via telehealth, will ensure that beneficiaries receiving a CMR via telehealth have the same opportunities to engage with their providers in real time as beneficiaries who receive a CMR in-person.

4. MTM Program Technical Changes [P. 33]

In the December 2022 proposed rule, CMS proposed several technical changes to the regulation text related to the Part D MTM program, including adding a definition for "MTM Program" to clarify the meaning of this term and replacing "MTMP" with "MTM program" to ensure that the terminology is used consistently.

CMS did not receive any comments regarding the proposed technical changes, and they are finalizing the changes as proposed.

Section 3. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System [P. 180]

A. Introduction [P.180]

In the December 2022 proposed rule, in addition to the policies addressed in the April 2023 final rule, CMS proposed to make changes in the specific measures used in the Star Ratings System:

- Remove the stand-alone Part C Medication Reconciliation Post-discharge measure;
- Add the updated Part C Colorectal Cancer Screening measure with the National Committee for Quality Alliance (NCQA) specification change;
- Add the updated Part C Care for Older Adults—Functional Status Assessment measure with the NCQA specification change;
- Add the Part D Concurrent Use of Opioids and Benzodiazepines measure;
- Add the Part D Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults measure; and
- Add the Part D Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults measure.

CMS also proposed a series of technical clarifications of the existing rules related to Quality Bonus Payment (QBP) appeals processes and weighting of measures with a substantive specification change.

In the December 2022 proposed rule, CMS proposed these changes to apply to the 2024 measurement period and the 2026 Star Ratings, but as discussed in and given the timing of this final rule, CMS is finalizing these policies (that is, data would be collected, and performance measured) for the 2025 measurement period and the 2027 Star Ratings unless otherwise stated.

In the November 2023 proposed rule, CMS proposed to update the Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) measure (Part D). CMS also proposed the following methodological enhancements, clarifications, and operational updates:

- Revise the process for identifying data completeness issues and calculating scaled reductions for the Part C appeals measures.
- Update how the Categorical Adjustment Index (CAI) and health equity index (HEI) reward are calculated in the case of contract consolidations.

- Revise an aspect of the QBP appeals process.
- Add that a sponsor may request CMS review of its contract's administrative claims data used for the Part D Patient Safety measures no later than the annual deadline set by CMS for the applicable Star Ratings year.

Unless otherwise stated, finalized changes would apply (that is, data would be collected and performance measured) for the 2025 measurement period and the 2027 Star Ratings.

B. Adding, Updating, and Removing Measures [P. 181]

2. Measure Updates [P. 182]

c. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) (Part D) - Substantive Change [P. 184]

After consideration of the comments received, CMS is finalizing the proposed update to move the MTM Program Completion Rate for CMR measure to the display page for at least two years before adding it to the Star Ratings. As discussed in the final rule, CMS is finalizing changes to the targeting criteria that will be effective on January 1, 2025. Therefore, the MTM Program Completion Rate for CMR measure will move to the display page entirely for the 2025 and 2026 measurement years and would return as a new measure to the Star Ratings program for the 2027 measurement year for the 2029 Star Ratings.

[PP. 184-185]

The summarized comments and responses from CMS are found on PP. 184-185. Excerpts from the comments and CMS responses are found below.

- A few commenters specifically did not support moving the MTM Program Completion Rate for CMR measure to the display page because they do not support changes to the MTM program targeting criteria.
- A few commenters expressed concern regarding the increased impact of the remaining Part D Star Rating measures if the MTM Program Completion Rate for CMR measure was moved to the display page and not included in the Star Ratings.
    - CMS Response: CMS understands the concerns raised by commenters that there would be one less Part D measure included in the calculations to determine the overall Star Rating for MA-PD plans and/or the Part D summary Star Rating; however, there is no legacy measure to include in the Star Ratings because the MTM-eligible population for the denominator would change. Due to these substantive increases to the MTM-eligible measure denominator population, and the rules for substantive measure updates, the MTM Program Completion Rate for CMR measure must move to the display page for at least 2 years before using the updated measure in the Star Ratings.
- A few commenters suggested that CMS work with a measure steward, such as the PQA, to develop alternate or companion measures that measure the success or impact of MTM services on health outcomes.

3. Measure Additions [P. 185]

a. Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS) (Part D) [P. 185]

CMS proposed to add the following three Part D measures to the 2026 Star Ratings (2024 measurement year), which are measures developed by the PQA: COB, Poly-ACH, and Poly-CNS. The new Part D measures are calculated from Prescription Drug Event (PDE) or CMS administrative data, so they do not require any new data

collections.

Additionally, as announced in the Advance Notice of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies the added measures would include a non-substantive update to align with the PQA measure specifications by using continuous enrollment (CE) and no longer adjusting for member-years (MYs).

These measures reflect the following performance:

- Concurrent Use of Opioids and Benzodiazepines (COB) (Part D)—analyzes the percentage of Medicare Part D beneficiaries 18 years and older with concurrent use of prescription opioids and benzodiazepines during the measurement period.
- Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH) (Part D)—analyzes the percentage of Medicare Part D beneficiaries, 65 years or older, with concurrent use of two or more unique anticholinergic medications during the measurement period.
- Polypharmacy Use of Multiple Central Nervous System-Active Medications in Older Adults (Poly-CNS) (Part D)—analyzes the percentage of Medicare Part D beneficiaries, 65 years or older, with concurrent use of three or more unique CNS-active medications during the measurement period.

After considering the comments CMS received and for the reasons outlined in the proposed rule and CMS' responses to the comments, CMS is finalizing the addition of the Poly-ACH and COB measures in the Star Ratings program beginning with the 2025 measurement year for the 2027 Star Ratings. The Poly-CNS measure will remain on the display page and not be added to the Star Ratings.

In addition, CMS announced the non-substantive updates to the Poly-CNS, Poly-ACH, and COB measures to align with the PQA measure specifications to use CE and no longer adjust for MYs in the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. CMS will make the update to change from MYs to CE for the 2024 measurement year for all three measures.

Table VII.1. Summary of New and Revised Individual Star Rating Measures for Performance Periods Beginning on or after January 1, 2025 [P. 190]

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Concurrent Use of Opioids and Benzodiazepines (COB)	The percentage of individuals ≥18 years of age with concurrent use of prescription opioids and benzodiazepines.	Drug Safety and Accuracy of Drug Pricing	Process Measure of Weight of 1	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	Clustering	MA-PD and PDP
Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH)	The percentage of individuals ≥65 years of age with concurrent use of ≥2 unique anticholinergic medications.	Drug Safety and Accuracy of Drug Pricing	Process Measure of Weight of 1	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year	Clustering	MA-PD and PDP
Medication Therapy Management (MTM)	The percent of MTM program enrollees, 18	Drug Safety and Accuracy	Process Measure of Weight of 1	Part D Plan Reporting Requirements	The calendar year 2 years prior to the	Clustering	MA-PD and PDP

Program Completion Rate for Comprehensive Medication Review (CMR)**	years or older, who received a CMR during the reporting period.	of Drug Pricing			Star Ratings year		

[PP. 185-189]

The summarized comments and responses from CMS are found on PP. 185-189. Excerpts from the comments and CMS responses are found below.

- A few commenters strongly supported incorporating the COB and the two Polypharmacy measures to the Star Ratings as these measures are important to address areas of significant risk to beneficiaries.
- A majority of commenters did not support moving the COB, Poly-ACH, and Poly-CNS measures from the display page to the Star Ratings. Additionally, commenters requested that only one of the two Polypharmacy measures be selected due to overlap of National Drug Codes (NDCs) and medication classes included in the measure specifications.
    - CMS Response:
        - The measures are important areas of focus for the Medicare Part D population from a clinical perspective. The PQA Measure Development Team, Stakeholder Advisory Panel, and the American Geriatrics Society (AGS) Beers Criteria Update Panel co-chairs recommended the two separate Polypharmacy measures (the Poly-CNS and Poly-ACH measures) because of different supporting evidence, concurrent use thresholds (three for Poly-CNS and two for Poly-ACH), additive pharmacodynamic effects, and associated clinical outcomes (falls with CNS-active medications and cognitive decline with anticholinergics). Based on clinical recommendations and supporting evidence, CMS concurs with the PQA, the measure steward, that two separate Polypharmacy measures are appropriate to assess these two areas of focus separately.
        - CMS conducted additional data analyses on overlap across the three measures from both medication specification and beneficiary-level perspectives based on public comments they received. CMS found that the COB and Poly-ACH measures do not have duplicative medication classes or overlapping NDCs. However, the Poly-CNS measure includes medication classes and NDCs that overlap with both the Poly-ACH and COB measures.
        - CMS does not expect a zero-percentage measure rate for these measures as, in some rare cases, it may be medically necessary for beneficiaries to take multiple anticholinergics. Additionally, CMS does not establish a pre-determined threshold to assign stars to these measures and uses the clustering methodology. Therefore, CMS does not have specific cut points or thresholds for performance of Part D contracts in the Star Ratings.
- Some commenters requested that CMS delay adding these measures to the Star Ratings by at least 2 years to provide sponsors additional time to prepare for the transition because it may be difficult to improve the measures or incentivize prescribers and to minimize unnecessary disruptions in therapy.
    - CMS Response: Sponsors have been on notice for more than 4 years that these measures could be added to the Star Ratings, and all three measures have been on the display page since 2021 (2019 measurement year). Part D plans have had sufficient time to gain experience with these measures and to prepare for these measures to be added to the Star Ratings.
- Commenters requested that CMS add socio-demographic status (SDS) risk adjustment to the COB and Polypharmacy measures because Medicare Advantage organizations, in particular those that offer dual eligible or special needs plans, will be disproportionately affected as these plans enroll a greater number of complex patients with mental health conditions or disabilities.

    - CMS Response: Currently these measures have not been tested for SDS risk-adjustment because the Poly-ACH, Poly-CNS, and COB measures are process measures and are not recommended for SDS risk adjustment by the PQA.
- Some commenters opposed the COB and Poly-CNS measures because they believe these measures contradict the updated CDC 2022 Clinical Practice Guideline for Prescribing Opioids for Pain.
    - CMS Response: The COB and Poly-CNS measure specifications do not contradict the CDC Guideline which recommends particular caution when prescribing opioid pain medication and benzodiazepines concurrently and that prescribers should consider whether benefits outweigh risks of concurrent prescribing of opioids and other central nervous system depressants. These measures do not include dosage thresholds in the measure specifications and are not intended to guide clinical-decision-making for individual patients, but rather, these measures evaluate the use of concurrent therapies.

C. Revising the Rule for Non-substantive Measure Updates [P. 190]

CMS proposed to revise the regulation text by adding that another example of a non-substantive change would include a new mode of data collection.

After considering the comments received and for the reasons outlined in the proposed rule and CMS' responses to the comments, CMS is finalizing the clarification to the regulation text. As this clarification is consistent with current practice and policy, CMS is applying it immediately on the effective date of the final rule and for measures in the 2025 Star Ratings where CMS has complied in adopting the non-substantive change.

[P. 191]

The summarized comments and responses from CMS are found on P. 191. Excerpts from the comments and CMS responses are found below.

- Commenters stated that a new mode of data collection should be considered a substantive change. A couple of commenters were concerned a change in survey modality would produce different survey results and that survey modality preferences differ by age groups, which may affect the population responding. A commenter expressed concerned that web-based respondents could create a source of bias in the data due to differences in socioeconomic factors, plan type, or geography and could impact contract performance.
- CMS response: CMS disagrees that changes to expand modes of data collection would be a substantive change to a measure. Notwithstanding an expansion of the modes of data collection, the denominator will remain the same. Expanding the modes of data collection will generally result in more data regarding performance on the measure. As a result, the measure will better reflect actual performance of the organization and provide more information to CMS and the public.

D. Weight of Measures with Substantive Updates [P.191]

CMS proposed to adopt regulation text clarifying how CMS treats measures with substantive updates when they return to the Star Ratings program. Historically, CMS has treated measures with substantive updates as new measures when they are added back to the Star Ratings following two or more years on the display page and adoption through rulemaking.

Currently, new measures receive a weight of 1 for their first year in the Star Ratings program.

CMS proposed to add language to clarify that when a measure with a substantive update moves back to Star Ratings from the display page following rulemaking, it is treated as a new measure for weighting purposes and

therefore would receive a weight of 1 for its first year back in the Star Ratings program. This is consistent with their current and prior practice and with the explanation provided in the January 2021 final rule about the weight provided to substantively updated measures for the first year they are returned to the Star Ratings. In the second and subsequent years after the measure returns to the Star Ratings after being on the display page with a substantive update, the measure would be assigned the weight associated with its category, which is what happens with new measures as well.

After considering the comments CMS received and for the reasons outlined in the proposed rule and their responses to the comments, CMS is finalizing the additional language added with a slight clarification that in subsequent years, a new or substantively updated measure will be assigned the weight associated with its category. As this clarification is consistent with current practice and policy, CMS is applying it immediately on the effective date of the final rule and to the 2025 Star Ratings.

[P. 192]

The summarized comments and responses from CMS are found on P. 192. Excerpts from the comments and CMS responses are found below.

- Some commenters noted that this proposal would result in a phase-in approach reducing potential volatility, and it provides plans sufficient notice to familiarize themselves with a measure's updated specifications, assess potential impacts, and incorporate changes to internal processes if needed. A commenter requested CMS confirm that when the three Part D medication adherence measures return to the Star Ratings after adding risk adjustment for sociodemographic status, they will each have a weight of 1 for the first year.
- CMS Response: In the April 2023 final rule, CMS finalized the substantive update to the three medication adherence measures for the 2028 Star Ratings (2026 measurement year). The first year (2028 Star Ratings) the updated medication adherence measures will be in the Star Ratings they will have a weight of 1, but then beginning with the following Star Ratings year, the weight will increase to 3, as these measures are categorized as intermediate outcome measures.