Optimizing Health by Advancing the Quality of Medication Use

MEMORANDUM

To: PQA Members

From: PQA

Date: April 18, 2023

Re: **Medicare Program; Contract Year 2024 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 (CMS-4201-F)**

The Centers for Medicare & Medicaid Services (CMS) has issued "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly." The rule, CMS-4201-F, was published in the federal register on April 12, 2023, and can be found here. An April 5 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 Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System [P. 144]

CMS did not address several proposals that were included in PQA's Points of Interest related to CMS-4201-P. These included proposals related to Guardrails, Hold Harmless Measure, Quality Bonus Payment (QBP) Rules, the MTM Program, and Proposed Part D Measure Additions. Since these were not addressed in this final rule, they are not included in this Points of Interest summary.

Summary Explanation

The page numbers listed in the following summary correspond to the document. An executive summary is provided on page 2 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 3-11.

Our goal with this summary is to isolate for your convenience the most relevant sections within the 226-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 gray 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-F

General Information

CMS intends to address all of the remaining proposals from the December 2022 proposed rule in subsequent rulemaking. Therefore, CMS plans to make provisions adopted in the subsequent, second final rule applicable to coverage beginning no earlier than January 1, 2025.

CMS notes that in this final rule, they are not addressing comments received on the provisions of the proposed rule that they are not addressing or finalizing at this time. Rather, they will address them at a later time, in a subsequent rulemaking document, as appropriate.

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

A. Risk Adjustment of PQA Stewarded Measures [P. 146]

CMS **finalized the implementation of risk adjustment based on sociodemographic status (SDS) characteristics**, a substantive update, **to the three Part D medication adherence measures**.

CMS will first display the updated SDS risk adjusted medication adherence measures for the 2024 measurement year (2026 display page), while the legacy adherence measures remain in the Star Ratings. Then, the updated SDS risk adjusted measures will replace the existing medication adherence measures beginning with the 2026 measurement year (2028 Star Ratings). CMS also intends to incorporate the SDS risk adjustment operationally to these measures reported by CMS to Part D sponsors in the last monthly patient safety report for the measurement year.

B. Health Equity Index [P. 158]

CMS developed a health equity index (HEI) factor that they proposed for use in the Part C and Part D Star Ratings to reward contracts for obtaining high measure-level scores for the subset of enrollees with specified social risk factors (SRFs). CMS' intent in implementing an HEI reward is to improve health equity by incentivizing MA, cost, and PDP contracts to perform well among enrollees with specified SRFs.

CMS confirmed they will replace the current reward factor described with the new HEI reward as proposed starting with the 2027 Star Ratings; the HEI for the 2027 Star Ratings would be calculated using data collected or used for the 2026 and 2027 Star Ratings (2024 and 2025 measurement years).

PQA Summary: CMS-4201-F

Medicare Program; Contract Year 2024 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

I. General Information [P. 1]

A. Dates

The provisions in this rule are applicable to coverage beginning January 1, 2024, except as otherwise noted.

B. Supplementary Information

CMS intends to address all of the remaining proposals from the December 2022 proposed rule in subsequent rulemaking. Therefore, CMS plans to make provisions adopted in the subsequent, second final rule applicable to coverage beginning no earlier than January 1, 2025.

CMS notes that in this final rule, they are not addressing comments received on the provisions of the proposed rule that they are not addressing or finalizing at this time. Rather, they will address them at a later time, in a subsequent rulemaking document, as appropriate.

II. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System [P. 144]

A. Introduction [P. 144]

CMS proposed in the December 2022 proposed rule other policies to amend the Part C and D Star Ratings but are not addressing those proposals in this final rule; those other proposals will be addressed in a subsequent, second final rule.

Any policies CMS proposed in the December 2022 proposed rule that are addressed in that subsequent rule would apply (that is, data will be collected and performance measured) for no earlier than the 2025 measurement period and the 2027 Star Ratings.

B. Definitions [P. 145]

CMS finalized adding the following new definition:

a. Health equity index: an index that summarizes contract performance among those with specified SRFs across multiple measures into a single score.

C. Contract Ratings [P. 145]

CMS finalized regulatory amendments to clarify:

a. That the overall and summary Star Ratings are calculated based on the measures required to be collected and reported for the contract type being offered for the Star Ratings year; and
b. For the first year after a contract consolidation, the Part C and Part D improvement measures will not be calculated for the consolidated contract.
    i. For the second year after a consolidation, the improvement measure is calculated using the enrollment-weighted measure scores for the current and prior year because scores for both years are available for the consolidated contract.

These amendments are consistent with CMS' current and historical processes for calculating Star Ratings and how the regulatory clarifications will be applied.

D. Adding, Updating, and Removing Measures [P. 146]

(1) Measure Removal

CMS finalized **removing** the Diabetes Care – Kidney Disease Monitoring (Part C) Measure – starting with 2024 Star Ratings (2022 measurement year).

(2) Measure Updates

a. Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Cholesterol (Statins) (Part D) – Substantive Change

CMS **finalized the implementation of risk adjustment based on sociodemographic status (SDS) characteristics**, a substantive update, **to the three Part D medication adherence measures**.

CMS will first display the updated SDS risk adjusted medication adherence measures for the 2024 measurement year (2026 display page). Then, the updated SDS risk adjusted measures will replace the existing medication adherence measures beginning with the 2026 measurement year (2028 Star Ratings). CMS also intends to incorporate the SDS risk adjustment operationally to these measures reported by CMS to Part D sponsors in the last monthly patient safety report for the measurement year.

CMS contracted with PQA, the steward of these measures, to examine the adherence measures for potential risk adjustment. **PQA recommended SDS risk adjustment** for the Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), and Medication Adherence for Cholesterol (Statins) measures.

PQA recommended and endorsed the following changes related to SDS in the PQA Measure Manual:

- **All three adherence measures should be risk adjusted for SDS characteristics** to adequately reflect differences in patient populations.
- The measures should be adjusted for the following beneficiary-level SDS characteristics: **age, gender, low-income subsidy/dual eligibility (LIS/DE) status, and disability status.**
- The measures should be stratified by these four beneficiary-level SDS characteristics (listed in the prior bullet) to allow health plans to identify disparities and understand how their patient population mix is affecting their measure rates.

The **PQA measure specifications were endorsed by the National Quality Forum (NQF)** in 2019.

When CMS implements SDS risk adjustment for the three adherence measures, the measures would no longer be included in determining the Star Ratings Categorical Adjustment Index (CAI).

[PP. 148-150]

The summarized comments and responses from CMS are found on P. 148-150. Excerpts from the comments and CMS responses are found below.

- The majority of commenters supported the proposal to implement SDS risk adjustment for the Part D Star Ratings medication adherence measures.
- Several commenters opposed the proposal to apply SDS risk adjustment for the medication adherence measures. Commenters were concerned about the complexity of the SDS risk adjustment, that it contradicts CMS' expressed interest to simplify the Part C and D Star Ratings, that it could make tracking individual performance complicated for plans, and that it could make it difficult for beneficiaries to understand when comparing plans.
    - CMS Response: While risk adjustment does add complexity, CMS does not have concerns about applying the SDS risk adjustment and has tested this change. The update to implement SDS risk adjustment aligns with the PQA's recommendations as the measure steward. CMS will work to provide technical and non-technical information as appropriate about the updated measures for plans, beneficiaries, and other interested parties to help understand the specifications and to make comparisons. CMS will continue to provide contract-level and beneficiary-level information to Part D sponsors through the patient safety reports to assist plans with tracking their performance improvement efforts on medication adherence measures.
- Commenters expressed concerns surrounding the adherence measures being excluded from the CAI adjustment and unintended harm or impacts to sponsors with high enrollment of beneficiaries with SRFs.

    - CMS Response: Currently, the Star Ratings CAI adjusts for the average within-contract disparity in performance for LIS/DE and/or disability status. The SDS risk adjustment for the adherence measures adjusts for additional beneficiary-level SDS characteristics: age, gender, LIS/DE status, and disability status. The CAI is designed to adjust for the impact of SES on measure scores and ratings when the measures do not already include an adjustment to account for SES or similar sociodemographic factors. Because case-mix adjustment (that is, risk adjustment) of a measure adjusts scores to account for certain respondent characteristics not under the control of the health or drug plan, adjusting again for the same or similar factors through the CAI is duplicative and unnecessary.
- One commenter requested that the risk adjustment for the three adherence measures be introduced earlier in the 2026 Star Ratings. A commenter was concerned with program stability of moving the risk adjusted measures to the display page for two years and then reintroducing the measures to the Star Ratings with a triple weight.
    - CMS Response: CMS will keep the three legacy adherence measures in the Star Ratings during the period when the updated adherence measures are placed on the display page. CMS and sponsors will have the opportunity to monitor the three updated measures' rates while on the display page. During the first year the SDS risk adjusted adherence measures will be in the Star Ratings with 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.
- Commenters suggested that SDS risk adjustment be provided to plans prior to year-end or possibly monthly to give plans an understanding of the impact of these adjustments.
    - CMS Response: CMS is unable to provide monthly patient safety reports with SDS risk adjustment. CMS intends to apply the SDS risk adjustment for the final medication adherence patient safety reports of the measurement year which is typically in July of the following calendar year. During the display page transition period, CMS will assess the feasibility of providing the medication adherence patient safety reports with SDS risk adjustment at an additional time period prior to the determination of the final rates.
- Commenters requested that CMS publish detailed methodology and analysis results for the SDS risk adjustment.
    - CMS Response: As a reminder, CMS provides detailed contract-level reports and user guides to Part D plan sponsors for each of the current Part D patient safety measures. Similarly, CMS will update the medication adherence measure report user guides to reflect the implementation of the SDS risk adjustment and provide SDS risk adjustment methodology.
- CMS received one comment encouraging CMS to adopt the PQA Proportion of Days Covered (PDC) Medication Adherence "combined" measure and to apply the case-mix adjustment to that measure.
    - CMS Response: The PQA endorsed the PDC composite health plan measure in 2022. CMS defers to the measure steward, PQA, regarding questions on the composite health plan measure specifications and evaluation for risk

adjustment. CMS would need to propose through rulemaking to add PQA's composite health plan measure as a new measure to the Part C and Part D Quality Star Ratings system. CMS will consider testing the new PQA measure in the future as part of our continued oversight and maintenance of the Star Ratings program.

- Commenters expressed concern that removing the IP/SNF stay adjustment may undermine or counteract the proposed SDS risk adjustment updates, may not simplify the measure, or that implementing SDS risk adjustment for the adherence measures and removing the adherence measures from the CAI may provide additional complexity to these calculations which may disadvantage some populations with more IP/SNF stays.
    - CMS Response: CMS understands these concerns about removing the IP/SNF stay adjustment in the context of adding the SDS risk adjustment. As noted in the proposed rule, CMS conducted testing on the impact of the combined changes of the SDS risk adjustment and removing the IP/SNF stay adjustment. Our [CMS] testing indicated that applying both the SDS risk adjustment and the IP and SNF stay adjustments added complexity to the measure and created concerns about the accuracy of the SDS risk adjustment. The IP/SNF stay adjustment does not align with current PQA measure specifications that were endorsed for the adherence measures.
- A few commenters suggested additional updates to the medication adherence measure specifications to: (1) apply the IP/SNF stay adjustment prior to or as part of the SDS risk adjustment; or (2) exclude beneficiaries who reside in long-term care (LTC) facilities.
    - CMS Response: As finalized in this rule, CMS will implement SDS risk adjustment for the following beneficiary-level SDS characteristics: age, gender, LIS/DE status, and disability status, as developed and endorsed by the PQA (the measure steward) and endorsed by NQF, for the three medication adherence measures. The PQA medication adherence measure specifications do not adjust for IP/SNF stays or exclude beneficiaries who reside in LTC.
- A commenter expressed concerns that the medication adherence performance measures used by plans to evaluate pharmacies may not be risk adjusted and recommended that CMS implement standardized pharmacy performance measures.
    - CMS Response: These comments are out of scope for the proposed SDS risk adjustment to the Star Ratings medication adherence measures used to evaluate Part D plan performance. The SDS risk adjusted medication adherence measures are endorsed by the PQA and used by CMS at the plan-level, not the pharmacy-level. CMS encourages the PQA and industry to continue to work together on developing a set of pharmacy performance measures through a consensus process and Part D sponsors to adopt such measures to ensure standardization, transparency, and fairness.

b. Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Cholesterol (Statins) (Part D) – Non-Substantive Changes [P. 150]

- The IP/SNF stay adjustment will be removed from the medication adherence measures starting with the 2026 measurement year (2028 Star Ratings).
- CMS will implement the CE to the medication adherence measures starting with the 2024 measurement year (2026 Star Ratings).

The comments that CMS received that were solely about the non-substantive updates are addressed in the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, which was issued by CMS on March 31, 2023.

(3) Measure Addition [P. 151]

CMS is finalizing the addition of the Kidney Health Evaluation for Patients with Diabetes (Part C) measure to the 2026 Star Ratings.

Table 2 includes a summary of finalized new and revised individual Star Rating measures for performance periods beginning on or after January 1, 2024. [P. 152]

(4) Measure Removal [P. 152]

CMS finalized adding a rule to **allow removal of a Star Ratings measure, without separate rulemaking,** when a measure steward other than CMS (for example, NCQA or PQA) retires a measure.

E. Patient Experience/Complaints and Access Measure Weights [P. 153]

CMS finalized **decreasing the weight of patient experience, complaints, and access measures from 4 to 2 beginning with the 2026 Star Ratings**. At a weight of 2, these measures would be weighted higher than process measures but not as high as outcome measures.

[PP. 154- 158]

See referenced pages for all comments and responses included in the final rule.

- The majority of commenters strongly supported CMS' response to stakeholder concerns regarding the overemphasis on patient experience/complaints and access measures in the Part C and D Star Ratings program.
- Some commenters noted that they recognize the importance and value of patient experience/complaints and access measures, but agree that they should not account for more than half of the overall Star Ratings.

F. Health Equity Index Reward [P. 158]

CMS developed a health equity index (HEI) factor that they proposed for use in the Part C and Part D Star Ratings to reward contracts for obtaining high measure-level scores for the subset of enrollees with specified SRFs. CMS' intent in implementing an HEI reward is to improve health equity by incentivizing MA, cost, and PDP contracts to perform well among enrollees with specified SRFs.

CMS will **replace the current reward factor** with the new HEI reward **starting with the 2027 Star Ratings**; the HEI for the 2027 Star Ratings would be **calculated using data collected or used for the 2026 and 2027 Star Ratings.**

CMS is finalizing the removal of the reward factor and addition of the HEI reward to the 2027 Star Ratings as proposed, with additional revisions to §§422.162(a) and 423.182(a) to modify the definition of "highly-rated contract" to remove references to CAI and reward factor and to instead reference applicable adjustments in §§ 422.166(f) and 423.186(f); to §§ 422.162(b)(1) and 423.182(b)(1) to remove references to the current reward factor and to instead reference applicable adjustments in §§ 422.166(f) and 423.186(f); and to §§ 422.166(f)(3)(i)(B) and 423.186(f)(3)(i)(B) to clarify that, for purposes of calculating the HEI, measure-level scores are used for contracts that have data for only the most recent year of the 2 years, but measure-level scores are not used for contracts that have data for only the first of the 2 years.

Table 3 is a **high-level summary of the steps CMS will take to calculate the HEI.** As stated in the table, the steps are: [P. 161]

> **Step 1:** Measure-level scores for each measure included in the HEI are calculated for each contract using data from the two most recent measurement years based on enrollees with the specified SRFs using a modeling approach that accounts for year.
> **Step 2:** Measures that are case-mix adjusted in the Star Ratings employ all standard case-mix adjustors except for adjusters that are the same as the SRFs included in the HEI, are strongly correlated with the included SRFs, or are conceptually similar to the included SRFs.
> **Step 3:** A contract needs to meet the reliability and minimum denominator criteria for at least half of the measures included in the HEI based on data from the two most recent measurement years and have at least 500 enrollees at the contract level in the most recent measurement year to have the HEI calculated.
> **Step 4:** For each measure using all contract-level scores calculated in Step 1/Step 2 that have at least 0.7 reliability and meet the minimum denominator criteria, points will be assigned as follows: 1 point to those contracts that score in the top third of all contracts, 0 points to those that score in the middle third of all contracts, and 1 negative point to those that score in the bottom third of all contracts.
> **Step 5**: For each contract, the HEI will be calculated as the weighted average of the points assigned in Step 4 using the Star Ratings measure weights and including only measures for which the contract met all inclusion criteria.

As discussed in the proposed rule, the HEI would be calculated separately for the overall and summary ratings since the set of included measures differs for the overall, Part C summary, and Part D summary ratings.

The HEI calculated for the overall rating would be based on all of the Part C and Part D measures that meet the inclusion criteria for the HEI. Measures would be excluded from the HEI if one or more of the following criteria are met:

- The focus of the measurement is not the enrollee but rather the plan or provider.
- The measure is retired, moved to display, or has a substantive specification change in either year of data used to construct the HEI.
- The measure is applicable only to special needs plans (SNPs).
- At least 25 percent of contracts are unable to meet the criteria described at proposed paragraph (f)(3)(iv), which provides that a measure is only included for the HEI for a contract if the measure has a reliability of at least 0.7 for the contract when calculated for the subset of enrollees with the specified SRF(s) and the contract meets the measure denominator requirement when the measure is calculated for only the enrollees with the specified SRF(s) (that is, the SRFs included in the HEI).

In order to qualify for an HEI reward contracts must have a minimum rating-specific HEI score of greater than zero. CMS proposed a tiered HEI reward structure based on the percentage of enrollees in each contract who have the specified SRFs. Requiring both a minimum HEI score and a minimum percentage of enrollees in a contract with the specified SRFs is intended to avoid rewarding contracts that serve very few enrollees with the specified SRFs or do not perform well among enrollees with the specified SRFs relative to other contracts.

Table 4 is a high-level summary of how the HEI score is converted into the HEI reward. [P. 162]

Table 4: Converting HEI Score Into HEI Reward

Percentage of Enrollees with Specified SRFs Threshold	Amount of Reward
% of enrollees in a contract with the specified SRFs < 0.5 of the median for all contracts.	Zero reward.
% of enrollees in a contract with the specified SRFs ≥ 0.5 of the median for all contracts and < the median for all contracts.	HEI reward will vary from 0 to 0.2 on a linear scale for contracts that have an HEI score > 0.
% of enrollees in a contract with the specified SRFs ≥ the median for all contracts.	HEI reward will vary from 0 to 0.4 on a linear scale for contracts that have an HEI score > 0.

While CMS is requiring a minimum HEI score of greater than zero for contracts to receive an HEI reward, CMS may consider increasing this minimum score over time to continue to encourage improved contract performance for enrollees with SRFs included in the HEI. Any such increase to the minimum HEI score would be proposed through subsequent notice-and-comment rulemaking.

Because enrollees in Puerto Rico are not eligible for LIS, CMS believes that a different approach is necessary for contracts with services areas wholly located in Puerto Rico. CMS at §§ 422.166(f)(3)(vii)(A) and (B) and 423.186(f)(3)(vii)(A) and (B) will use a modified calculation to determine the percentage of enrollees with SRFs included in the HEI for contracts with service areas wholly located in Puerto Rico. CMS will limit this treatment to contracts with service areas wholly in Puerto Rico because its analysis indicates that for plans with services areas that include Puerto Rico and other locations, only a small portion of the enrollment is in Puerto Rico. [P. 162]

[PP. 163-174]

Comments and responses on this proposal were extensive. See referenced pages for all comments and responses noted in the final rule.

G. Extreme and Uncontrollable Circumstances [P. 174]

(1) CMS is finalizing the revision to remove the 60 percent rule beginning with the 2026 Star Ratings for non-CAHPS measures as proposed without modification.

Beginning with the 2024 Star Ratings, measure scores that are extreme outliers will be removed through Tukey outlier deletion, a standard statistical method to remove extreme outliers prior to applying the clustering methodology to determine the cut points. The combination of mean resampling implemented with the 2022 Star Ratings and Tukey outlier deletion will alleviate the impact of any extreme outliers. Thus, if a contract is impacted by an extreme and uncontrollable circumstance and as a result has a significantly lower score on a measure, the score will be removed if it is an extreme outlier.

(2) CMS is finalizing their proposal to clarify in § 422.166(i)(3)(iv) the timing for Health Outcomes Survey (HOS) measure adjustments for extreme and uncontrollable circumstances.

H. Calculation of Star Ratings [P. 176]

CMS is finalizing the technical amendment to fix the Tukey outlier deletion codification error from the May 2022 final rule and the non-substantive technical change to move the sentence about removal of Tukey outer fence outliers earlier in §§422.166(a)(2)(i) and 423.186(a)(2)(i), since Tukey outlier deletion is applied prior to the other steps. The Tukey outlier deletion will be applied beginning with the 2024 Star Ratings.