



Optimizing Health by Advancing the Quality of Medication Use

June 1, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8016

Attention: CMS-1744-IFC

Dear Administrator Verma:

The Pharmacy Quality Alliance (PQA) appreciates the opportunity to comment on the interim final rule on “Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” (CMS-1744-IFC).

PQA is a national quality organization dedicated to improving medication safety and appropriate use. As a measure developer, researcher, educator and convener, PQA’s quality initiatives support better medication use and value-based care. A non-profit organization with 250 diverse members across healthcare, PQA was established in 2006 as a public-private partnership with the Centers for Medicare & Medicaid Services shortly after the implementation of the Medicare Part D Prescription Drug Benefit. [PQA members](#) include community and specialty pharmacy organizations, pharmacists and other healthcare providers, pharmacies, health plans, pharmacy benefit managers, life sciences, technology vendors, government agencies, health information technology partners, academia and researchers.

PQA’s comments on the interim final rule follow.

PQA commends the steps that the Centers for Medicare & Medicaid Services (CMS) has taken in the Interim Final Rule with Public Comment (IFC) to address the impact of the Coronavirus Disease (COVID-19) pandemic and Public Health Emergency (PHE) on Part C and Part D Quality Rating Systems.

The provisions of the IFC address the immediate needs of health and drug plans to focus on providing needed care to Medicare beneficiaries affected by COVID-19. We encourage CMS to continue to monitor the impact of COVID-19 for the remainder of 2020 and into 2021 to see if additional Star Rating changes are necessary.

PQA hosted 18 interviews in April and May 2020 with member organizations, primarily health plans and pharmacy benefit managers, to gain insights on the anticipated impact of COVID-19 on Medicare

Part D Star Ratings and other medication-related challenges they are observing or anticipate. PQA would be pleased to share a summary of these interviews with CMS to complement the comments received directly from the public.

Below are comments related to specific sections of the IFC, followed by additional comments related to the impact of COVID-19 on Part C and Part D Quality Rating Systems and the healthcare system.

Y. Addressing the Impact of COVID-19 on Part C and Part D Quality Rating Systems

II Provisions of the Interim Final Rule

Y. Addressing the Impact of COVID-19 on Part C and Part D Quality Rating Systems

3. Provisions of IFC

PQA commends CMS on making modifications to the calculation of 2021 and 2022 Part C and D Star Ratings to address the expected impact of the Public Health Emergency (PHE) for the COVID-19 pandemic on data collection and performance.

b. Adjustments to the 2021 Star Ratings Methodology Due To Lack of HEDIS and CAHPS Data

PQA supports CMS' modifications to the 2021 Star Ratings, using data from the 2020 Star Ratings for measures based on HEDIS and Medicare CAHPS data (i.e., HEDIS data from 2018 measurement year and CAHPS data from June 2019).

c. Use of 2020 Star Ratings To Substitute for 2021 Star Ratings in the Event of Extraordinarily Compromised CMS Capabilities or Systemic Data Issues

In the event that there is a systemic data quality issue for all plans as a result of the PHE for the COVID-19 pandemic, PQA supports CMS substituting the score and star for the measure used in the 2020 Star Ratings in the calculation of the 2021 Star Ratings. As an example, sponsors report Medication Therapy Management (MTM) data to CMS by March 2020, and these data undergo independent data validation beginning in April. While validation activities can be conducted remotely between the plans' staff and data validation reviewers, there may be other difficulties in completing the work this year on time and consistent with CMS requirements due to the significant impact of the PHE for the COVID-19 pandemic. Therefore, CMS would use sponsors' MTM Program Completion Rate for Comprehensive Medication Review measures' scores and stars from the 2020 Star Ratings as the sponsors' 2021 Star Ratings on those measures.

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d. 2022 Star Ratings

i. Guardrails

PQA appreciates CMS' anticipation of an impact on performance for the 2020 measurement period (for 2022 Star Ratings) as health and drug plans and their providers adapt their current practices in response to the COVID-19 pandemic in caring for the most vulnerable patients, such as the elderly and those with chronic health conditions.

PQA supports CMS delaying the implementation of the guardrails for the 2022 Star Ratings, so that cut points can decrease by more than 5 percentage points if national performance declines resulting from the pandemic. However, PQA recommends that CMS monitor the impact of delaying implementation of the guardrails in the event that national performance improves for some measures during the 2020 measurement period. For example, plans may observe an improvement on performance of the MTM Program Completion Rate for Comprehensive Medication Review measure with many members sheltering in place. Additionally, adherence measure performance could be inflated if the flexibilities granted to plans during the PHE to relax "refill-too-soon" edits and extend days' supply for Part D drugs results in members stockpiling medications. If national performance on some measures improves for some measures, this could disproportionately impact some health and drug plans given the prominent geographic variation of COVID-19.

ii. Improvement Measure

PQA supports CMS' revised methodology for the Part C and D improvement measure for the 2022 Star Ratings to expand the hold harmless rule to include all contracts at the overall and summary rating levels, recognizing that the PHE and COVID-19 pandemic may result in a decline in industry performance.

Additional Comments

Anticipated Impact of COVID-19 on Statin Use in Persons with Diabetes

COVID-19 is likely to have an impact on performance on the Statin Use in Persons with Diabetes (SUPD) measure. With shelter-in place orders in many areas and healthcare facilities rescheduling non-urgent outpatient visits, access to primary care providers may be limited. Even with the promotion of telehealth visits, starting a statin typically involves baseline laboratory data, such as liver function tests. Delaying the implementation of the guardrails and expanding the hold harmless rule for the Part C and D improvement measure for the 2022 Star Ratings will be helpful in mitigating the impact of the pandemic. However, given that the SUPD measure will be triple weighted for the 2022 Star Ratings, CMS may want to consider additional steps to mitigate the impact of COVID-19 on measure performance. One option to consider would be to expand the hold harmless rule to the SUPD for the 2022 Star Ratings, applying the higher of the Star Ratings from Rating Year 2021 or 2022.

Geographic Variation of COVID-19

PQA encourages CMS to consider that the prominent geographic variation of COVID-19 and local responses to the pandemic could translate to disparate impact on some geographic areas being more impacted than others and whether additional Star Ratings adjustments are necessary and appropriate. The geographic variation of the impact of COVID-19 could be further compounded by

sociodemographic factors that impact measure performance. We are supportive of implementation of the PQA-developed risk adjustment methodology for sociodemographic status factors for the three medication adherence measures used in the Medicare Part D Star Ratings Program.

Rolling Back Part D COVID-19 Flexibilities

PQA commends CMS on the temporary regulatory waivers issued in response to the COVID-19 PHE related to Part D drugs, such as waiving or relaxing prior authorization requirements, relaxing “refill-too-soon” edits, and relaxing any plan-imposed policies for home or mail delivery. PQA encourages CMS to consider the impact on patients when flexibilities implemented in response to the pandemic are rolled back. Rather than viewing the temporary increased access to medications favorably, beneficiaries may view any reduced flexibility negatively, and this could impact performance on patient experience/complaint measures.

Social Determinants of Health

Even prior to the pandemic, many health and drug plans have implemented initiatives to address social determinants of health (SDOH) and social isolation. COVID-19 provided a critical opportunity to connect with members through medication therapy management (MTM) interventions to combat loneliness, food insecurity, behavioral health, access to care, and costs. For comprehensive medication reviews (CMRs) and other outreach, some plans are using SDOH and COVID-19-specific questions to identify members at risk. This provides an opportunity to refer members to case managers, behavioral health services, or other needed services. PQA suggests that a standard set of questions could be used in MTM sessions that identify SDOH barriers to access and adherence.

Value-Based Arrangements

Although the Part C and D Star Ratings are for rating the Medicare health and drug plans (not pharmacies), the downstream impact of the program on the healthcare system is undeniable, including the contractual arrangements between plans and provider groups or pharmacies. PQA is concerned about whether the changes made by CMS in response to COVID-19 for the 2022 Star Ratings for health and drug plans will translate to commensurate modifications to their value-based arrangements. We recommend that CMS continue to monitor the impact of COVID-19 on the entire healthcare system.

PQA appreciates CMS’ thoughtful consideration of our comments submitted in response to this interim final rule. If you have questions, please do not hesitate to contact us.

Respectfully,



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