



March 6, 2020

Demetrios Kouzoukas
Principal Deputy Administrator & Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Attention: CMS-2020-0003

Dear Mr. Kouzoukas,

The Pharmacy Quality Alliance (PQA) appreciates the opportunity to comment on the 2021 Advance Notice and applauds the Centers for Medicare & Medicaid Services (CMS) for providing a forward look at the Star Ratings program, proposing enhancements, and soliciting input on future measures and concepts to enhance the Star Ratings over time.

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 2021 Advance Notice follow.

- [p. 66] **Extreme and Uncontrollable Circumstances Policy.** CMS states that "the same policy as used for adjustments to 2020 Star Ratings based on extreme and uncontrollable circumstances will be continued for CY 2021 Star Ratings."
 - PQA has heard from multiple members that circumstances beyond natural disasters, such as prescription drug recalls or drug shortages, should be considered as extreme and uncontrollable circumstances that affect performance on measures in the Star Ratings program. We recommend that CMS evaluate this policy and the impact of extreme and uncontrollable circumstances on beneficiaries and the Star Ratings program further.

- [p. 71] **Concurrent Use of Opioids and Benzodiazepines (COB), Use of Opioids at High Dosage in Persons Without Cancer (OHD), Use of Opioids from Multiple Providers in Persons Without Cancer (OMP), and Use of Opioids at High Dosage and from Multiple Providers in Persons Without Cancer (OHDMP) (Part D).** We support CMS implementing the sickle cell disease exclusion we added to our PQA opioid measures; and therefore, starting with the 2020 year of service data, excluding beneficiaries with a sickle cell diagnosis at any time during the measurement year from these measures.

This change reflects the recommendations in the [CDC Guideline for Prescribing Opioids for Chronic Pain](#), current published evidence, and subject matter expert and stakeholder feedback.

- [p. 72] We support CMS considering implementation of PQA's sociodemographic status (SDS) risk adjustment recommendations for the 2022 measurement year or beyond for PQA's three adherence measures – **Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins)** – used in the Part D Star Ratings.
 - PQA finalized our recommendations for SDS risk adjustment for the three PQA health plan adherence measures – PDC-Diabetes All Class, PDC-Renin Angiotensin System Antagonists, and PDC-Statins – in Medicare Part D, as follows:
 - The measure rates should be risk adjusted for SDS characteristics to adequately reflect differences in patient populations.
 - The measure rates should be adjusted for the following beneficiary-level SDS characteristics: age, gender, dual eligibility/Low-Income Subsidy (LIS) status, and disability status.
 - The measure rates should be stratified by the beneficiary-level SDS characteristics listed above to allow health plans to identify disparities and understand how their patient population mix is affecting their measure rates.
- [pp. 75-76] **Generic Utilization (Part D).** PQA applauds CMS' goal of lowering prescription drug prices for all Americans and efforts to increase access to generics and biosimilars in Medicare. PQA would welcome the opportunity to support CMS in determining whether and how measures of generic and biosimilar utilization in Medicare Part D could help achieve goals related to prescription drug costs and patient access.
 - Based on initial feedback from PQA's Board of Directors and our multi-stakeholder members, we believe there are complex issues related to these measure concepts that could impact the measures' feasibility or lead to unintended consequences. The role of formularies, plan designs, rebates and state substitution rules are among the factors that warrant study and evaluation to determine whether and how best effective measures could be developed.
 - As an experienced, multi-stakeholder and consensus-based organization, we believe PQA is best positioned to support CMS and the industry to explore these issues.

- [pp. 76-78] **Initial Opioid Prescribing (IOP) Measures (Part D)**. PQA supports CMS' plans to begin reporting the *Initial Opioid Prescribing for Long Duration* (IOP-LD) measure in the Patient Safety reports for the 2020 measurement year, to add the measure to the display page for 2023 and 2024, and to consider adding the measure to the Star Ratings in the future.
 - PQA also looks forward to CMS' plans to perform additional analyses of the *Initial Opioid Prescribing at High Dosage* (IOP-HD) and *Initial Opioid Prescribing for Long-Acting or Extended Release Opioids* (IOP-LA) measures and monitor notable utilization trends in the future.
 - PQA will submit the IOP-LD measure to NQF for endorsement consideration during the spring 2020 cycle.
 - PQA's three initial opioid prescribing measures – IOP-HD, IOP-LD and IOP-LA – were endorsed by PQA's membership in May 2019. The measures are part of PQA's Opioid Core Measure Set, which now has seven measures to evaluate patients with prescriptions for opioids. The other measures in the set evaluate: *Concurrent Use of Opioids and Benzodiazepines* (NQF #3389); *Use of Opioids at High Dosage in Persons Without Cancer* (NQF #2940); *Use of Opioids from Multiple Providers in Persons Without Cancer* (NQF #2950); and *Use of Opioids at High Dosage and from Multiple Providers in Persons Without Cancer* (NQF #2951).

PQA appreciates CMS' thoughtful consideration of our comments submitted in response to the 2021 Advance Notice. If you have questions, please do not hesitate to contact us.

Respectfully,



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