



March 1, 2019

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-2018-0154

Dear Mr. Kouzoukas,

The Pharmacy Quality Alliance (PQA) appreciates the opportunity to comment on the 2020 Draft Call Letter and applauds the Centers for Medicare & Medicaid Services (CMS) for providing a forward look at the Star Ratings program, proposing enhancements to the 2020 Star Ratings, and soliciting feedback on possible future measure updates and concepts.

PQA is a transparent, consensus-based measure developer, established in 2006 as a public-private partnership by CMS, under the leadership of former CMS Administrator Dr. Mark McClellan. Today, we are a non-profit, multi-stakeholder, quality organization with over 240 members. Shortly after the implementation of the Medicare Part D Prescription Drug Benefit, PQA was launched with a focus to develop measures for use by CMS in the Medicare Part C & D Programs. PQA members include community pharmacy organizations, specialty pharmacy organizations, pharmacists and other healthcare providers, pharmacies, health plans, pharmacy benefit managers, life sciences, technology vendors, government agencies, health information technology partners, researchers and academia.

PQA's comments on the 2020 Draft Call Letter follow.

- [pp. 112-113] Categorical Adjustment Index. We are pleased that CMS noted PQA's recommendations on sociodemographic (SDS) risk adjustment of the three medication adherence measures—**Medication Adherence for Diabetes Medications**, **Medication Adherence for Hypertension**, and **Medication Adherence for Cholesterol**—and further noted that if the risk-adjusted version of the measures (NQF #0541) are endorsed by NQF, CMS will consider how to implement the PQA recommendations for these Star Ratings measures for the 2021 measurement year or beyond.
 - We would like to provide a status update regarding our activities related to NQF endorsement maintenance for NQF #0541. PQA included its SDS risk adjustment methodology for the Proportion of Days Covered (PDC)-3 Rates measure in the NQF

testing form as part of our intent to submit for NQF endorsement maintenance for the Spring 2019 cycle under the Primary Care and Chronic Illness project. We anticipate NQF's final determination of re-endorsement in Dec. 2019/Jan. 2020, according to the NQF timeline.

- [pp. 135-136] PQA supports CMS' plans to add the **Concurrent Use of Opioids and Benzodiazepines (COB)**, **Polypharmacy Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH)**, and **Polypharmacy Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS)** measures to the display page for 2021 and 2022, and to consider these measures for the 2023 Star Ratings.
 - The PQA COB measure was endorsed by NQF (#3389) at the end of 2018, making it PQA's fourth NQF-endorsed opioid prescribing measure. Concurrent prescribing of opioids and benzodiazepines is associated with an increased risk for potentially fatal overdose and should be avoided whenever possible.
 - The PQA Poly-ACH measure evaluates concurrent prescribing of two or more anticholinergic medications, which may increase the risk for cognitive decline in older adults. The Poly-CNS measure evaluates concurrent prescribing of three or more CNS-active medications, which may increase the risk for falls in older adults.
 - The PQA Measure Update Panel will review the polypharmacy measures in light of the recent publication of the [2019 Updated AGS Beers Criteria](#), and we will communicate any changes to CMS.
- [pp. 136-137] We support CMS implementing the changes we made to our three PQA measures that assess the use of opioids from multiple providers and/or at high dosage in persons without cancer, and having these changes reflected in the Patient Safety reports for the 2019 measurement year.

The changes to the measures are highlighted, below:

- **Measure 1: Use of Opioids at High Dosage in Persons without Cancer (OHD):** The 2019 OHD measure (for measurement year 2018) evaluates an average daily MME of ≥ 90 over a period of ≥ 90 days (vs. > 120 MME/day for ≥ 90 consecutive days), reported as a percentage (vs. XX per 1,000).
- **Measure 2: Use of Opioids from Multiple Providers in Persons without Cancer (OMP):** The 2019 OMP measure now evaluates ≥ 4 prescribers and ≥ 4 pharmacies within ≤ 180 days (vs. anytime during the measurement year), reported as a percentage (vs. XX per 1,000).
- **Measure 3: Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP):** The OHDMP changes align with those listed above for the OHD and OMP measures, reported as a percentage (vs. XX per 1,000).

The changes reflect the recommendations in the [CDC Guideline for Prescribing Opioids for Chronic Pain](#), current published evidence, and stakeholder feedback.

We support CMS' proposal to include all three revised measures on the 2021 display page, and consideration to add these three measures to the 2023 Star Ratings.

- [p. 137] PQA supports CMS' plans to retire the **High Risk Medication (HRM)** and **Diabetes Medication Dosing (DMD)** display measures for 2021 and to no longer report these measures in the Patient Safety reports for the 2019 measurement year. We agree that having a parsimonious list of measures enables plans to better focus their resources.
- Medication Therapy Management (MTM). We support CMS for its interest to enhance the MTM program. The PQA Quality Metrics Expert Panel is reviewing testing results for the draft measure, **Medication Therapy Problem Resolution**, which uses MTM program encounter data documented using SNOMED CT and RxNORM codes. In the second quarter of 2019, PQA anticipates endorsement consideration by PQA membership of this draft measure that evaluates the percentage of medication therapy interventions that resolve medication therapy problems among individuals participating in a Medication Therapy Management (MTM) program. A higher rate indicates better performance.
 - The draft measure is intended to be a monitoring measure for MTM programs, which may be used for standardized reporting requirements for monitoring purposes but not for accountability (e.g., public reporting, benchmarking, performance payments).

We encourage CMS to consider this monitoring measure, if endorsed by PQA membership, for MTM reporting.

- We support CMS for its efforts to strengthen and broaden its commitment to address the opioid crisis. PQA is committed to developing measures to add to our Opioid Core Measure Set, providing a more comprehensive set to support safer prescribing. In the second quarter of 2019, PQA anticipates endorsement consideration by PQA membership of three new measures that align with the CDC guideline, which will evaluate the percentage of individuals 18 years and older with initial opioid prescriptions:
 1. **Initial Opioid Prescribing at High Dosage (average daily MME of 50 or more)**
 2. **Initial Opioid Prescribing for Long Duration (more than 7 days' supply)**
 3. **Initial Opioid Prescribing for Long-Acting or Extended-Release Opioids**

We encourage CMS to consider adding these measures to Part C & D quality programs, if endorsed by PQA membership, to address early opioid use that may increase the risk for chronic opioid use or opioid use disorder.

Finally, we reiterate PQA's interest to work with CMS to develop a standardized set of measures for use in plan-pharmacy contracting. CMS, in the proposal related to Pharmacy Price Concessions in the Negotiated Price (§ 423.100), within CMS-4180-P, stated that it is "considering an option to develop a standard set of metrics from which plans and pharmacies would base their contractual agreements."

- If CMS decides to establish a standard set of metrics, those metrics should be developed by an established measure developer:
 - (1) with experience developing evidence-based, clinical quality measures for Medicare Part D that address the safe and appropriate use of medications,
 - (2) that serves as a neutral convener of all relevant stakeholders on this issue, including health plans, pharmacy benefit managers, chain and independent pharmacies, government agencies, specialty pharmacy providers, pharmacist practitioner organizations,

- (3) that develops measures through a fully-transparent consensus-based process, and
- (4) that is willing to steward these measures on behalf of CMS, including completing necessary maintenance at least annually.

We respectfully recommend that CMS work with PQA, as the most appropriate organization to develop these measures. Initially established by CMS as a public-private partnership in 2006 for the purpose of developing measures for Medicare Part D, PQA has a proven track record of developing and maintaining measures for use within the Medicare Part D Star Ratings Program, the display program and the patient safety reports produced for plan sponsors. PQA, as a neutral convener, is in a unique position to gather the necessary perspectives to create successful measures, given its membership is composed of pharmacy organizations, pharmacists, health plans and pharmacy benefit managers among other medication quality-interested organizations.

Given its experience, PQA is best-positioned to develop evidence-based measures and importantly, to test the measures for their intended use (i.e., level of analysis and populations of focus), to ensure they are feasible, valid and reliable. The organization selected by CMS to develop a standard set of measures should receive adequate resources from CMS, so that the measure set can be developed and implemented in a timely manner and stewarded on behalf of CMS on an ongoing basis.

PQA appreciates CMS' thoughtful consideration of our comments submitted in response to the 2020 Draft Call Letter. If you have questions, please do not hesitate to contact us.

Respectfully,



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