Optimizing Health by Advancing the Quality of Medication Use

January 16, 2018

PQA Comment Letter on the CMS Proposed Rule for the Medicare Program – Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program

RE: File code CMS-4182-P

The Pharmacy Quality Alliance (PQA) applauds the Centers for Medicare & Medicaid Services (CMS) for efforts to continually review and refine the Medicare Prescription Drug Benefit (Part D). We appreciate the opportunity to submit comments in response to the Proposed Rule to revise the Medicare Advantage program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations, initially distributed on 11/16/17 and published in the Federal Register on 11/28/2017.

PQA is a transparent, consensus-based measure developer, established in 2006 as a public-private partnership by CMS, under the leadership of the former CMS Administrator, Dr. Mark McClellan. Shortly after the implementation of the Medicare Part D Prescription Drug Benefit, PQA's focus was to develop metrics for use by CMS inside the Medicare Part C&D Programs.

Since that time, PQA has become a non-profit organization with more than 225 members including healthcare payers, health plans, community pharmacies, physician providers, life sciences organizations, state and federal government agencies, academic institutions, standard setting/accreditation organizations and health information technology (HIT) partners. PQA members have the opportunity to shape the measures we develop by serving on advisory panels and measure development groups to draft, test, refine, and endorse performance measures that focus on medication-use quality in high priority areas or to fill gaps in existing performance measures.

PQA comments on various sections of the proposed rule are summarized on the attached pages.

5911 KINGSTOWNE VILLAGE PARKWAY, SUITE 130
ALEXANDRIA, VA 22315
T 703.347.7963 W WWW.PQAALLIANCE.ORG

Current Part D Opioid DUR Policy and Overutilization Monitoring System (OMS)

1. In response to the CMS request for comments on the clinical guidelines proposed for 2019, and sponsors' systems capabilities to account for alternatives that would involve identifying more or fewer potential at-risk beneficiaries:

   - PQA Comment:
     - PQA is evaluating proposed updates aligned with the CDC Guidelines for Prescribing Opioids for Chronic Pain (e.g., 90 morphine milligram equivalents [MME] per day as a high-dose threshold), to the three PQA opioid overuse measures, *Use of Opioids at High Dosage in Persons without Cancer (OHD), Use of Opioids from Multiple Providers (OMP),* and *Use of Opioids at High Dosage and from Multiple Providers (OHDMP),* which will more closely align with current criteria used in the OMS.
     - PQA's *Concurrent Use of Opioids and Benzodiazepines* measure is an additional tool to address the opioid crisis. This measure was added to the 2018 Medicaid Adult Core Measure Set and will be submitted for National Quality Forum endorsement consideration in 2018. PQA would be pleased to work with CMS if there is interest in using this measure in any of the quality measurement programs.

Medicare Advantage and Part D Prescription Drug Program Quality Rating System

2. In response to the CMS request for feedback from stakeholders on how well the existing stars measures create meaningful quality improvement incentives and differentiate plans based on quality:

   - PQA Comment:
     - PQA was created to develop measures necessary to differentiate health plan quality and to drive interventions to improve quality. PQA will continue to monitor how we can assist CMS related to new measure needs and for opportunities to improve existing PQA measures so that they best represent quality of care.

Adding, Updating, and Removing Measures

3. CMS proposes general rules to govern adding, updating, and removing measures.

   - PQA Comment:
     - PQA applauds CMS's use of the Call Letter attachment to the Advance Notice and Rate Announcement to announce new measures, substantive updates to existing measures, removal of measures, and to solicit feedback and encourages the continued use of these important and timely communications.

4. For the 2021 Star Ratings, CMS proposes to have measures that encompass outcome, intermediate outcome, patient/consumer experience, access, process, and improvement measures.

   PQA Comment:
   - PQA supports using a mix of different types of measures in the Star Ratings. Although outcome measures are of great interest, medical claims data are needed to calculate such

measures, thereby limiting their utility to those plans with access to and the ability to integrate medical and prescription claims (i.e., MA-PD).
    - Although outcome measures are more challenging to develop and collect, and often require more sophisticated risk-adjustment methodologies, PQA will continue development of outcome measures to address adverse medication events, and welcomes input for future measure development.

5. Regarding addition of new measures: CMS's general guidelines for deciding whether to propose new measures through future rulemaking will use the criteria of importance, performance gap, reliability and validity, feasibility and alignment.

    - PQA Comment:
        - PQA supports the criteria outlined for deciding whether to propose new measures for the Star Ratings.

6. CMS states in the proposed rule that the rulemaking process will create a longer lead time for changes, in particular to add a new measure to the Star Ratings or to make substantive changes to measures. CMS then provides an example timeline for adding a new measure to the Star Ratings. In the scenario provided, the new measure has already been developed, and is endorsed by the NQF.

    - PQA Comment:
        - PQA requests that CMS confirm whether the rulemaking process will indeed create a longer lead time for a new measure to be added to the Star Ratings, and if so, to provide the length of time that would be added to the current process.
        - PQA encourages the timely addition of new measures that address important measure gaps, and support the strategic goal of improving the quality of care for Medicare beneficiaries.

7. In response to the CMS request for comment on the proposal to add non-substantive updates to measures and using the updated measure (replacing the legacy measure) to calculate Star Ratings:

    - PQA Comment:
        - PQA supports adding non-substantive measure updates to the Star Ratings under the proposed authority. The regulation text is sufficiently extensive regarding examples or situations involving non-substantive updates.
        - The process proposed for adding substantive updates to the Star Ratings that is intended to be similar to the process used for adopting new measures under proposed paragraph (c), may unnecessarily slow the update process.
        - In the case of legacy measures continuing to be included in the Star Ratings while the updated measure is on the display page for at least two years, we are concerned that this could delay the use of a superior measure with improved validity, reliability, or clinical guideline support.
        - PQA requests that CMS clarify how the determination is made as to whether a change to a measure is substantive.

8. **Measure Set for Performance Periods Beginning on or after January 1, 2019**
   CMS is proposing the measures included in Table 2B on pp. 214-216 to be collected for performance periods beginning on or after January 1, 2019 for the 2021 Part D Star Ratings.

   - PQA Comment:
     - PQA is pleased with the inclusion of the *Statin Use in Persons with Diabetes (SUPD)* measure and the three *Medication Adherence* measures (diabetes medications, hypertension [RAS antagonists], cholesterol [statins]), as intermediate outcome measures, each with a weight of 3, and the process measure, *MTM Program Completion Rate for CMR* measure, with a weight of 1, in the Part D Star Ratings.

PQA appreciates CMS's thoughtful consideration of our comments submitted in response to the Proposed Rule for the Medicare program.

Respectfully,

Laura Cranston, RPh
Chief Executive Officer
Pharmacy Quality Alliance, Inc.
LCranston@PQAalliance.org
(703) 347-7963