



Optimizing Health by Advancing the Quality of Medication Use

April 6, 2020

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

Attention: CMS-4190-P

Dear Administrator Verma:

The Pharmacy Quality Alliance (PQA) appreciates the opportunity to comment on CMS-4190-P, the proposed rule for “Medicare and Medicaid Programs: Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.”

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, patient advocacy organizations, life sciences, technology vendors, government agencies, health information technology partners, academia and researchers.

PQA’s comments on the proposed rule follow. The page numbers provided in italicized parentheses are for reference and correspond to the first page of a section within the rule, as published in the [Federal Register on February 18, 2020](#).

Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102) (*p. 9005*)

CMS proposes to codify the existing guidance and parameters for special supplemental benefits for chronically ill enrollees. PQA supports this proposal, as we believe these special supplemental benefits can help address the social determinants of health that affect patient access, medication adherence and health outcomes.

Implementation of Several Opioid Provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (*p. 9025*)

On Mandatory Drug Management Programs (DMPs) (§ 423.153)

In support of the CMS proposal to require mandatory implementation of DMPs by Part D sponsors, for plan years beginning on or after January 1, 2022, as required under section 2004 of the SUPPORT Act, [PQA is partnering with the Chesapeake Regional Information System for our Patients \(CRISP\)](#) to map four PQA opioid measures to Maryland's Prescription Drug Monitoring Program (PDMP) data. PQA's opioid measures currently are calculated using administrative claims data. The partnership will support proactive reporting on the four PQA opioid measures between PDMPs and CMS, and addresses provisions of the SUPPORT for Patients and Communities Act, which requires states by October 1, 2021, to have a qualified PDMP and requires certain Medicaid providers to check information about some beneficiaries' prescription drug histories before prescribing controlled substances. The partnership is made possible by funding from CMS, and we are pleased to support qualified PDMPs to report on PQA opioid measures and contribute to program evaluation. The project aims to create opioid measure specifications that PDMPs across the country can utilize.

On Inappropriate Prescribing of Opioids

Beginning with plan year 2021, Part D plan sponsors are required to submit to the Secretary information on investigations, credible evidence of suspicious activities of providers or suppliers related to fraud, and other actions taken by the plans related to inappropriate opioid prescribing. The Secretary is required to issue regulations that define the term inappropriate prescribing with respect to opioids, identify a method to determine if providers are inappropriately prescribing, and identify the information plan sponsors are required to submit. PQA supports national efforts to reduce inappropriate prescribing of opioids.

- PQA's Opioid Measure Set provides important and timely tools to address the opioid epidemic. The seven measures in the set evaluate individuals with prescriptions for opioids in combination with benzodiazepines, at high-dosage, from providers, or initial opioid prescriptions. These prescribing patterns are associated with an increased risk of opioid misuse, overdose, or death.
- PQA notes that individuals who meet specific criteria are excluded from these measures. In addition to individuals in hospice care and those with cancer, we have recently updated our opioid measure specifications to exclude individuals with a sickle cell disease diagnosis. This change is based on subject matter expert and stakeholder feedback and aligns with the scope of recommendations in the [CDC Guideline for Prescribing Opioids for Chronic Pain](#).

Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186) (*p. 9043*)

PQA supports CMS' effort to increase transparency and give advance notice regarding enhancements to the Part C and D Star Ratings program, including the use of rulemaking any future changes to the methodology for calculating the ratings, addition of new measures, and substantive changes to the measures.

CMS proposes to further increase the stability of cut points by modifying the cut point methodology for non-CAHPS measures through direct removal of outliers. PQA supports CMS' efforts to further increase the predictability and stability of the Star Ratings system.

CMS proposes to modify the classification of the Statin Use in Persons with Diabetes (SUPD) measure from an intermediate outcome classification to be a process measure, starting with the 2023 Star Ratings. As the developer and steward of this measure, PQA supports this proposed modification, as PQA classifies SUPD as a process measure. In 2019, in response to questions around the appropriate classification of the measure, PQA sought qualitative and quantitative input from subject matters experts – including clinicians, health plan representatives, and researchers – from across its multi-stakeholder membership. Based on input from subject matter experts, PQA retained the classification of SUPD as a process measure. This aligns with the National Quality Forum definition for process measures, as prescribing a statin is a “step that should be followed to provide good care” rather than an outcome of such care.

Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514) (p. 9063)

CMS proposes to establish a requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreement. PQA does not take a position on this proposal, but we do believe that collecting pharmacy performance measures can inform industry in its efforts to develop a standard set of pharmacy performance measures.

CMS encourages the 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.

PQA is pleased that CMS acknowledges, encourages and provides recommendations for the development of a set of pharmacy performance measures through a consensus process. We appreciate CMS' recognition of our efforts and progress to work with the industry to establish a consensus set of measures. Like CMS, we are encouraged by the progress being made.

Developing and adopting pharmacy performance measures is an important step towards a higher-quality health care system. A standard, national set of pharmacy measures can incentivize and support pharmacist-provided care, which can play an important role in improving patient experiences and health outcomes. Regarding the development of these measures, PQA believes:

1. PQA is the right organization to continue bringing the industry together to develop a set of pharmacy performance measures through a consensus and transparent process. We are an established measure developer:
 - with experience developing evidence-based, clinical quality measures for Medicare Part D that address the safe and appropriate use of medications,
 - that serves as a neutral convener of all relevant stakeholders on this issue, including patients, health plans, pharmacy benefit managers, chain and independent pharmacies,

- government agencies, specialty pharmacy providers, pharmacist practitioner organizations, and
- o that stewards our measures, including completing necessary maintenance at least annually.

We have a proven track record of developing and maintaining measures for use within the Medicare Part D quality programs, including the Star Ratings, the display page 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 that our membership is composed of pharmacy organizations, pharmacists, health plans, pharmacy benefit managers, and patient advocacy groups among other medication quality-interested organizations.

PQA members have the opportunity to shape the measures PQA develops by serving on advisory groups and technical expert panels 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. Our measure development process is patient-centered and includes participation from individuals with lived experience that relates to the measures under development. Patient partners participate on advisory groups and panels to provide the patient perspective throughout all phases of measure development. Additionally, PQA provides public comment periods at various points within our measure development process. This allows measure concepts and draft measures to be vetted even more broadly beyond PQA's membership, providing all healthcare organizations that would be impacted by a standard set of measures the opportunity to provide feedback.

Given our experience and consensus approach to measure development, 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.

2. [PQA is continuing consensus-based work](#) with the industry in 2020 to develop additional measures. Insights learned during the initial work are informing our approach to our continued efforts in building a set of pharmacy measures. We are encouraged by the progress made and our current focus on de novo pharmacy measure concepts, focused on patient health outcomes and areas of care and quality performance that pharmacists can impact.
 - o We began in early 2019 a consensus-driven process to identify and prioritize measure concepts that could constitute a set of pharmacy performance measures. Through this process, PQA developed an initial standard set of measures appropriate for assessing pharmacy performance and use in accountability programs. This initial phase of work included an expedited process to develop pharmacy measures adapted from existing PQA health plan measures used in Part D quality programs. PQA conducted this work in an expedited fashion to develop an initial set of pharmacy measures that could be made available for Contract Year 2021 within Medicare.
 - o The work resulted in [three PQA-endorsed pharmacy performance measures](#) – *Proportion of Days Covered (PDC): Renin Angiotensin System Antagonists (Pharmacy) (PDC-RASA-PH)*, *PDC: Statins (Pharmacy) (PDC-STA-PH)*, and *PDC: Antiretroviral Medications (Pharmacy) (PDC-ARV-PH)* – which are calculated using administrative claims data and reported at the aggregate Medicare line of business.

3. CMS should commit appropriate funding to support the development of a set of pharmacy performance measures.
 - o Pharmacy performance measures, focused on pharmacist-provided care, pharmacy-based services and beneficiary outcomes, will require novel data sources not previously used in performance measurement, and more extensive testing to ensure that they are feasible, valid and reliable.
 - o The allocation of appropriate resources will allow a measure set to be developed and implemented in a timely manner.

CMS encourages Part D sponsors to use a third party, independent organization that is free of conflict of interest to assess pharmacy performance on such measures (including data aggregation, development of measure thresholds and cut points, and definition of applicable pharmacy types for each measure).

PQA agrees that a third party, independent organization that is free of conflict of interest is needed to assess pharmacy performance on such measures. The industry would benefit from CMS clarifying the characteristics of an "independent organization that is free of conflict of interest," and PQA believes such an organization:

- Works with the stakeholders that are engaged in offering Medicare Part D programs and providing medication-related services on a beneficiary's behalf, including PBMs, health plans and pharmacies;
- Does not develop its own measures;
- Reports on performance to health plans, PBMs and pharmacies;
- Provides tools and resources to educate stakeholders on the measures they are reporting on; and
- Is not owned by a health plan, pharmacy benefit manager (PBM) or pharmacy;

CMS recommends that pharmacy performance measures established for use in Part D adhere to six principles. PQA believes these principles need greater clarification:

- Definitions are needed for many of the terms and concepts in the principles, including "outcomes," "beneficiaries served," "right level of attribution," "pharmacy type," and "fair," to support successful development and use of standardized measures.
- Regarding the second principle that says measures should "be specified at the right level of attribution and appropriate level of comparison considering pharmacy type," PQA believes it also is important to note the importance of meeting minimum denominator size requirements needed for reliability, when measures are used for accountability purposes. Further, PQA updated our [Measure Use and License Policy](#) in October 2019 to ensure industry clarity that "PQA Measures must be used according to their specifications for accountability purposes."
- Regarding the sixth principle that says measures should "use threshold minimums if appropriate," clarity is needed regarding the criteria for threshold minimums and who should establish those.

In addition to clarifying principles for pharmacy performance measures, PQA encourages CMS to develop a timeline for use of these measures in Part D. That timeline should be informed by public

comment or industry input, considering that network pharmacy agreements are often developed 12-15 months in advance of a contract year.

CMS says, in the future, it may develop measures to consider for use in the Part D Star Ratings that, for example, assess Part D plan sponsors' uptake of a standard set of pharmacy performance measures. In developing any such measures, PQA believes it is critical to ensure that patients are cared for equitably and appropriately regardless of plan sponsor.

CMS also may develop in the future measures to consider for use in the Part D Star Ratings that evaluate the percent of high-performing pharmacies in the sponsors' pharmacy network. PQA agrees in principle that it is important to assess pharmacies and determine which are high performing. What constitutes a "high-performing" pharmacy should be defined by CMS with public comment or industry input. In developing any such measures related to this, CMS should consider potential unintended consequences, including the narrowing of networks, and the impact that could have on some pharmacies and the options available to beneficiaries.

PQA appreciates CMS' thoughtful consideration of our comments submitted in response to CMS 4190-P. If you have questions, please do not hesitate to contact us.

Respectfully,

A handwritten signature in cursive script that reads "Laura J. Cranston".

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