

PQA Update on Development of Pharmacy Measures October 15, 2019

The <u>Pharmacy Quality Alliance</u> (PQA) is developing a standard set of measures that would be appropriate for pharmacy-level accountability. This is the second update on our work to develop pharmacy measures. The <u>initial update</u>, shared on September 26, is available on PQA's website. Periodic updates will be provided to ensure PQA members and stakeholders have timely information about this important work. This update is focused on:

- Progress in developing pharmacy measures adapted from existing PQA health plan measures;
- PQA's plans to convene a Pharmacy Measures Advisory Group in early 2020 to prioritize de novo pharmacy measure concepts for development in the medium and long term; and
- Comments PQA received on medium- and long-term measure development opportunities and PQA's responses to those comments.

Progress in Developing Pharmacy Measures Adapted from Existing PQA Health Plan Measures

PQA continues to make progress in developing pharmacy measures that can be completed in the short term, by January 2020. PQA has twice convened the Pharmacy Measures Technical Expert Panel (TEP), which was appointed to provide input on draft measure concept specifications, including pharmacy-patient attribution models, exclusions, treatment period definitions and the inclusion of mail order and long-term care pharmacies.

PQA is now conducting initial feasibility analyses to assess the proposed attribution models and plans to move forward with draft measure testing of the set of measure concepts in the near future. The TEP will meet again on October 28 to review the results of the feasibility analyses. PQA's timeline for adapting plan measures for pharmacy-level performance has been updated to be more detailed. The following table provides an updated timeline for this work. This timeline is a projection and is subject to change based on the development process.

PQA's Pharmacy Measure Development Timeline (September 2019-January 2020) for pharmacy measures adapted from existing PQA health plan measures		
Pharmacy Measures Technical Expert Panel (TEP) Meeting #1	September 16	
TEP Meeting #2	September 30	
TEP Meeting #3	October 28	
Ad hoc Quality Metrics Expert Panel (QMEP) Meeting (to review	October 29	
draft specifications & feasibility testing)		
QMEP Meeting (to review testing results)	December 4	
QMEP Vote (to approve measure concepts for endorsement	December 5-13	
consideration by membership)		
PQA Open Comment Period with detailed memo (note that this also	December 18-January 7	
will include several measures to be considered for retirement)		
All-Member Webinar (review & address comments)	January 16	
PQA Endorsement Vote	January 16-30	
This timeline is subject to change.		

Additional updates on PQA's short-term measure development work will be provided throughout the process.

Developing De Novo Pharmacy Measures in 2020

PQA will convene a Pharmacy Measures Advisory Group in early 2020 to prioritize de novo pharmacy measure concepts for development in the medium and long term. These measures will focus on patient health outcomes and areas of care and quality performance that pharmacists can impact. The advisory group will be selected following a self-nomination process. PQA will broadly communicate to its members the opportunity to submit nominations for the group. All proposed measure concepts that subsequently move forward for development will progress through PQA's consensus-based development and endorsement process to then be available for use.

This and other issues are addressed in Appendix A, which provides PQA's responses to the broad themes included in the public comments received on the medium- and longer-term development of pharmacy performance measures.

Questions about PQA's pharmacy measure development should be directed to PQA's Performance Measurement Team at MeasureDev@pqaalliance.org.

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Public Comments Received on PQA's Medium- and Long-Term Pharmacy Measure Development

Background

Community and specialty pharmacy providers have advocated for the development of a new standard set of measures that can be used in pharmacy-plan and pharmacy-PBM agreements. The Centers for Medicare & Medicaid Services (CMS) and the U.S. Congress, through proposed regulation and legislation, have also demonstrated interest in a new standard set of measures. To address this interest, PQA hosted an in-person workshop to inform its measure development strategy and to gain input on and develop consensus for a standard set of measures that would be appropriate for pharmacy-level accountability. Workshop participants reached consensus on prioritized measures that could be incorporated in value-based models in Medicare Part D and other programs in the future.

To gain further insight on the proposed measure set and on PQA's approach to pharmacy performance measure development, PQA held an open comment period from August 22-September 6, 2019. A total of 30 comments were received. This document summarizes comments and provides PQA responses related to the medium and longer-term development of pharmacy performance measures. Please note that this is a summary-level document and is not intended to address every aspect of each comment received. Additionally, responses to questions on specific measure concepts are not meant to reflect final measure design decisions and are subject to change as development continues.

Broad Themes

Support for Development of Pharmacy Performance Measures

Virtually all commenters expressed support for the development of a pharmacy performance measure set.

PQA Response:

PQA is pleased that commenters agree with the multi-stakeholder consensus and support PQA's development of these measures to meet the need for valid and reliable pharmacy performance measures.

Stakeholder Inclusion and Discussion

Commenters expressed support for PQA's process of facilitating discussion across stakeholders and encouraged a continued approach based on consensus from different types of organizations, especially those most affected by the new proposed measure set. Commenters noted that it will be important for PQA members and other stakeholders to understand, and provide input on, the process that will be used to finalize the proposed set of measures.

PQA Response:

PQA is committed to continuing to develop this set of measures in a transparent, inclusive manner and looks forward to continuing to receive valuable stakeholder input. In addition to the technical expert panel currently working to specify measure concepts for short-term development, PQA plans to convene a multi-stakeholder pharmacy measures advisory group in early 2020 to help identify, refine,

and prioritize measure concepts for medium- and longer-term development. All proposed measure concepts that move forward for development will progress through PQA's consensus-based development and endorsement process to then be available for use. PQA would also like to emphasize that in this context, 'short-term', 'medium-term', and 'long-term' refer to development timelines rather than the intended duration of measure use.

Transparency and Financial Impacts

Commenters noted that direct and indirect remuneration (DIR) fees in their current state are damaging to the financial health of pharmacies and expressed concern that new measures may not solve the problem. Commenters also suggested that for certain activities (e.g. performing HbA1c tests), appropriate financial incentives should be included to offset resource costs. Other commenters requested that PQA provide details about the application of pharmacy measures beyond Part D to other lines of business, including commercial use, and to confirm that reimbursement model changes would fall outside the scope of this measure development project. Commenters also emphasized the importance of transparency in the measurement of pharmacy quality, noting that transparency drives accountability and actionability.

PQA Response:

PQA appreciates commenters' excellent questions regarding measure implementation. While PQA will continue to evaluate opportunities for the measures to be used in value-based contracts, it is important to note that PQA's primary goal is to develop robust pharmacy performance measures that will be adopted by plans/pharmacy benefit managers and pharmacies — even in the absence of federal or legislative mandates — to be used for more transparent and consistent quality measurement and accountability. Structural changes to payment models and policies such as DIR are important subjects but fall outside the scope of this measure development project.

Expansion of the Role of the Pharmacist

Commenters expressed support for measures that elevate the role of pharmacists within the care team, citing pharmacists' ability to improve patient outcomes. However, commenters also noted that these measures may challenge the traditional "in-and-out" view of pharmacies that many patients currently hold. Changing this perspective may take time.

PQA Response:

PQA agrees that pharmacists are a critical element of the care team and believes in the development of measures that fully capture the value pharmacy provides to patients. PQA also acknowledges that traditional patient views of pharmacy may need to evolve over time in some cases.

Emphasis on Patient Outcomes

Commenters voiced support for measurement that drives improved patient outcomes. Some commenters expressly called for the development of outcome measures over process measures, and other commenters voiced support for specific proposed outcome measures such as HbA1c and blood pressure control. Some commenters also noted the importance of evaluating risk adjustment for outcome measures (and potentially other measure types).

PQA Response:

PQA is in strong agreement with commenters' emphasis on measures that assess patient outcomes, in alignment with broad efforts from CMS and other national organizations to promote the development of outcome measures. The current challenge that needs to be addressed is the lack of access to data

from pharmacies to assess outcomes. However, as data interoperability across care settings evolves, PQA is eager to develop outcome measures to evaluate pharmacy performance and plans to convene an interoperability advisory group in 2020 to advance this work.

PQA agrees that risk adjustment is important to avoid potentially incorrect inferences about the quality of care delivered. PQA is also aware that risk adjustment can only account for measurable and available data, so it is of the utmost importance to keep data availability challenges for all lines of business in mind when creating risk-adjusted measures. As appropriate, PQA will assess the need for risk adjustment for outcome measures and potentially other measure types, to ensure that performance is reflective of the quality of care provided and not the underlying characteristics of the patient population.

Local Regulation

Commenters noted that local regulation related to scope of practice, and training or waivers required to complete certain services (e.g. HbA1c tests), must be considered during development and implementation.

PQA Response:

PQA appreciates commenters raising this important consideration and will ensure that these nuances are considered during measure development.

Suggested New Measures

Commenters identified several potential measurement areas for future development. Proposed pharmacy measure concepts and priority areas included:

- Anticoagulation (i.e. adherence, direct oral anticoagulant prescribing, outcomes)
- Oncology (proportion of days covered, turnaround time, medication therapy problem resolutions, gap days, refill persistency)
- Immunizations (administration of allowable immunizations, other outcome measures)
- Respiratory conditions (asthma and chronic obstructive pulmonary disease medication adherence, asthma control)
- Specialty measures related to persistence and abandonment
- Measures that address care coordination
- Patient education measures (e.g. patient knowledge of their therapy)
- Measures regarding services such as first fill counsels, number of patient follow-up calls, patient home visits, or time spent educating patients on newly diagnosed conditions
- Other measures for potential adaptation include medication optimization, blood sugar control, depression, cholesterol goals, high risk medications in the elderly, total costs of care, hospitalizations, emergency department visits, readmissions, medication reconciliation, medication synchronization, patient satisfaction, and offering text message service reminders for patients.

PQA Response:

PQA is grateful for the many valuable proposed measure concepts provided. These concepts will be discussed and evaluated by the PQA team as well as the pharmacy measures advisory group that PQA will convene in early 2020.

Measure Concept-Specific Comments: Community Pharmacy

PQA Note:

PQA is deeply appreciative of the many thoughtful comments provided on proposed measure concepts. Because these ideas are in an early conceptualization stage, many questions on specific aspects of measure construction cannot yet be answered definitively. However, commenters' questions and ideas will serve as the basis for important discussions within the PQA team and with the pharmacy measures advisory group as measure concepts are refined and prioritized. PQA will offer additional open comment periods to allow for continued broad stakeholder input, including input on measure concept prioritization, draft specification and subsequent steps in the development process.

Pharmacist Attestation/Ability to Report on Clinical HEDIS Measures

While commenters generally were supportive of the inclusion of HEDIS measures, many requested clarity on which specific HEDIS measures are being proposed. Commenters asked how attestations might be validated, and several cited concerns that attestation is not high value, noting that measures should require reporting and improvement. One commenter expressed potential feasibility concerns, and another suggested that PQA consider standards and audits to guarantee the validity of self-reported data that would be used in measures.

PQA Response:

PQA will seek input from the pharmacy measures advisory group that will be convened in early 2020 when assessing HEDIS measures proposed to be adapted and will provide additional opportunities for members to comment on specific measures proposed for inclusion in the set of measures. PQA acknowledges the importance of valid data sources for standardized performance measurement and will consider that as part of any measure's scientific acceptability assessment (i.e., whether a measure is valid and reliable). PQA appreciates commenters notes on the lower value of attestation measures vs. improvement or outcome measures.

Medication Therapy Management Concepts: Immunization ACIP Compliance and Medication Therapy Problem Resolution

Commenters noted that the lack of standardization in medication therapy management (MTM) implementation across pharmacies may present a barrier, with one commenter noting that MTM measures may not be appropriate for pharmacy performance measurement because not all health plans use pharmacies to provide MTM services. One commenter requested clarity on eligibility criteria, noting that eligibility based on patient reporting may be error prone.

One commenter asked if MTM interventions could take place in-person or over the phone, and another asked how often an immunization measure would be assessed and questioned who would have primary responsibility for administering an immunization (i.e. pharmacist vs. physician). One commenter suggested PQA consider applying immunization measures to the adult and adolescent populations. One commenter requested clarity on whether the medication therapy problem resolution (MTPR) measure concept would give credit for verbal accounts of changed therapy or would rely on claims to verify, noting that pharmacists do not have direct control over changing regimens and suggested the measure therefore merits weighting. One commenter noted that the health plan MTM program version of the MTPR measure concept is currently in use for monitoring and not accountability and requested clarity on whether this would be true for the pharmacy version.

PQA Response:

The variation in MTM implementation will be an important consideration across all pharmacy MTM measure concepts and will be carefully evaluated by PQA and the pharmacy measures advisory group. Eligibility verification, as well as whether assessments can be completed via phone and who will be completing assessments, will be important considerations. PQA has outreach efforts underway with subject matter experts to further explore the feasibility of creating pharmacy measures for MTM-related measure concepts, including the ability to accurately attribute MTM-eligible beneficiaries to pharmacies.

PQA will explore the applicability of immunization measures to adolescent populations. Regarding the MTPR measure, PQA believes that pharmacists can influence performance on this measure, including through coordination with prescribers to change regimens if needed in order to resolve medication therapy problems. However, identifying an appropriate patient-pharmacy attribution model for the measure concept could be challenging. For the same reasons the health plan MTM program version of the MTPR measure concept is designated as a monitoring measure, we anticipate a pharmacy version also being a monitoring measure. That said, the use of such a measure can bring value by promoting standardized documentation that can support future outcome measures.

Blood Pressure and HbA1c Measures (Documentation/Reporting/Improvement)

While commenters were supportive of clinical measures, several commenters did not believe that documentation measures are high-value and encouraged the prioritization of reporting on improvement and outcome measures. Many commenters also requested several data-related clarifications, including the standard process of submitting data and proposed data sources (lab values versus pharmacy system data versus patient-reported), and expressed concern that pharmacies may lack the infrastructure to support data capture and reporting on these measure concepts.

Commenters noted that communication with other providers will be important to avoid duplication of tests and services (e.g. blood pressure testing at the physician's office and then again in the pharmacy), and care coordination should be emphasized to avoid the creation of siloes. Similarly, commenters asked how responsibility on these measures would be distributed across different members of the care team.

Commenters raised questions about how pharmacists should be reimbursed for providing clinical services such as HbA1c testing. Commenters noted that provision of clinical services in pharmacy represents a workflow change for pharmacists, and that training may be required in accordance with local regulations. One commenter noted that some pharmacies may not have the resources and training required to complete clinical testing. One commenter noted that use of an e-care plan may help to capture the information required for these measure concepts and noted that pharmacies could perform tests in-pharmacy, obtain results from a lab, or obtain patient-reported results.

Commenters emphasized that improvement measures are higher value and priority than measures that require only documentation. Commenters noted that improvement measures may necessitate a payment model outside of standard reimbursement that reflects the enhanced role of pharmacists. One commenter noted that measures should focus on clinically significant improvements. Another noted that external factors like diet and exercise play a role in improving these types of metrics, confounding the pharmacy/pharmacist ability to influence such measure concepts.

PQA Response:

PQA appreciates commenters' input on clinical documentation, reporting, and improvement measures. As PQA further refines the measure concepts, the feasibility of different data sources will be carefully evaluated, as well as the ways in which proposed measures might affect pharmacy workflows. Similarly, PQA will continue to take potential limitations related to pharmacy resources and training into account.

PQA agrees that coordination across different members of the care team will be important to avoid duplication of services. However, we suggest that these potential measure concepts may drive improved communication across care teams as they collaborate, with aligned incentives, to achieve shared goals. Regarding payment models and reimbursement, PQA agrees that these are important topics but notes that such discussions are out-of-scope for this measure development project.

Ensuring that improvement measures capture clinically significant improvements that matter to patients will be an important element of development. PQA agrees that improvement measures should take into account the fact that many members of the care team, as well as external factors such as diet and exercise, have an effect on clinical metrics such as blood pressure and HbA1c. Use of the eCare Plan, and the specifics of how tests can be performed and reported, will be the subject of further discussion during development.

Primary Medication Non-Adherence

Commenters had a variety of specific questions and recommendations for the measure. Commenters asked how the measure would handle discontinuations due to a switch to a lower-cost alternative or the identification of a drug-drug interaction. One commenter asked whether the measure only applies to new prescriptions.

One commenter asked how "chronic medications" would be defined. One commenter noted that this measure may be difficult for pharmacies to capture, and another asked if this measure is directly under the pharmacy's control. One commenter asked how transferred and discontinued medications would be accounted for. One commenter noted that e-prescriptions may vary by geographic areas, which could affect denominators.

PQA Response:

PQA first notes that the current version of this PQA-endorsed measure is a pharmacy performance measure (with a lower rate indicating better performance), though there has been limited adoption. Questions and comments received will be explored when considering further refinement of the measure.

In the current version of the measure, switching to a lower cost alternative would not meet the numerator criteria unless the lower cost drug is not an appropriate alternative (see measure specifications for medication tables). In situations where drug-drug interactions are identified, the pharmacy should coordinate with the prescriber to prescribe an appropriate alternative. As with all PQA medication-related measures, a value set containing the list of chronic medications would be included in the measure specifications.

High-Level Concepts: Transitions of Care, Behavioral Health (e.g., PHQ-2), Opioid Measures (e.g., Medication-Assisted Treatment, Substance Use Disorder, Naloxone), Patient-Reported Outcome Performance Measures

Commenters supported the high-level concepts suggested by PQA, noting that they address priority focus areas. One commenter did not believe pharmacists should be the primary entities responsible for the quality of transitions of care. One commenter noted that pharmacists may not be trained to provide behavioral health services. When working with patient-reported data, commenters emphasized the use of validated instruments and the use of sufficient, representative samples of patients at the pharmacy level.

PQA Response:

PQA is pleased that the proposed high-level concepts align with commenters' priorities. PQA staff will continue to seek input from the pharmacy measures advisory group to identify and prioritize measure concepts within these topic areas.

Measure Concept-Specific Comments: Specialty Pharmacy

Specialty Pharmacy Turnaround Time

Commenters asked whether turnaround time is linked to improved patient outcomes. One commenter asked whether this measure would align with URAC measure specifications to provide separate turnaround times for "clean" versus "intervened" prescriptions. One commenter asked about the target timeframes and noted that pharmacists may not have direct control over turnaround time due to the influence of other parts of the health system, such as health plan approval. One commenter noted that the measure may introduce unintended consequences if pharmacies were to bypass valuable services such as patient assistance programs in an attempt to decrease turnaround time.

PQA Response:

PQA notes that the Specialty Pharmacy Turnaround Time measure concept was prioritized for development in 2018 and currently is in PQA's development pipeline. Turnaround time is an important measure of medication access and can also influence outcomes for certain therapies where timely initiation of therapy is critical. PQA's multi-stakeholder task force that drafted the measure concept specifications considered points similar to those raised during this comment period, and the draft measure specifications align with the task force's consensus decisions, including reporting one rate that is inclusive of "clean" and "intervened" prescriptions. PQA will share additional information on this measure concept as it progresses through the development process.

Drug-Drug Interaction Consultation

Commenters asked whether there will be specific requirements for the consultation, and how those would be measured. One commenter noted wide variation in drug-drug interactions according to severity, probability, and interaction type. One commenter asked what fraud, waste, and abuse protections could be developed to support a self-reported drug-drug interaction consultation, and another asked about documentation requirements.

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PQA thanks commenters for raising importance considerations related to this measure concept. PQA and the pharmacy measures advisory group will evaluate these points as the measure concept is further refined.

Early Persistence to Oral Oncolytics

One commenter recommended expedited development of this measure concept. One commenter noted that many oral oncolytics can be filled through multiple channels, which may affect adherence calculations. Another noted that some oral oncolytics have cyclical dosing based on lab values, and dosage may vary based on patient tolerance or undesirable lab values.

PQA Response:

PQA agrees that oral oncolytics is a priority focus area and looks forward to input from the pharmacy measures advisory group to refine the measure concept, while taking into consideration noted challenges such as cyclical dosing and dosage adjustment that can impact accurate assessment of adherence or persistence.

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