NATIONAL QUALITY FORUM

Memo

April 10, 2018

To: Patient Safety Standing Committee

From: NQF staff

Re: Post-comment web meeting to discuss public comments received and NQF member expression of support

Purpose of the Call

The Patient Safety Standing Committee will meet via web meeting on April 17, 2018 from 1pm to 3pm ET. The purpose of this call is to:

- Review and discuss comments received during the post-evaluation public and member comment period;
- Provide input on proposed responses to the post-evaluation comments;
- Review and discuss NQF members' expression of support of the measure under consideration; and
- Re-vote on the measure that did not reach consensus on a recommendation by the Committee.

Standing Committee Actions

1. Review this briefing memo and draft report.
2. Review and consider the full text of all comments received and the proposed responses to the post-evaluation comments.
3. Review the NQF members' expression of support of the submitted measure.
4. Be prepared to provide feedback and input on proposed post-evaluation comment responses.
5. Review and re-discuss the measure where consensus was not achieved in order to reach consensus.

Conference Call Information

Please use the following information to access the conference call line and webinar:

NQF/Co-Chairs dial-in #:	1-888-802-6696 (*NO CONFERENCE CODE REQUIRED)*
Committee/Public dial-in #:	1-855-223-0818 (*NO CONFERENCE CODE REQUIRED)*
Web Link:	http://nqf.commpartners.com/se/Rd/Mt.aspx?324476
Registration Link:	http://nqf.commpartners.com/se/Rd/Rg.aspx?324476

***In order to vote, Committee members should use their individual webinar links sent via email.**

Background

Patient safety-related events occur across healthcare settings from hospitals to clinics to nursing homes and include healthcare-associated infections (HAIs), medication errors, falls, and other potentially avoidable occurrences. Medical errors are preventable patient safety events that are estimated to cause hundreds of thousands of preventable deaths each year in the United States. NQF's portfolio of patient safety measures spans various topic areas and is designed to measure and report on patient safety events and practices across a variety of settings. However, significant gaps remain in the measurement of patient safety and how providers approach minimizing the risk of patient safety events. There is also a recognized need to expand avoidable patient safety measures beyond the hospital setting, as well as harmonize safety measures across sites and settings of care.

NQF has over a 10-year history of focusing on patient safety. Through various projects, NQF has previously endorsed over 100 consensus standards related to patient safety; these measures are important tools for tracking and improving patient performance.

The 25-member Patient Safety Standing Committee oversees the NQF Patient Safety measure portfolio. The Committee evaluates both newly submitted and previously endorsed measures against NQF's measure evaluation criteria, identifies gaps in the measurement portfolio, provides feedback on how the portfolio should evolve, and serves on any ad hoc or expedited projects in its designated topic areas.

On January 23, 2018, the Patient Safety Standing Committee evaluated one new measure: 3316e *Safe Use of Opioids – Concurrent Prescribing* (Centers for Medicare & Medicaid Services/Mathematica Policy Research). The Committee did not reach consensus on this measure.

Comments Received

NQF solicits comments on measures undergoing review in various ways and at various times throughout the evaluation process. First, NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). Second, NQF solicits member and public comments during a 16-week comment period via an online tool on the project webpage.

Pre-evaluation Comments

NQF solicits comments prior to the evaluation of the measures via an online tool on the project webpage. For this evaluation cycle, the commenting period opened on November 28, 2017 and closed on March 30, 2018. As of January 2018, no comments were submitted.

Post-evaluation Comments

The draft report was posted on the project webpage for public and NQF member comment on March 1 for 30 calendar days. During this commenting period, NQF received six comments from six member organizations:

Member Council	# of Member Organizations Who Commented
Consumer	0
Health Plan	0
Health Professional	3
Provider Organization	1
Public/Community Health Agency	1
Purchaser	0
QMRI	0
Supplier/Industry	1

We have included all comments that we received in the comment table (Excel spreadsheet) posted to the Committee SharePoint site. This comment table contains the commenter's name, comment, and draft responses (including measure steward/developer responses) for the Committee's consideration. Please review this table before the meeting and consider the individual comments received and the proposed responses to each.

In order to facilitate discussion, the majority of the post-evaluation comments have been categorized into major topic areas or themes. Although all comments may be discussed, the intent is not to discuss each individual comment on the April 17 post-comment call. Instead, we will spend the majority of the time considering the six themes discussed below, and the set of comments as a whole. Please note that the organization of the comments into major topic areas is not an attempt to limit Committee discussion. Measure stewards/developers were asked to respond to the comments. Where there was a specific comment that required a response, NQF staff proposed draft responses for the Committee to consider.

Consensus Not Reached

3316e Safe Use of Opioids – Concurrent Prescribing (Centers for Medicare & Medicaid Services/Mathematica Policy Research)

During the measure evaluation web meeting, the Committee indicated its strong support of measures that address the opioid crisis. However, Committee members had concerns about how this particular measure was specified (e.g., it was too broad to encompass every clinical situation), and they also had concerns about unintended consequences. Committee members questioned whether the developer presented sufficient data to demonstrate that the measure is an accurate assessment of inappropriate prescriptions. Some Committee members raised concern that the denominator exclusions did not account for instances where prescribing two opioids together or an opioid and a benzodiazepine together may be appropriate. Specifically, the Committee described several patient populations with chronic pain—such as patients with sickle cell disease—where a prescription for both a short-acting and long-acting opioid may be appropriate care. In addition, because this is measure is intended to assess inappropriate prescriptions of opioids or an opioid and benzodiazepine in inpatient and emergency department (ED) settings, there were concerns that the measure does not assess whether there was a pre-existing prescription (i.e., present on admission exclusions) for medication

combinations. Because these situations were not explicitly excluded from the measure, Committee members were concerned that the measure could potentially cause patient safety problems, particularly if facilities are compelled to change existing outpatient regimens to meet the measure rather than customizing individualized medication regimens as appropriate for certain patients. During the measure evaluation web meeting, consensus was not reached on the reliability, validity, and usability subcriteria. The Committee should review the comments that were received, and then re-discuss and re-vote on the measure.

Six comments were submitted for this measure. All supported the measure concept generally, but expressed concerns about the measure as currently specified, including concerns about whether the measure contains appropriate denominator exclusions (e.g., sickle cell disease, chronic substance abuse treatment, and certain hematological and neurological conditions); potential unintended consequences (such as emergency physicians making changes to medication regimens managed by outpatient physicians); the potential to de-emphasize the importance of adequate pain control; and promoting rapid dose tapers that could be harmful to patients. One commenter's recommendation to improve the validity of the measure was for the measure to determine dosing thresholds.

Comments and Their Disposition

Themed Comments

Six major themes were identified in the post-evaluation comments, as follows:

1. Theme 1 – Potential Need for Additional Exclusions
2. Theme 2 – Dosing Thresholds
3. Theme 3 – Unintended Consequences
4. Theme 4 – Limited Testing
5. Theme 5 – Measurement Period Timeframe
6. Theme 6 – Need for Voluntary Data Collection Before Implementation in Accountability Programs

Theme 1 - Potential Need for Additional Exclusions

Six commenters recommended potentially necessary exclusions, such as patients with sickle cell disease, patients undergoing chronic substance abuse treatment, patients with certain hematological and neurological conditions, and patients coming into the emergency department with existing concurrent prescriptions.

Measure Steward/Developer Response

We recognize that there may be some clinically necessary situations for concurrent prescriptions of opioids and benzodiazepines and we agree with the need to properly treat these patients. As recommended by our expert panels, we looked into single-condition exclusions, specifically sickle cell disease and substance use therapy and found that a very small portion of cases eligible for the numerator (0 to 3.4 percent) fell into these [sic] category. Furthermore, after reviewing the testing results, clinicians from our expert workgroup recommended continuing to include patients for whom concurrent prescribing is medically necessary because experts stated these populations (1) have the highest risk of receiving concurrent prescriptions; and (2) can experience a lag in

adverse events. In addition, there are currently no guidelines supporting exclusion of patients who may require concurrent prescriptions from the measure, other than cancer and palliative care. However, we will consider these comments and evaluate opportunities to refine the measure.

Proposed Committee Response

Thank you for your comment. The Committee will review these comments during their deliberations on the Post-Comment Call scheduled on April 17 to re-vote on the criteria where consensus was not reached and this measure's overall suitability for endorsement.

Theme 2 – Dosing Thresholds

One commenter recommended determining dosing thresholds to identify inappropriate versus appropriate concurrent prescribing.

Measure Steward/Developer Response

The existing professional organizations, states, and federal agency developed guidelines for opioid prescribing share some common elements, including dosing thresholds, cautious titration, and risk mitigation strategies such as using risk assessment tools, treatment contracts, and urine drug testing. However, there is considerable variability in the specific recommendations (e.g., range of dosing thresholds of 90 MME/day to 200 MME/day), audience (e.g., primary care clinicians versus specialists), use of evidence (e.g., systematic review, grading of evidence and recommendations, and role of expert opinion), and rigor of methods for addressing conflict of interest. There's currently not an evidence base strong enough to specify a certain threshold deemed safe for the inpatient setting so we did not include dosing thresholds in the specification.

Proposed Committee Response

Thank you for your comment. The Committee will review these comments during their deliberations on the Post-Comment Call scheduled on April 17 to re-vote on the criteria where consensus was not reached and this measure's overall suitability for endorsement.

Theme 3 – Unintended Consequences

Six commenters expressed concerns about potential unintended consequences of the measure, such as emergency physicians making changes to patients' medication regimens instead of outpatient physicians or primary care providers; potential incentives to reduce emphasis on pain control; and/or promoting rapid dose tapers that could be harmful to patients.

Measure Steward/Developer Response

We recognize that there may be some clinically necessary situations for concurrent prescriptions of opioids and benzodiazepines and we agree with the need to properly treat these patients. As recommended by our expert panels, we looked into single-condition exclusions, specifically sickle cell disease and substance use therapy and found that a very small portion of cases eligible for the numerator (0 to 3.4 percent) fell into these [sic] category. Furthermore, after reviewing the testing results, clinicians from our expert workgroup recommended continuing to include patients for whom concurrent

prescribing is medically necessary because experts stated these populations (1) have the highest risk of receiving concurrent prescriptions; and (2) can experience a lag in adverse events. In addition, there are currently no guidelines supporting exclusion of patients who may require concurrent prescriptions from the measure, other than cancer and palliative care. However, we will consider these comments and evaluate opportunities to refine the measure.

Proposed Committee Response

Thank you for your comment. The Committee will review these comments during their deliberations on the Post-Comment Call scheduled on April 17 to re-vote on the criteria where consensus was not reached and this measure's overall suitability for endorsement.

Theme 4 – Limited Testing

Two commenters expressed concern about the limited testing conducted for this measure, with one commenter suggesting that the testing should be expanded beyond two EHR systems, and another suggesting that rural and nonacademic hospitals should have been included.

Measure Steward/Developer Response

We agree that voluntary data collected by this measure, as it is currently specified, could potentially serve as a useful starting point for hospitals and clinicians and may be advantageous for performance improvement. Data collected at the national level during the initial implementation phase may offer more evidence for actionable refinements than retesting the measure at only a few hospitals.

We agree that it is important to understand performance in rural and non-academic hospitals. We attempted to recruit a broad variety of hospitals and, in accordance with NQF guidelines, include data from at least two different EHR systems.

Overall, performance rates from site were on par with the literature. Field testing also showed that overall concurrent prescribing rate of 18.2% in the inpatient setting and 6.1% in ED settings, which aligned with the literature, that is, studies of multiple claims and prescription databases have shown that among patients who receive opioids in an inpatient or outpatient hospital setting, 5 to 15 percent of patients receive concurrent opioid prescriptions, and 5 to 20 percent receive concurrent opioid and benzodiazepine prescriptions.

Proposed Committee Response

Thank you for your comment. The Committee will review these comments during their deliberations on the Post-Comment Call scheduled on April 17 to re-vote on the criteria where consensus was not reached and this measure's overall suitability for endorsement.

Theme 5 – Measurement Period Timeframe

One commenter expressed concern that the measurement period timeframe is not clearly specified, suggesting that it is unclear whether CMS and others would implement the measure using 12 months, 24 months, or another period. A two-year timeframe was used for the

opportunity for improvement information and in testing; however, the specifications and HQMF do not require this two-year period.

Measure Steward/Developer Response

We developed the Safe Use of Opioids—Concurrent Prescribing measure for the Hospital Inpatient Quality Reporting (IQR) and Hospital Outpatient Quality Reporting (OQR) programs. CMS will determine the proposed measurement period at a future date if the measure is implemented.

Proposed Committee Response

Thank you for your comment. The Committee will review these comments during their deliberations on the Post-Comment Call scheduled on April 17 to re-vote on the criteria where consensus was not reached and this measure's overall suitability for endorsement.

Theme 6 – Need for Voluntary Data Collection Before Implementation in Accountability Programs

While noting that the measure may be useful for quality improvement and information-gathering purposes, some commenters recommended collecting data voluntarily for one to two years before the measure is implemented for accountability purposes (such as payment or public reporting programs).

Measure Steward/Developer Response

We agree that voluntary data collected by this measure, as it is currently specified, could potentially serve as a useful starting point for hospitals and clinicians and may be advantageous for performance improvement. Data collected at the national level during the initial implementation phase may offer more evidence for actionable refinements than retesting the measure at only a few hospitals.

Proposed Committee Response

Thank you for your comment. The Committee will review these comments during their deliberations on the Post-Comment Call scheduled on April 17 to re-vote on the criteria where consensus was not reached and this measure's overall suitability for endorsement.

NQF Member Expression of Support

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support ('support' or 'do not support') for each measure submitted for endorsement consideration to inform the Committee's recommendations. Three NQF members indicated that they did not support the measure: See Appendix A.

Appendix A: NQF Member Expression of Support Results

Measure 3316e did not receive support from NQF members. Results for measure 3316e are provided below.

3316e Safe Use of Opioids – Concurrent Prescribing (Centers for Medicare & Medicaid Services/Mathematica Policy Research)

Member Council	Support	Do Not Support	Total
Consumer	0	0	0
Health Plan	0	0	0
Health Professional	0	2	2
Provider Organization	0	0	0
Public/Community Health Agency	0	0	0
Purchaser	0	0	0
QMRI	0	0	0
Supplier/Industry	0	1	1
All Councils	**0**	**3**	**3**